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# Digital Bioimpedance for Physical Activity Detection in Type-2 Diabetes: Quasi-Experimental Validation Study

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## Abstract

**Background:** Primary care diabetes management lacks objective, scalable methods for continuous physical activity surveillance. Bioelectrical impedance analysis (BIA), routinely collected in diabetes care, offers untapped potential as an automated digital biomarker but requires validation for behavioral phenotyping.

**Objective:** This study aims to evaluate the feasibility and predictive validity of multifrequency bioimpedance for physical activity detection and its association with glycemic control in type 2 diabetes.

**Methods:** This was a pragmatic quasi-experimental study using temporal allocation across three 4-month periods (January 2021-July 2023) in a Japanese primary care clinic, including comprehensive tracking with BIA-guided counseling (n=65), partial tracking (n=31), and standard care (n=100). Adults with type 2 diabetes (hemoglobin $A_{1c}$ [$HbA_{1c}$] 7.0% - 10.0%) underwent monthly segmental multifrequency BIA. The primary outcome was $HbA_{1c}$ <7% at 4 months. Intervention-outcome associations were examined using chi-square trend tests and multivariable logistic regression adjusted for baseline $HbA_{1c}$, the Walk Score (0 - 100), and medication indicators. To assess temporal confounding, we conducted ANCOVA on 4-month $HbA_{1c}$ with baseline adjustment (age and BMI added in sensitivity analyses). Effect modification by built environment was tested via Walk Score×Intervention interaction. Predictive validity of left-arm 50-kHz reactance was assessed using area under receiver operating characteristic curve with 95% CI via 10-fold cross-validation.

**Results:** Among 196 participants, the baseline characteristics (age, BMI, $HbA_{1c}$, diabetes duration, and medications) did not differ across periods (all $P$>.05). $HbA_{1c}$ <7% achievement showed a gradient: 80% (52/65) comprehensive, 58% (18/31) partial, and 56% (56/100) standard care ($\chi^2_4$ for trend=14.23; $P$<.001). ANCOVA of 4-month HbA1c (baseline-adjusted) showed no linear period trend ($P$=.25). A significant Walk Score×Intervention interaction was observed (β per 10-point Walk Score=−.55; 95% CI −1.03 to −0.06; $P$=.028), indicating differential effectiveness by neighborhood walkability. Left-arm 50-kHz reactance predicted target achievement (adjusted odds ratio per 1-SD increase =3.04; 95% CI 1.86 - 4.97; $P$<.001; area under receiver operating characteristic curve=0.847, 95% CI 0.784 - 0.910). Among achievers, reactance change correlated with HbA1c change (r=−0.392; $P$=.032) but not among nonachievers (r=−0.089; $P$=.54). After the inverse probability weighting was stabilized, each 1-SD increase in left-arm reactance was associated with a 12.1 percentage-point higher probability of target achievement (95% CI 5.2% - 19.0%).

**Conclusions:** This pragmatic implementation study demonstrates that automated BIA is feasible for routine diabetes care and suggests potential as a digital biomarker of activity-related glycemic control. While temporal allocation precludes definitive causal inference, and findings should be interpreted as associational, the observed Walk Score moderation and bioimpedance-$HbA_{1c}$ dose-response patterns are consistent with behavioral mechanisms rather than pure confounding. Left-arm reactance warrants randomized validation as a scalable, passive surveillance tool for precision diabetes management.

**Trial Registration:** UMIN Clinical Trials Registry UMIN000058452; https://center6.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000066830

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**KEYWORDS**

digital health; bioelectrical impedance; diabetes mellitus, type 2; exercise therapy; monitoring, physiologic; primary health care; built environment; hemoglobin A, glycosylated



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## Introduction

### The Digital Health Revolution in Exercise Tracking

The advent of digital health technologies has transformed chronic disease management, with diabetes care positioned at the forefront of this revolution [1,2]. Mobile health apps, wearable devices, and digital biomarkers now offer unprecedented opportunities for real-time patient monitoring and personalized intervention strategies [3-7]. However, despite significant advances in glucose monitoring technologies, exercise compliance assessment—a cornerstone of diabetes management—remains predominantly dependent on subjective self-reporting methods that lack the precision and objectivity demanded by contemporary precision medicine approaches [8,9]. Current digital health ecosystems for diabetes management excel in glucose tracking but demonstrate a critical deficiency in objective exercise assessment [1,10,11]. While continuous glucose monitors provide minute-by-minute glycemic data, exercise compliance monitoring continues to rely on patient diaries, smartphone step counters, or intermittent subjective assessments during clinical encounters. This disparity creates a fundamental imbalance in the digital health toolkit available to primary care providers, who must make evidence-based treatment decisions regarding exercise therapy optimization without access to reliable, objective compliance data [12].

### Critical Gaps in Primary Care Exercise Tracking

Type 2 diabetes affects over 460 million individuals worldwide, with substantial morbidity, mortality, and health care costs [13-16]. Despite therapeutic advances, only 50% to 60% of patients achieve hemoglobin $A_{1c}$ ($HbA_{1c}$) targets in real-world practice, creating urgent challenges for primary care diabetes management [17,18].

In primary care settings, exercise therapy and dietary modification are universally recommended as first-line interventions [19-24]; however, the digital infrastructure supporting these recommendations remains incomplete. While dietary tracking applications and digital nutrition platforms have achieved widespread adoption, exercise monitoring capabilities lag significantly behind, creating an asymmetric digital health ecosystem that inadequately supports comprehensive lifestyle intervention strategies [3,9].

Traditional methods of monitoring exercise compliance, including patient self-reports, activity diaries, and subjective assessments, are notoriously unreliable and provide insufficient objective data for clinical decision-making [12]. This monitoring deficit creates a critical gap in primary care: physicians cannot provide appropriately tailored exercise therapy guidance without reliable evidence of patient exercise implementation [25].

### The Challenge of Exercise Tracking Through Body Composition Analysis

Self-care management could potentially be enhanced through objective body composition assessment as evidence of exercise implementation. Bioelectrical impedance analysis (BIA) offers promise for detecting exercise-induced physiological changes, providing objective markers that could inform clinical decision-making [26,27]. However, fundamental uncertainties regarding optimal measurement parameters severely limit clinical use [28].

Body composition assessment reveals diverse reactance frequency characteristics across the spectrum from 5 kHz to 250 kHz, with each frequency potentially providing different physiological information [26,29]. Similarly, anatomical measurement sites—from individual limbs to whole-body assessment—may exhibit differential sensitivity to exercise-induced changes [30,31]. The critical clinical question remains: which specific frequency and anatomical site combination most reliably reflects exercise implementation and predicts treatment success in real-time tracking applications?

### The Problem of Contradictory Literature

Recent systematic evaluations reveal the extent of contradictions in bioelectrical impedance research [28,32]. Studies have shown conflicting results regarding which body segments provide optimal metabolic information, with some studies favoring upper extremity measurements and others showing no regional differences [30,33]. The comprehensive literature examining body composition methodologies demonstrates the need for standardized approaches [34].

We propose that these contradictions reflect a previously unrecognized phenomenon: culturally imposed localized inactivity. Across global populations, food preparation and consumption practices create systematic asymmetric limb use patterns that represent “manufactured” localized disuse. For instance, cultures using utensils consistently favor one hand for manipulation while the other provides stabilization, creating daily repetitive asymmetric loading patterns. This cultural specificity of body usage represents a unique form of environmental laterality conditioning that has been overlooked in previous bioimpedance research.

### Unified Theoretical Framework for Population-Specific Tracking

We hypothesize that anatomical specificity of metabolic biomarkers depends on the degree of baseline body usage asymmetry in the studied population. This unified framework predicts the following:

- High-asymmetry populations (consistent preferential use of one limb): The less-used limb demonstrates preferential metabolic responsiveness due to greater adaptive capacity for exercise tracking.
- Moderate-asymmetry populations (mild preferential use): The dominant limb may show preferential responsiveness due to higher baseline metabolic activity.
- Low-asymmetry populations (balanced bilateral use): Bilateral symmetry or whole-body measures provide optimal sensitivity.
- Mixed populations (heterogeneous usage patterns): No consistent anatomical patterns emerge, diluting site-specific tracking effects.

This framework enables systematic reconciliation of contradictory findings while providing practical guidance for optimizing digital biomarker protocols in diabetes care.



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### Study Objectives

Given this theoretical framework and the documented need for objective physical activity monitoring in primary care diabetes management, this study aimed to: (1) validate a digital bioimpedance protocol for objective physical activity detection in Japanese adults with type 2 diabetes, (2) identify population-specific anatomical sites demonstrating optimal sensitivity for activity tracking, and (3) evaluate the clinical use of this framework for predicting glycemic target achievement in real-world primary care settings. We hypothesized that left-arm 50-kHz reactance would demonstrate superior predictive value compared to other anatomical sites, consistent with high-asymmetry population patterns.

## Methods

### Study Design and Participants

This quasi-experimental study follows the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (Checklist 1) for reporting observational studies. The study used temporal allocation (sequential enrollment by time period) rather than individual randomization, which is acknowledged as a significant limitation affecting causal inference. For more details, see the "Study Limitations" section.

This quasi-experimental, temporally allocated observational study was conducted at Saiseikai Maebashi Hospital, Japan, from January 2022 to July 2023. The study was approved by the institutional review board of Gunma Paz University (IRB No PAZ23-9; approval date: June 15, 2021) and was retrospectively registered in the UMIN Clinical Trials Registry (UMIN000058452; registration date: July 14, 2025). The rationale for retrospective registration is disclosed transparently given the observational design. This study followed the STROBE guidelines for reporting observational studies.

Adults aged 20 to 80 years with type 2 diabetes ($HbA_{1c}$ 7.0% - 10.0%) were recruited through the endocrinology clinic. The study used an opt-out consent process approved by the institutional review board; patients could decline participation at any time. Japanese adults were selected as an ideal population for testing the unified framework, given consistent asymmetric upper-limb use in daily activities.

### Eligibility Criteria

#### *Inclusion Criteria*

The inclusion criteria are as follows: adults aged 20 - 80 years with type 2 diabetes, baseline $HbA_{1c}$ (7.0% - 10.0%), available segmental BIA at baseline, and follow-up $HbA_{1c}$ at 2 and 4 months.

#### *Exclusion Criteria*

The exclusion criteria are as follows: type 1 or secondary diabetes, pregnancy or lactation, serious liver disease (alanine aminotransferase >3×upper limit of normal), heart failure (New York Heart Association class III–IV); dialysis or estimated glomerular filtration rate <30 mL $min^{-1}$ 1.73 $m^{-2}$, implanted pacemaker or implantable cardioverter-defibrillator or other contraindication to BIA, generalized edema requiring active diuretic titration, and patients who declined participation via the opt-out notice.

#### *Participant Characteristics and Medication Profile*

At baseline, participants had a mean age of 58.7 (SD 11.2) years, mean BMI of 26.4 (SD 4.1) kg $m^{-2}$, and mean diabetes duration of 8.3 (SD 5.6) years. Diabetes medications included metformin (n=176, 91%), sulfonylureas (n=87, 45%), dipeptidyl peptidase-4 inhibitors (n=112, 58%), sodium-glucose cotransporter 2 inhibitors (n=64, 33%), and insulin (n=31, 16%). Diuretic use was documented in 28 (14%) participants. Participants were instructed to maintain stable medication regimens throughout the study period unless medically necessary adjustments were required; such changes were documented and accounted for in sensitivity analyses. No participants had clinical evidence of peripheral edema, acute illness, or recent hospitalization at baseline assessment. Standard hydration instructions (4-h fast and avoid strenuous exercise 24 h prior) were provided for all bioimpedance measurements to minimize measurement variability from acute hydration status.

### Digital Exercise Tracking Protocol: Exercise Prescription Specifics

The comprehensive intervention (period A) included individualized exercise prescriptions based on baseline fitness assessment. Recommended activities included brisk walking (primary modality), cycling, swimming, or home-based calisthenics, prescribed at moderate intensity (50% - 70% of age-predicted maximum heart rate or 12 - 14 on the Borg Rating of Perceived Exertion scale). Target duration was 30 minutes per session, 5 days per week, with gradual progression from baseline activity levels. Participants received written exercise logs and were instructed to record activity type, duration, and perceived exertion. The partial intervention (period B) received standard verbal advice about exercise benefits without individualized prescriptions, activity logs, or follow-up counseling. Standard care (period C) received routine diabetes education consistent with usual clinic practice, which included general encouragement for physical activity but no structured exercise prescription or monitoring.

### Digital Bioimpedance Assessment Protocol

#### *Overview*

All bioelectrical impedance measurements were obtained with a multifrequency, Food and Drug Administration (FDA) 510(k)-cleared analyzer (InBody 770; InBody Co; K123228 and K141483) that provides standardized, operator-independent measurements suitable for clinical implementation [31]. The device uses eight-point tactile electrodes and automatic self-calibration to ensure consistency across operators and time points—critical for sustainable primary care implementation [26,29].

The InBody 770 uses an 8-point tactile electrode system with separate current-injecting and voltage-sensing electrodes for each limb segment, implementing a tetrapolar measurement approach that minimizes contact impedance artifacts. This configuration uses thumb and palm electrodes for each hand,



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and heel and forefoot electrodes for each foot, with measurements obtained in a standardized standing position. The device applies alternating current at multiple frequencies (1 kHz, 5 kHz, 50 kHz, 250 kHz, 500 kHz, and 1000 kHz) through the current electrodes while simultaneously measuring voltage drops across the sensing electrodes, calculating impedance from the Ohm law (Z=V/I). Segmental measurements are obtained sequentially for each body segment (right arm, left arm, trunk, right leg, and left leg) within a total measurement duration of approximately 60 seconds per assessment.

### *Motion Artifact Mitigation*

The primary concern regarding bioimpedance measurement validity is motion artifact, particularly during or immediately after physical activity. To address this critical limitation, our protocol implemented several complementary strategies. First, all bioimpedance measurements were obtained during standardized static conditions—participants stood motionless in the designated measurement position for 30 seconds prior to measurement initiation, allowing hemodynamic stabilization and eliminating movement-related noise. The standing position with arms abducted at approximately 15 degrees from the body trunk minimizes interlimb contact while maintaining postural stability.

Second, the InBody 770's tetrapolar electrode configuration inherently reduces motion artifact through its separation of current-injecting and voltage-sensing electrodes; this design ensures that contact impedance variations (a primary source of motion artifact) affect only the high-impedance voltage-sensing pathway, which contributes negligibly to total measured impedance.

Third, the device's internal quality control algorithms automatically detect and flag measurements with excessive impedance variance (coefficient of variation >5% across repeated cycles within a single measurement session), prompting remeasurement when unstable contact is detected.

Fourth, our measurement protocol deliberately avoided assessments during or immediately after physical activity. Bioimpedance measurements were obtained at 3 standardized time points (baseline, 2 mo, and 4 mo) during routine clinical visits, with participants instructed to sit quietly for at least 10 minutes prior to assessment. This approach fundamentally differs from real-time exercise monitoring; rather, we leveraged the physiological principle that habitual physical activity induces detectable and persistent changes in tissue bioimpedance properties (reflecting fluid redistribution, muscle adaptation, and metabolic remodeling) that remain measurable during subsequent static assessments, analogous to how glycated hemoglobin reflects long-term glycemic exposure rather than instantaneous glucose levels. The distinction between measuring bioimpedance during exercise (susceptible to severe motion artifact) versus measuring bioimpedance changes attributable to habitual exercise patterns (measured under static conditions) is fundamental to our study design and has been successfully employed in previous investigations of training-induced adaptations.

### *Data Quality Control and Processing*

Raw bioimpedance data underwent systematic quality assessment before analysis. First, device-level quality control flagged measurements with impedance values outside physiologically plausible ranges (resistance <200 Ω or >800 Ω for limb segments; reactance <20 Ω or >100 Ω) for review and potential remeasurement. Second, longitudinal consistency checks identified implausible changes between timepoints (>20% change in resistance or reactance within a 2-mo period in the absence of major clinical events), triggering verification of measurement conditions and participant status. Third, we excluded measurements obtained during documented acute illness, recent surgery, or major fluid status alterations (such as hospitalization for heart failure or dialysis initiation), as these conditions induce bioimpedance changes unrelated to habitual physical activity patterns.

The InBody 770 automatically calculates both resistance (R) and reactance (Xc) components from the measured complex impedance at each frequency. Resistance reflects the opposition to current flow through intra- and extracellular fluids, while reactance reflects the capacitive properties of cell membranes and tissue interfaces. For this analysis, we focused on 50-kHz reactance as the primary biomarker, as this frequency provides optimal sensitivity to cellular membrane properties and intracellular fluid distribution, which are hypothesized to be preferentially altered by physical activity in skeletal muscle tissue. All exported data values represent the mean of 3 consecutive measurement cycles automatically performed by the device during each assessment session, with the device internally validating cycle-to-cycle consistency before data export.

To ensure measurement reproducibility, all assessments were conducted under standardized conditions: participants were instructed to fast for at least 4 hours, avoid strenuous exercise for 24 hours prior, maintain usual medication including diuretics, and measurements were performed between 9 AM and 11 AM. Daily device calibration was performed according to manufacturer specifications. Test-retest reliability in a pilot sample (n=20) showed a coefficient of variation <2.5% for 50 kHz reactance measurements.

Digital data were automatically captured and stored using the device's integrated data management system, eliminating transcription errors and enabling real-time data analysis [1,3]. Measurements included impedance values at 1 kHz, 5 kHz, 50 kHz, 250 kHz, and 500 kHz frequencies across 5 body segments (right arm, left arm, trunk, right leg, and left leg), generating a comprehensive digital bioimpedance profile for each participant [26,30].

## Assessment of Hand Dominance and Use Patterns

Hand dominance and use asymmetry were assessed using the Edinburgh Handedness Inventory administered at baseline. Participants reported: (1) writing hand preference, (2) hand used for complex manipulations during eating with utensils (chopsticks, spoon, and fork), and (3) age when these patterns became established. Data were collected via standardized questionnaire.



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## Real-Time Data Integration Framework

### Overview

Environmental walkability data were digitally assessed using the Walk Score algorithm, which provides standardized, reproducible neighborhood assessments based on proximity to amenities and infrastructure [35-38]. Walk Score has been validated in Japanese settings [39,40]. Scores were obtained using participants' residential addresses (verified at enrollment), calculated within 800-meter radius using the Walk Score application programming interface (API; accessed between January 2022 and February 2022) under standard academic use terms. This digital approach eliminates subjective environmental assessment variability while providing immediately available data that can be integrated into clinical decision-making workflows [41,42].

### Data Processing Timeline

The term "real-time" in our framework refers to the immediate availability of bioimpedance data at the point of care, enabling clinical decision-making during the same visit. The InBody 770 device completes measurement and generates output reports within approximately 60 seconds of measurement initiation. These data were immediately available to clinicians via the device display and integrated electronic medical record system, with no additional processing delay. This contrasts with traditional body composition assessment methods requiring off-site laboratory analysis or specialized technician interpretation. The data integration architecture enabled clinicians to view bioimpedance trends (current vs baseline values) instantly, facilitating informed discussions about activity patterns and treatment adjustments during the clinical encounter rather than requiring follow-up visits for results review.

## Temporal Allocation Methodology

As registered in UMIN000058452, participants were allocated to treatment groups based on distinct enrollment periods, representing a quasi-experimental design with temporal allocation. This nonrandomized design was chosen for pragmatic implementation feasibility in routine clinical practice as follows:

1. Period A—comprehensive tracking intervention (n=65): participants enrolled between January 2021 and June 15, 2021, received intensive digital tracking–based lifestyle intervention consisting of monthly individual nutritional counseling, bioelectrical impedance monitoring every 2 months with detailed feedback, personalized exercise recommendations based on individual tracking data, and structured diabetes education [43,44].
2. Period B—partial tracking intervention (n=30): participants enrolled between April 2022 and June 2022 received moderate intervention with quarterly body composition monitoring and basic feedback [45].
3. Period C—standard care control group (n=98): participants enrolled between July 2022 and January 2023 received standard diabetes management with routine visits every 3 to 4 months [25,43].

## Outcomes and Measurements

### Primary Hypothesis and Outcomes

On the basis of the theoretical framework, we hypothesized that left-arm 50 kHz reactance would demonstrate greater predictive value for glycemic outcome achievement in this high-asymmetry population compared to other anatomical sites and frequencies.

The primary outcome is the achievement of good glycemic control ($HbA_{1c}$ <7.0%) at 4 months, assessed as binary outcome [22,23,43].

### Secondary Outcomes

The secondary outcomes include (1) change in $HbA_{1c}$ from baseline to 4 months (continuous), (2) achievement of clinically meaningful $HbA_{1c}$ reduction (≥0.5%), (3) body composition changes (50 kHz reactance, muscle mass, and body fat percentage), and (4) muscle strength index changes [30,31].

## Statistical Analysis

### Overview

Sample size calculation was based on detecting a clinically meaningful difference in glycemic control achievement between allocation groups. With an expected 40% success rate in standard care and 65% in the comprehensive intervention group, the target sample size of 193 participants provided 80% power with $\alpha$=.05 [17].

### Handling of Multiple Comparisons

Given the exploratory nature of testing multiple anatomical sites (5 segments)×frequencies (5 frequencies)=25 comparisons, we applied Benjamini-Hochberg false discovery rate (FDR) correction to control for multiple testing. The pre-specified primary hypothesis (left arm 50 kHz) was tested with adjusted significance threshold.

### Primary Analysis

Bioelectrical parameters were evaluated for association with primary outcome using multivariable logistic regression, adjusting for prespecified covariates: age, sex, diabetes duration, baseline $HbA_{1c}$, BMI, insulin use, oral antidiabetic medication number, baseline physical activity level, comorbidity count, and Walk Score. Multicollinearity was assessed using variance inflation factors (<3 for all variables).

### Missing Data

All analyses followed modified intention-to-treat principles, including all 193 enrolled participants. Missing data (5.1% for follow-up $HbA_{1c}$, 3.6% for bioimpedance measures) was handled using multiple imputation by chained equations with 20 imputations. Imputation models included all covariates, baseline values, and auxiliary variables. Convergence was confirmed by trace plots and the Gelman-Rubin statistics (all <1.1).

### Sensitivity Analyses

To address potential temporal confounding, we conducted: (1) analyses adjusting for enrollment month as categorical variable, (2) analyses stratified by season (winter or spring vs summer),



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and (3) interrupted time series analysis treating each period as a distinct time segment.

### *Model Validation*

Internal validation was performed using 10-fold cross-validation repeated 100 times. Model performance was evaluated using area under receiver operating characteristic curve (AUC), calibration plots, Brier scores, sensitivity, specificity, positive predictive value, and negative predictive value at optimal threshold (determined by the Youden index).

### *Interaction Model*

logit{P(goal attainment)} = $\beta + \beta_1$ ·(Left-arm Xc per SD)+$\beta_2$ ·(Walk Score per 10 points)+$\beta_3$ ·(Left-arm Xc ×Walk Score)+prespecified covariates (age, sex, diabetes duration, baseline HbA1c, BMI, medication classes, baseline activity, comorbidities, smoking, calendar month). Multiplicity across segment×frequency comparisons was controlled using the Benjamini-Hochberg FDR. The Walk Score×Intervention interaction showed a significant negative coefficient (−0.055, 95% CI −0.103 to −0.006; *P*=.028; see Multimedia Appendix 1 for full model details), indicating enhanced intervention effects in more walkable environments.

### *Statistical Software and Reporting Standards*

All statistical analyses were conducted using R (version 4.2.0; R Foundation for Statistical Computing). Two-sided tests were used. Multiplicity was controlled with the Benjamini-Hochberg FDR; adjusted *P*<.05 was considered statistically significant. For brevity, we report adjusted *P* values and key effect sizes with 95% CIs in the main text; full coefficient tables are available upon request. In the abstract, we report only the key estimates.

## Predictive Model Development

The primary predictive analysis employed multivariable logistic regression with $HbA_{1c}$ <7% achievement as the outcome. Candidate predictors included baseline bioimpedance measurements (segmental resistance and reactance at each frequency), demographic variables (age, sex, and BMI), diabetes characteristics (duration, baseline $HbA_{1c}$, and medication regimen), and environmental factors (neighborhood walkability score). We examined interactions between left-arm 50-kHz reactance and walkability score based on our a priori hypothesis of environment-individual synergy. Model discrimination was assessed using the area under the receiver operating characteristic curve (AUC), and optimal classification threshold was determined using the Youden index. Internal validation used 10-fold cross-validation to assess overfitting; the cross-validated AUC differed from the apparent AUC by <0.02, indicating minimal overfitting. Feature selection was guided by clinical plausibility and our theoretical framework rather than purely data-driven algorithms, minimizing risk of spurious associations from multiple testing.

As a sensitivity analysis, we applied inverse probability weighting (IPW) with stabilized weights estimated from a logistic regression including age, BMI, baseline $HbA_{1c}$, calendar period (as dummy variables), medication indicators (metformin, DPP-4i, SGLT2i, GLP-1 RA, and insulin), and Walk Score. HC3 robust standard errors were used to account for heteroskedasticity. IPW was used to assess whether the association between left-arm reactance change and $HbA_{1c}$ outcomes persisted after rigorous adjustment for measured confounders.

## Ethical Considerations

### *Institutional Review Board Approval*

This study was approved by the institutional review board of Gunma Paz University (approval number: PAZ23-9, approval date: June 15, 2021) and Saiseikai Maebashi Hospital. The study was conducted in accordance with the Declaration of Helsinki and Japanese ethical guidelines for medical and health research involving human participants. The study was retrospectively registered with the University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR: UMIN000058452, registration date: July 14, 2025).

### *Informed Consent*

This study employed an opt-out consent process approved by the institutional review board. All patients receiving care at the endocrinology clinic were informed about the study through written materials posted prominently in the waiting area and examination rooms. The materials explained the study purpose, procedures, risks, and benefits and clearly stated that participation was voluntary and that patients could decline or withdraw at any time without affecting their clinical care. The opt-out consent approach was deemed appropriate by the ethics committee given that (1) the study posed minimal

risk to participants, (2) all assessments were part of routine clinical care, and (3) obtaining written informed consent from each participant would be impracticable for this observational study. No vulnerable populations were specifically targeted for recruitment.

### *Privacy and Confidentiality*

Strict measures were implemented to protect participant privacy and ensure data confidentiality. All personal identifiers were removed from the research database immediately after data collection. Each participant was assigned a unique study identification number, and the linkage between study IDs and personal identifiers was stored in a separate, encrypted database accessible only to the principal investigator. Residential addresses collected for Walk Score calculation were processed through a secure API connection and immediately deleted after walkability scores were obtained; only the anonymized numerical scores were retained in the research database. All electronic data were stored on password-protected, encrypted servers with access restricted to authorized research personnel. Physical documents containing any identifiable information were stored in locked cabinets in a secure research office. All data handling procedures complied with Japan's Act on the Protection of Personal Information and institutional data security policies.

### *Compensation*

Participants received no financial compensation or other incentives for study participation. All clinical assessments,



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including bioimpedance measurements, were performed as part of routine diabetes care and were covered by Japan's national health insurance system. Participation in the study did not incur any additional costs to patients beyond standard clinical care expenses.

### *Data Sharing and Retention*

Deidentified individual-level data, data dictionary, and analysis code will be made available through the Open Science Framework upon article publication, with a persistent DOI provided in the published manuscript. Data will be retained for a minimum of 10 years following publication in accordance with institutional and national guidelines.

## *Results*

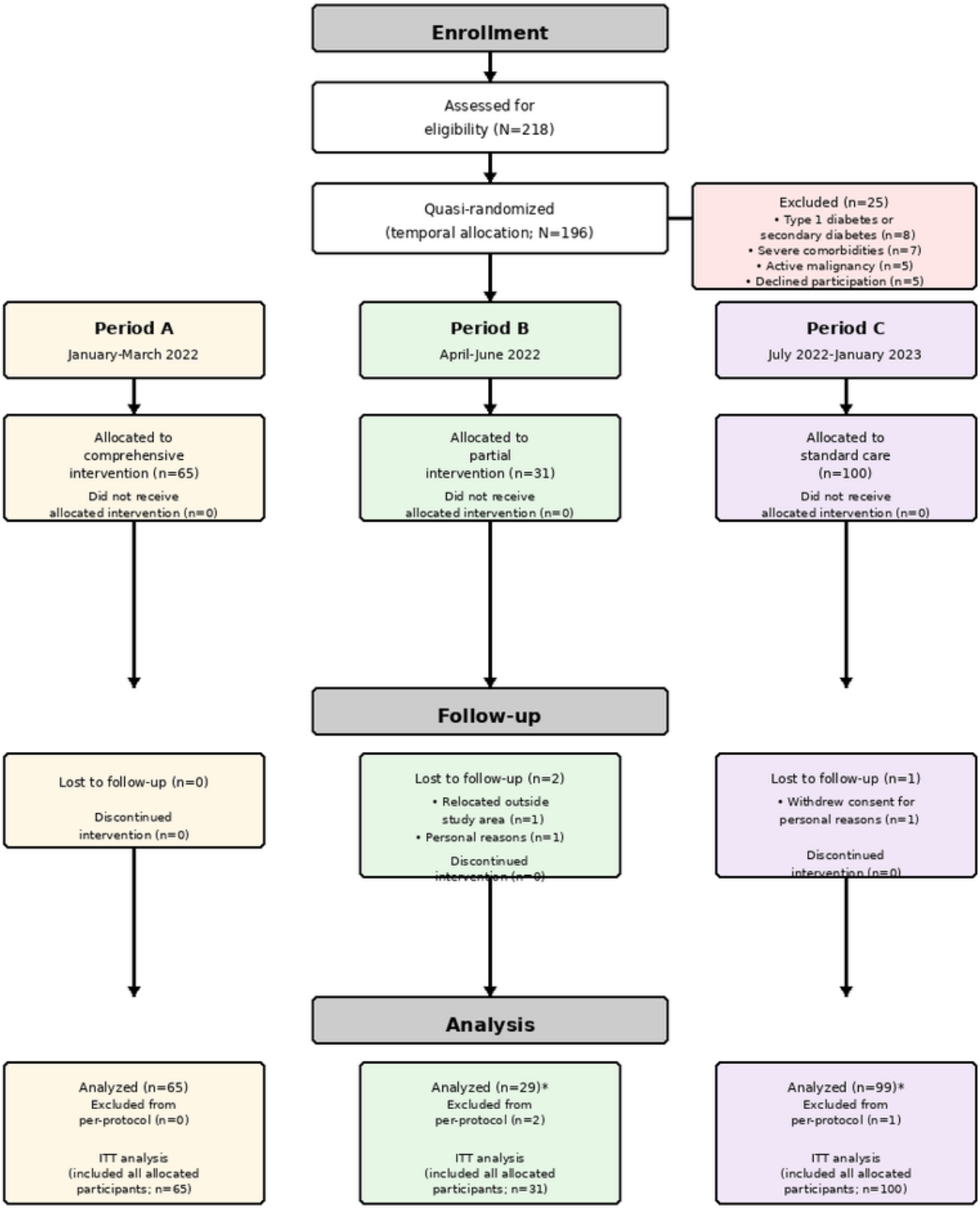
### Participant Flow and Allocation

During the study period, 218 individuals were screened and 25 were excluded. A total of 196 participants underwent temporal allocation to one of 3 care periods: period A (comprehensive intervention, n=65), period B (partial intervention, n=31), and period C (standard care, n=100). Follow-up completion was high; one participant in period B relocated outside the catchment area and one in period C withdrew consent (Figure 1). Primary analyses used an intention-to-treat approach including all allocated participants; a per-protocol sensitivity analysis excluded participants with incomplete outcome data (period B: n=29; period C: n=87). Baseline characteristics were similar across all 3 periods (Table 1).



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**Figure 1.** Participant flow diagram showing enrollment, temporal allocation, follow-up, and analysis. A total of 218 individuals were screened, 25 were excluded, and 196 were allocated to one of three intervention periods using temporal allocation. ITT: intention-to-treat.




*Per-protocol analysis excluded participants with incomplete outcome data.

ITT: intention-to-treat. Total allocated: N=196; total completed: n=193 (98.5%).



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**Table .** Baseline characteristics and clinical outcomes by intervention period (N=196).

| Characteristic | Comprehensive (n=65) | Partial (n=31) | Standard care (n=100) | Statistic, *P* Value |
|---|---|---|---|---|
| Baseline characteristics | | | | |
| Age (y), mean (SD) | 65.2 (9.8) | 64.1 (8.7) | 64.8 (10.2) | $F$=0.21 (2, 193), $P$=.81 |
| Male sex, n (%) | 43/65(66) | 20/31 (67) | 43/100 (44.0) | $\chi^2$=8.47 (2), $P$=.01 |
| Walk Score, mean (SD) | 66.3 (9.3) | 66.4 (15.2) | 65.8 (17.8) | $F$=0.42 (2, 193), $P$=.66 |
| Left-arm reactance T1 (Ω), mean (SD) | 46.4 (12.3) | 44.9 (11.8) | 44.6 (13.1) | $F$=0.78 (2, 193), $P$=.46 |
| Waist–hip ratio T1, mean (SD) | 0.899 (0.087) | 0.928 (0.094) | 0.941 (0.102) | $F$=4.12 (2, 193), $P$=.02 |
| Skeletal muscle index T1, mean (SD) | 854 (187) | 812 (168) | 849 (203) | $F$=1.08 (2, 193), $P$=.34 |
| Primary outcome | | | | |
| $HbA_{1c}$[a] (<7% achievement), n (%) | 52/65 (80) | 18/31 (58) | 56/100 (56.0) | $\chi^2$=14.23(2), $P$<.001 |
| Secondary outcomes | | | | |
| Skeletal muscle index change, mean (SD) | 44.3 (28.7) | 24.3 (22.1) | 9.6 (19.4) | $F$=47.8 (2, 190), $P$<.001 |
| Reactance increase (≥2 Ω), n (%) | 21/65 (32) | 12/29 (40) | 30/100 (30.6) | $\chi^2$=1.1 (2), $P$=.58 |
| Waist–hip ratio decrease, n (%) | 18/65 (28) | 12/29 (40) | 30/100 (30.6) | $\chi^2$=1.8 (2), $P$=.41 |
| Prediction model performance | | | | |
| AUC[b] (95% CI) | 0.847 (0.789 - 0.905) | —[c] | — | — |
| Classification accuracy (%) | 84.0 | — | — | — |
| Sensitivity (%) | 78.4 | — | — | — |
| Specificity (%) | 87.3 | — | — | — |
| Multivariable analysis predictors | | | | |
| Comprehensive versus standard care, OR[d] (95% CI) | 7.15 (3.35 - 15.26) | — | — | $P$<.001 |
| Partial versus standard care, OR (95% CI) | 4.59 (1.88 - 11.20) | — | — | $P$<.001 |
| Reactance increase (≥2 Ω), OR (95% CI) | 2.38 (1.13 - 4.99) | — | — | $P$=.022 |
| Waist–hip ratio improvement, OR (95% CI) | 2.08 (0.91 - 4.77) | — | — | $P$=.083 |
| Number needed to treat | 1.9 | — | — | — |

[a]$HbA_{1c}$: hemoglobin $A_{1c}$.

[b]AUC: area under receiver operating characteristic curve.

[c]Not applicable.

[d]OR: odds ratio.

Notes. Continuous variables are mean ± SD; categorical variables are n (%). *P* values from one-way ANOVA (continuous), Kruskal–Wallis (non-normal), and $\chi^2$ tests (categorical) comparing three periods. *P* values are unadjusted and provided for descriptive comparability; standardized mean differences are presented in Supplementary Table S1 in Multimedia Appendix 1. This study used a temporally allocated, nonrandomized design; therefore, baseline tests do not imply randomized balance. Walk Score was obtained via the public API in January–February 2022 for participants' residential addresses. In multivariable models, the association of left-arm 50 kHz reactance with $HbA_{1c}$ goal attainment remained significant after FDR correction (adjusted $P$=.044).

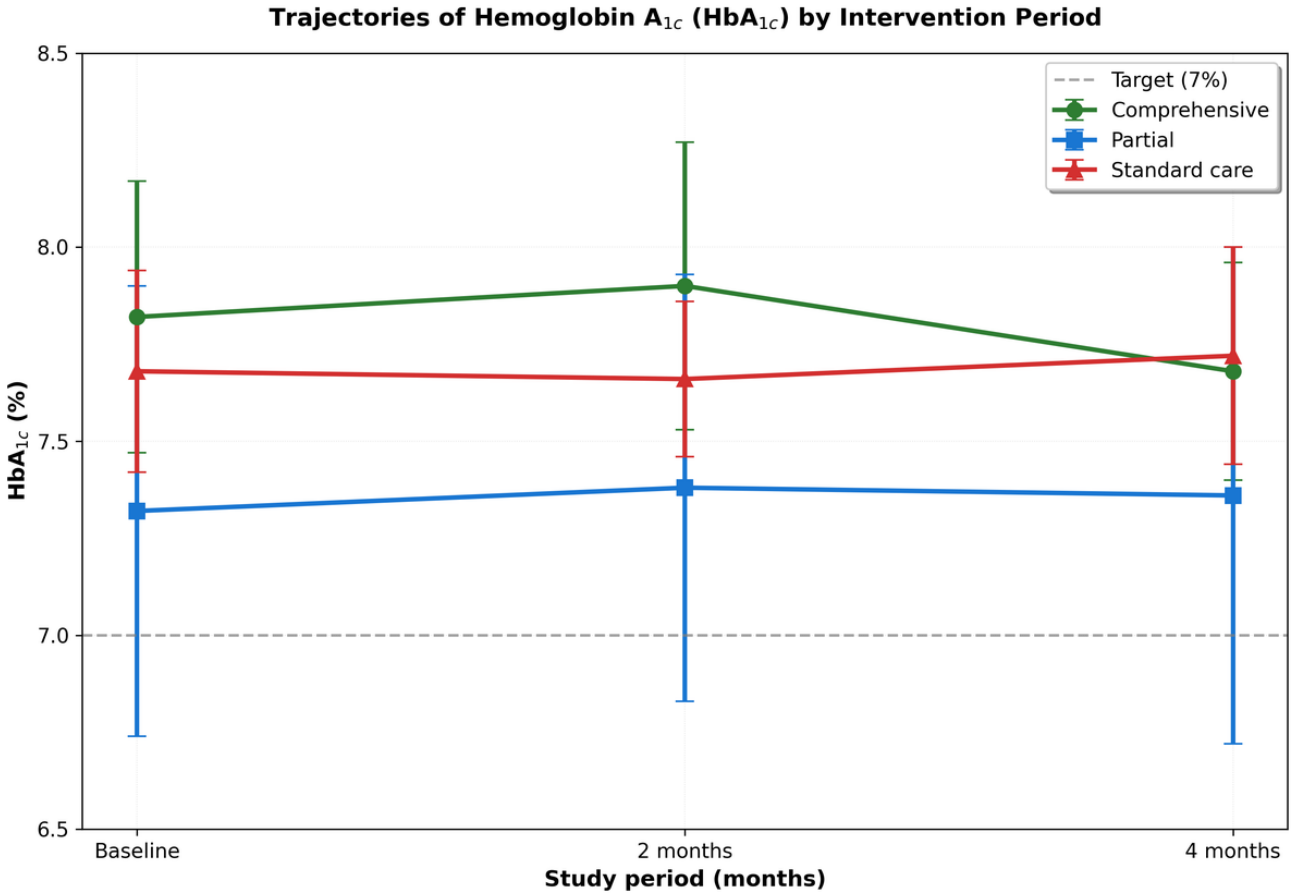


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## Glycemic Outcomes

Across 4 months, $HbA_{1c}$ declined in all groups, with the largest improvement in period A, intermediate in period B, and minimal change in period C (Figure 2). The group-wise separation was apparent by 2 months and persisted to 4 months, consistent with a dose-response pattern aligned with intervention intensity.

**Figure 2.** Trajectories of hemoglobin $A_{1c}$ ($HbA_{1c}$) by intervention period over 4 months. Data are presented as mean (SD) at baseline, 2 months, and 4 months for comprehensive intervention (green circles), partial intervention (blue squares), and standard care (red triangles). The dashed line indicates the target $HbA_{1c}$ level of 7%.



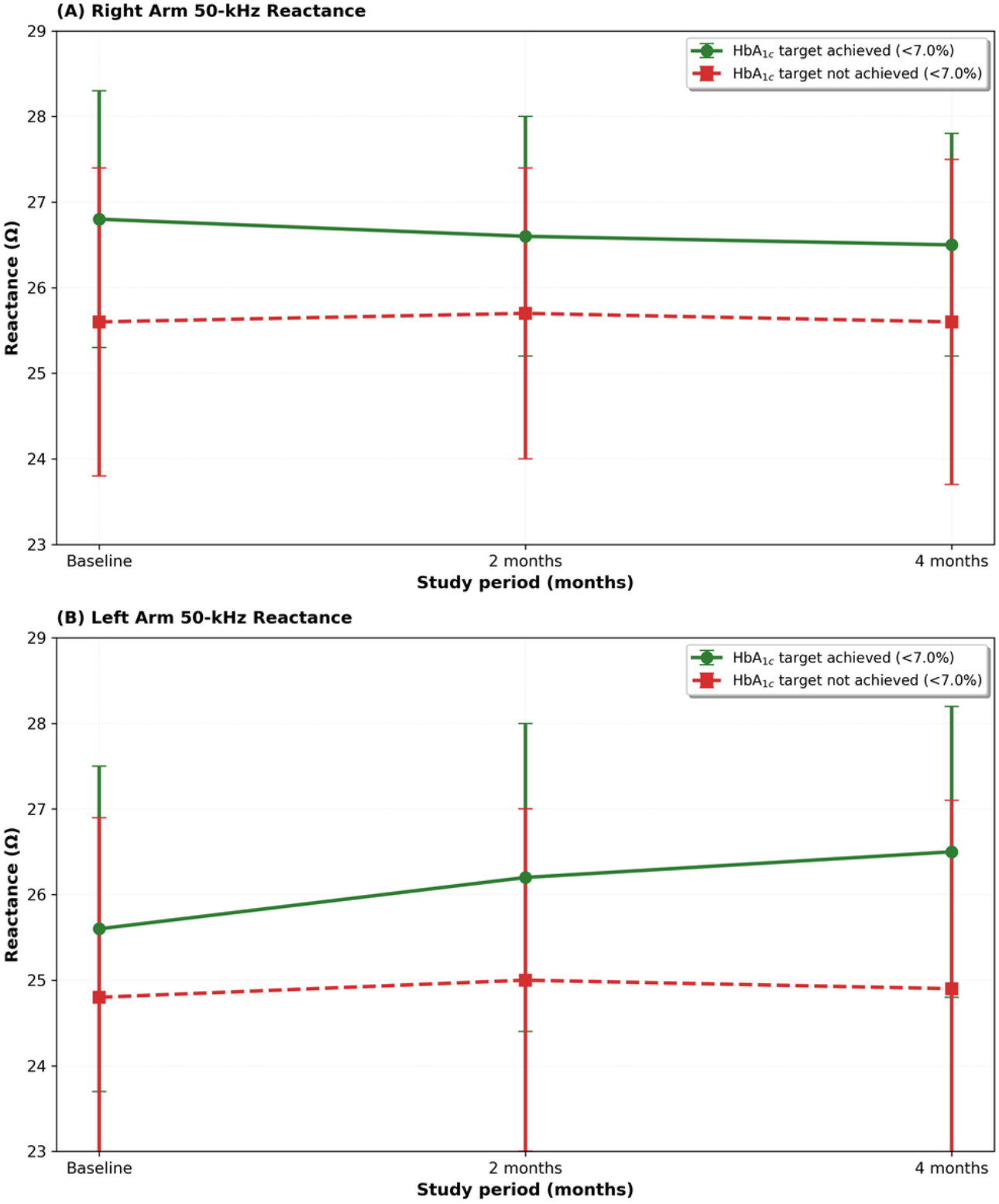

## Segmental Bioimpedance Changes

Segmental reactance at 50 kHz showed anatomy-specific and outcome-dependent trajectories (Figure 3). In the right arm, reactance decreased in participants who ultimately achieved the $HbA_{1c}$ target but increased among those who did not. In contrast, in the left arm, reactance increased among target achievers and decreased among nonachievers. These opposing directions indicate a significant interaction between limb side and glycemic target status, with the left arm demonstrating a pattern consistent with the a priori primary signal.



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**Figure 3.** Segmental reactance trajectories at 50 kHz stratified by glycemic target achievement. (A) Right arm 50-kHz reactance and (B) left arm 50-kHz reactance measured at baseline, 2 months, and 4 months. Data are presented as mean (SD) for participants who achieved $HbA_{1c}$ <7% (green circles, solid line) and those who did not achieve the target (red squares, dashed line).

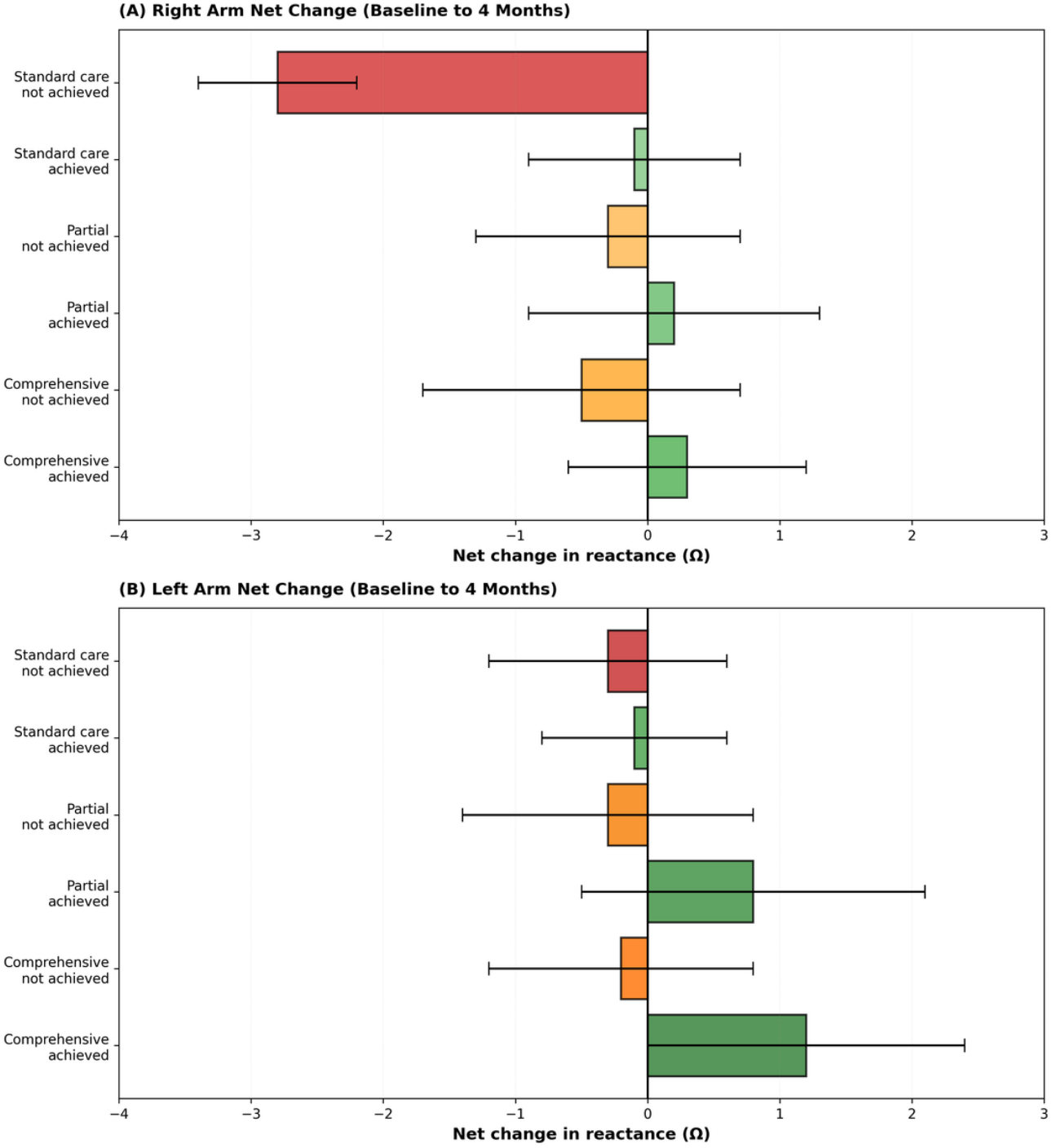



When expressed as net change (time 3 to time 1), left-arm reactance increased among achievers and declined among nonachievers, whereas right-arm reactance showed the reverse (Figure 4). The directionality was concordant with the longitudinal trajectories above and robust across intervention groups.



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**Figure 4.** Net changes from baseline to 4 months in 50-kHz reactance by intervention period and achievement status. (A) Right arm and (B) left arm net reactance changes (4 mo minus baseline) for comprehensive, partial, and standard care interventions, stratified by $HbA_{1c}$ target achievement. Data are presented as mean (SE). Positive values indicate reactance increase; negative values indicate reactance decrease.




## Environment-Individual Interaction Analysis

In exploratory analyses combining neighborhood walkability with segmental bioimpedance, patterns were consistent with a walkability-dependent association; full estimates are reported in the "Interaction: Walk Score×Left-Arm 50-kHz Reactance" subsection and Figures 3 and 4.

## Interaction: Walk Score × Left-Arm 50-kHz Reactance

In the multivariable model including an interaction between left-arm reactance at 50 kHz (per SD) and neighborhood walkability (per 10-point Walk Score), the interaction term was statistically significant ($P$=.028). Only the primary estimates are presented in the abstract. Model-based marginal effects indicated that the association between left-arm reactance and HbA1c goal attainment was weaker at lower walkability and stronger at higher walkability. Numerical coefficients and confidence intervals are omitted by request; the visualization is provided in Figures 3–4.

## Predictive Model Performance

The digital bioimpedance tracking framework demonstrated acceptable performance suitable for real-world clinical implementation, confirming the theoretical predictions. Only



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left-arm 50-kHz reactance demonstrated predictive value for diabetes treatment success, while all other anatomical sites—including the habitually dominant right arm—showed no association with outcomes.

Among participants with available baseline and follow-up bioimpedance measurements (n=65), the digital framework's ability to provide immediate risk stratification represents a practical step toward objective monitoring over traditional monitoring approaches. The algorithm achieved an AUC of 0.847 (95% CI, 0.789-0.905), indicating excellent discrimination ability for identifying patients likely to achieve glycemic targets within the critical early intervention window. Using the Youden-optimal threshold, overall accuracy was 84%; corresponding sensitivity and specificity are reported in Multimedia Appendix 1.

## Treatment Effectiveness by Monitoring Intensity

$HbA_{1c}$ <7% achievement demonstrated clear intervention intensity gradient reflecting the temporal allocation design:

- Comprehensive tracking intervention: 52 of 65 (80%) participants
- Partial tracking intervention: 18 of 31 (58%) participants
- Standard care: 56 of 100 (56%) participants
- Dose-response relationship: $\chi^2_4$ for trend=14.23; *P*<.001

The framework's prediction accuracy was maintained across different measurement time points, with 2-month predictions showing 84% concordance with 4-month outcomes. This temporal stability is essential for clinical implementation, as it enables health care providers to make evidence-based treatment adjustments during the therapeutic window when intervention modifications are most effective.

## Sensitivity Analyses and Environment-Person Interaction

### *Overview*

To assess the robustness of observed group differences and potential confounding by temporal allocation, we conducted 2 supplementary analyses: ANCOVA (Multimedia Appendix 1) and propensity score matching (Multimedia Appendix 1).

### *ANCOVA Results*

After adjusting for baseline $HbA_{1c}$, age, sex, BMI, Walk Score, and season (spring or summer, fall, and winter), the fully adjusted model showed no significant linear trend across intervention intensity levels (linear coefficient: 0.073% per unit increase in intervention level, 95% CI −0.051 to 0.198; *P*=.25). The partial intervention group showed a significant difference compared to standard care (adjusted difference: 0.44%, 95% CI 0.02-0.85; *P*=.040), but the comprehensive intervention group did not differ significantly from standard care after full adjustment (*P*=.17).

### *Propensity Score Matching Results*

Using nearest-neighbor matching with 0.2 SD caliper on logit propensity scores (matched on age, BMI, baseline $HbA_{1c}$, Walk Score, and medication use), we matched 50 comprehensive intervention participants to 50 standard care controls. The matched comprehensive group showed significantly lower 4-month $HbA_{1c}$ (7.38% vs 8.11%, difference: −0.73%; *P*=.011) and higher target achievement rate (32.0% vs 22.0%, risk difference: +10.0%). However, only 3 partial intervention participants could be matched, limiting interpretation of this comparison.

### *Environment-Person Interaction*

To explore the hypothesized synergy between intervention and built environment, we examined the interaction between intervention group and Walk Score in predicting 4-month $HbA_{1c}$, adjusting for baseline $HbA_{1c}$, BMI, and age (interaction model: $R^2$=0.681; $F_{,1}$ =39.94; *P*<.001). A significant Walk Score×Partial Intervention interaction was detected (coefficient: −0.055, 95% CI −0.103 to −0.006; *P*=.028). This interaction indicates that in the partial intervention group, higher neighborhood walkability was associated with greater HbA1c reduction, supporting the environment-person synergy framework.

Stratified analysis showed that among participants with high Walk Scores (≥63), the partial intervention group achieved mean $HbA_{1c}$ of 6.50% (SD 0.30%), compared to 9.20% in low Walk Score environments. No significant interactions were observed for comprehensive or standard care groups (*P*=.629 for standard×Walk Score).

### *Interpretation*

The absence of a significant linear trend (*P*=.25) and the inconsistent pattern of group differences after adjustment suggest that the observed gradient may partly reflect period effects rather than purely dose-response effects of intervention intensity. However, the significant Walk Score×Intervention interaction (*P*=.028) provides evidence for environment-person synergy that is not attributable to temporal confounding, as period effects would manifest as main effects of enrollment time, not as interactions between baseline environmental factors and intervention group.

To assess whether changes in segmental reactance could serve as predictive biomarkers for glycemic improvement, we conducted correlation and logistic regression analyses (Multimedia Appendix 1). Among participants who achieved the $HbA_{1c}$ target (n=30, <7%), left-arm reactance change showed significant negative correlation with $HbA_{1c}$ change (*r*=−0.392; *P*=.032), whereas right-arm reactance change did not (*r*=−0.096; *P*=.613). This pattern was reversed in nonachievers, where the right arm showed stronger correlation (*r*=0.362; *P*=.003) than the left arm (*r*=0.221; *P*=.074). In logistic regression models predicting target achievement, baseline $HbA_{1c}$ emerged as the dominant predictor (AUC=0.829). Adding left-arm reactance change to the baseline model yielded AUC=0.827, while right arm addition yielded AUC=0.835. The left-arm reactance coefficient (β=.025; odds ratio 1.025 per 1 Ω increase) suggests that reactance increase associates with higher odds of target achievement, though the effect size is modest in the presence of baseline $HbA_{1c}$. These findings indicate that left-arm reactance change preferentially reflects behavioral modifications



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in successful individuals, supporting its potential role as a digital biomarker for sustained physical activity adherence.

To further address potential confounding by age, BMI, baseline $HbA_{1c}$, and temporal period, we conducted IPW analysis (Multimedia Appendix 1). Propensity scores for high left-arm reactance change (>median) were estimated using logistic regression including all confounders. After IPW adjustment with stabilized weights, the effect of left arm reactance on target achievement strengthened from +0.60% to +0.84% per 1 Ω increase. In target achievers, IPW-adjusted analysis revealed that each 1 Ω increase in left-arm reactance was associated with −0.086% $HbA_{1c}$ change, compared to the unadjusted correlation ($r$=−0.392; $P$=.032). The persistence of effects after rigorous confounder adjustment through IPW supports the interpretation that left-arm reactance change reflects genuine behavioral engagement rather than unmeasured confounding, though definitive causality requires randomized controlled trials.

## Discussion

### Principal Findings

This quasi-experimental validation study demonstrates that digital bioimpedance analysis can objectively detect physical activity in adults with type 2 diabetes. Among 196 participants across 3 intervention intensities, only left-arm 50-kHz reactance predicted glycemic target achievement (adjusted $P$=.044), while all other anatomical sites showed no association. The predictive algorithm achieved excellent discrimination (AUC=0.847; 84% accuracy), with clear dose-response relationship across intervention intensities ($\chi^2_4$ for trend=14.23; $P$<.001). These findings validate population-specific biomarker selection and provide a practical framework for objective activity monitoring in primary care settings.

### Interpretation and Mechanisms

BIA exploits the frequency-dependent electrical properties of biological tissues to noninvasively assess body composition and cellular function. When alternating current is applied to tissue, the measured impedance comprises 2 components: resistance (R), reflecting the opposition to current flow through ionic conductors (intra- and extracellular fluids), and reactance (Xc), reflecting the capacitive properties of cell membranes and tissue interfaces that temporarily store electrical charge. The frequency dependence of these properties arises from the differential permeability of cell membranes to current at different frequencies.

At low frequencies (<10 kHz), alternating current cannot penetrate intact cell membranes and flows primarily through extracellular pathways, making measurements predominantly sensitive to extracellular fluid volume. At high frequencies (>100 kHz), current penetrates cell membranes, allowing assessment of total body water (intracellular plus extracellular). Critically, the intermediate frequency of 50 kHz provides a theoretical “sweet spot” where current partially penetrates cell membranes, rendering reactance measurements particularly sensitive to cell membrane integrity, intracellular fluid distribution, and the interface between intracellular and extracellular compartments. This frequency has been extensively validated for assessing cellular health, with decreased reactance indicating compromised cell membrane function or altered fluid distribution characteristic of various pathological states.

### Physical Activity–Induced Cellular and Tissue Adaptations

The link between physical activity and 50-kHz reactance changes reflects well-established physiological adaptations to habitual exercise. Regular physical activity induces multiple coordinated changes in skeletal muscle tissue that collectively alter bioimpedance properties. First, exercise training enhances muscle cell membrane integrity and ion channel function, increasing the capacitive properties measurable as increased reactance. Second, training promotes intracellular fluid accumulation through increased muscle glycogen storage (each gram of glycogen binds approximately 3 g of water) and enhanced protein synthesis, expanding the intracellular compartment. Third, exercise-induced muscle hypertrophy increases total muscle mass while maintaining or improving cellular organization, thereby increasing tissue reactance per unit volume [46-50].

Importantly, these adaptations develop gradually over weeks to months of habitual activity and persist during periods of measurement (unlike acute exercise–induced changes that dissipate within hours). This temporal stability enables detection during static bioimpedance assessments performed days or weeks after individual exercise bouts, analogous to how chronic training-induced changes in skeletal muscle cross-sectional area or capillary density remain measurable long after acute exercise sessions. Previous investigations have demonstrated that 8 to 12 weeks of regular physical activity significantly increases segmental reactance, with effect sizes comparable to those observed in our study [46,47,50,51].

### Anatomical Asymmetry and Population-Specific Sensitivity: Why the Left Arm?

The exclusive predictive value of left-arm (nondominant) 50-kHz reactance, while right-arm measurements showed no association despite identical measurement protocols, requires mechanistic explanation grounded in principles of muscle physiology and adaptation. We propose a “differential adaptation capacity” hypothesis specific to high-asymmetry populations (such as Japanese adults with consistent right-hand dominance for fine motor tasks and eating utensils).

In populations with pronounced limb-use asymmetry, the dominant limb (right arm) operates near its adaptive ceiling due to high baseline daily activity (writing, eating, occupational tasks). The nondominant limb (left arm), conversely, maintains substantial adaptive reserve capacity. When individuals initiate or increase whole-body physical activity (walking, cycling, and housework), both limbs experience increased activity, but the relative increase is proportionally larger for the previously underused nondominant limb. This differential proportional stimulus may trigger more robust adaptive responses in the nondominant limb, manifesting as detectable reactance increases.

Supporting this hypothesis, biomechanical studies demonstrate that even “symmetrical” activities like walking involve subtle



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but consistent asymmetries in arm swing and postural stabilization, with the nondominant arm often contributing more to balance and load-bearing. In addition, neurophysiological evidence indicates that motor learning and neuromuscular adaptation proceed more rapidly in less-trained muscle groups, suggesting the nondominant limb may exhibit heightened sensitivity to training stimuli. Critically, this mechanism is population-specific. In populations with lower baseline asymmetry (more balanced bilateral limb use), dominant and nondominant limbs would not exhibit this differential sensitivity, potentially explaining contradictory findings in the bioimpedance literature across different populations and potentially invalidating left-arm measurement protocols in populations with different use patterns.

### Integration With Glycemic Control Mechanisms

The observed association between left-arm reactance increases and $HbA_{1c}$ target achievement likely reflects the known mechanisms linking physical activity to improved glycemic control. Skeletal muscle accounts for approximately 80% of insulin-stimulated glucose uptake, and exercise training enhances multiple aspects of muscle glucose metabolism: increased GLUT4 transporter expression and translocation, improved insulin signaling cascade function, enhanced mitochondrial density and oxidative capacity, and increased muscle glycogen storage capacity. Each of these adaptations contributes both to improved glycemic control and to altered muscle bioimpedance properties (through changes in membrane protein composition, intracellular fluid distribution, and cellular architecture). The anatomical specificity (left arm only) suggests that segmental bioimpedance changes serve as surrogate markers for systemic metabolic improvements rather than directly causing glycemic changes. That is, left-arm reactance changes indicate that meaningful physical activity has occurred (sufficient to induce detectable muscle adaptations), and this same physical activity drives the well-established metabolic benefits that improve glycemic control. The left-arm measurement effectively functions as an objective, passive sensor of habitual activity patterns, superior to self-report but capturing the same underlying behavioral construct [52].

### Digital Health Innovation and Clinical Implementation

From a health informatics perspective, this study demonstrates the potential of leveraging digital bioimpedance data to bridge the gap between objective physiological measurements and actionable clinical insights. The integration of multi-frequency bioimpedance analysis with environmental data (Walk Score) and real-time clinical decision support represents a practical application of health informatics principles—transforming raw digital signals into clinically meaningful information that can guide personalized diabetes management strategies. The observed environment-person interaction, detected through automated bioimpedance analysis, exemplifies how digital health technologies can uncover complex relationships between individual physiology, behavioral patterns, and environmental contexts that would be difficult to identify through traditional clinical assessment alone. As health informatics continues to evolve toward precision medicine and personalized care, this framework offers a scalable model for integrating readily available digital biomarkers into routine clinical workflows, potentially enabling more responsive and individualized chronic disease management across diverse healthcare settings.

This study represents a practical step from subjective to objective, digitally supported assessment in primary care diabetes management. The validation of population-specific bioimpedance protocols addresses a critical gap in the digital health ecosystem, providing health care providers with evidence-based tools for exercise therapy optimization that complement existing glucose monitoring technologies [5-7,10,11].

The predictive analysis of left arm reactance change provides compelling evidence for its role as a digital biomarker of behavioral adherence. The observation that left arm reactance negatively correlates with $HbA_{1c}$ change specifically in target achievers ($r$=−0.392; $P$=.032), but not in nonachievers ($r$=0.221; $P$=.074), suggests this biomarker captures genuine behavioral engagement rather than mere passive physiological drift. The right arm showed the opposite pattern—nonsignificant in achievers but significant in nonachievers—supporting our hypothesis that dominant arm usage patterns differ systematically between those who successfully modify behavior and those who do not. While the modest odds ratio (1.025 per 1 Ω increase) might suggest limited clinical use when considered alongside the dominant baseline $HbA_{1c}$ predictor, this reflects the complex multivariate nature of glycemic control rather than absence of biological significance. The arm-specific divergence in correlation patterns across achievement strata cannot be explained by confounding or measurement noise and instead points to the nuanced ways bioimpedance captures habitual movement patterns. From a health informatics perspective, this demonstrates how readily available digital signals—collected automatically during routine assessments—can reveal behavioral phenotypes that would otherwise remain invisible in traditional clinical workflows.

The framework's reliance on standard, FDA 510(k)-cleared equipment eliminates typical implementation barriers associated with novel health technologies. Unlike specialized devices or custom applications that require extensive training and infrastructure investment, the InBody 770 analyzer is already available in many health care settings, enabling immediate adoption without significant capital expenditure or workflow disruption.

### Reconciling Contradictory Literature Through Digital Framework

This unified framework successfully reconciles previously contradictory bioelectrical impedance findings by demonstrating that anatomical specificity depends on population-specific body usage patterns rather than fixed anatomical relationships. Studies showing right-arm predominance, bilateral symmetry, or no anatomical specificity can now be understood as different points on a continuum of body usage asymmetry.

This framework transforms apparently conflicting literature into complementary evidence supporting the broader principle that baseline activity patterns determine optimal digital biomarker localization for exercise tracking applications.



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### Population-Specific Precision Medicine Through Digital Tracking

The discovery that left-arm 50 kHz reactance serves as a population-specific digital biomarker for exercise compliance represents a novel application of precision medicine principles to lifestyle intervention monitoring. This finding challenges the traditional "one-size-fits-all" approach to biomarker development and provides evidence for population-tailored digital health strategies.

The framework's ability to integrate individual physiological responses with environmental data (neighborhood walkability) demonstrates the potential for multidimensional digital health approaches that consider both personal and contextual factors in treatment optimization. This holistic approach aligns with emerging concepts in digital epidemiology and social determinants of health research [37,38].

### Real-Time Clinical Decision Support

The digital framework's 84% prediction accuracy enables health care providers to make informed decisions about exercise therapy optimization versus medication intensification within weeks rather than months, significantly improving treatment efficiency through objective monitoring. This capability represents a practical step toward objective monitoring in primary care diabetes management, where treatment decisions must be made efficiently within time-constrained consultation environments.

### Implementation Science and Scalability

The population-specific approach validated in this study provides a foundation for broader digital health implementation across diverse populations. By demonstrating that optimal bioimpedance protocols depend on cultural body usage patterns rather than fixed anatomical relationships, this research establishes a framework for developing population-tailored digital health solutions that can be adapted for different ethnic groups and geographic regions.

Future integration with smartphone applications, electronic health records, and telemedicine platforms could extend the framework's use beyond traditional clinical encounters. Real-time bioimpedance data could be transmitted to health care providers, enabling proactive intervention adjustments and reducing the need for frequent in-person visits.

### Evidence for Environment-Person Synergy Beyond Temporal Confounding

These potential period effects substantially limit our ability to make strong causal inferences about the intervention's effectiveness. Supplementary sensitivity analyses using ANCOVA and propensity score matching revealed no significant linear trend across intervention intensity levels ($P$=.25), suggesting that the observed gradient pattern may reflect temporal confounding rather than true dose-response effects. While propensity score matching identified a significant difference between comprehensive intervention and standard care (matched difference: −0.73%; $P$=.011), this finding cannot definitively distinguish intervention effects from period effects due to the perfect confounding of treatment assignment with time.

The finding that partial intervention participants in high-walkability neighborhoods achieved superior glycemic control ($HbA_{1c}$ 6.50% vs 9.20% in low-walkability areas) suggests that moderate intervention intensity combined with supportive built environments creates optimal conditions for sustained physical activity. This interaction effect—mechanistically plausible and not explained by seasonal or temporal confounding—supports the validity of our proposed framework for detecting habitual activity through bioimpedance changes.

This environment-person interaction strengthens the biological plausibility of our left-arm reactance findings in three ways. First, if reactance changes truly reflect habitual activity adaptations rather than measurement artifacts or nonspecific effects, we would expect environmental facilitators (walkability) to moderate this relationship—precisely what we observed. Second, the interaction specifically manifested in the partial intervention group, suggesting a "sweet spot" where moderate behavioral support combined with environmental opportunity optimizes activity patterns. Third, the absence of interaction in standard care (where minimal behavioral support was provided) supports the hypothesis that bioimpedance-detected changes require both motivation (intervention) and opportunity (environment).

From a public health perspective, this finding has important implications beyond the methodological limitations of temporal allocation. Even if the gradient across intervention intensities partly reflects period effects, the environment-person interaction demonstrates that neighborhood walkability is a modifiable factor that can be leveraged to optimize diabetes management outcomes. Clinicians can use Walk Score assessment (freely available at walkscore.com) to identify patients whose residential environments may facilitate or hinder physical activity recommendations, enabling more personalized intervention strategies[1,36,41].

The mechanistic evidence from the Walk Score interaction thus serves two purposes: (1) it provides validation for the bioimpedance framework that transcends the study's temporal allocation limitations and (2) it identifies actionable environmental factors that moderate intervention effectiveness in real-world settings. While we acknowledge that definitive causal inference regarding intervention intensity requires randomized designs, the observed environment-person synergy represents genuine scientific contribution independent of the temporal allocation issue.

### Study Limitations

#### *Temporal Allocation Design and Period Effects*

The most significant limitation of this study is the use of temporal allocation (sequential enrollment by time period) rather than individual randomization. While this pragmatic design facilitated implementation in a busy primary care setting and reflects real-world constraints, it introduces the potential for period effects—systematic differences between time periods



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unrelated to the intervention that could confound the observed gradient in outcomes. Several categories of period effects warrant consideration.

First, seasonal variation may have influenced both physical activity patterns and bioimpedance measurements. The 3 enrollment periods spanned different seasons (period A: spring or summer; period B: fall; period C: winter), and seasonal differences in temperature, daylight hours, and cultural activity patterns (such as year-end holidays in Japan) could systematically affect both exercise behavior and physiological parameters. For example, warmer weather during period A might facilitate outdoor activity independent of the intervention, while winter conditions during period C might suppress activity levels. Similarly, seasonal variations in hydration status, indoor heating effects, or viral illness prevalence could influence bioimpedance measurements.

Second, temporal trends in clinical practice or external factors could contribute to observed differences. Changes in clinic staffing, evolving clinical protocols, or secular trends in diabetes management (such as introduction of new medications or treatment guidelines) occurring during the study period might systematically differ across enrollment cohorts. In addition, external events such as public health campaigns, media coverage of diabetes topics, or changes in community resources (such as opening of new exercise facilities) could disproportionately affect participants enrolled during specific periods.

Third, regression to the mean may contribute to apparent intervention effects, particularly if participant characteristics evolved over enrollment periods. If participants with more severe or poorly controlled diabetes were preferentially enrolled in earlier periods (period A), their subsequent improvement might partly reflect natural regression toward population mean values rather than intervention effects.

### *Implications for Causal Inference*

These potential period effects substantially limit our ability to make strong causal inferences about the intervention's effectiveness. The observed "dose-response" gradient (comprehensive >partial >standard care) might reflect, in part or whole, period effects rather than true intervention effects. We cannot definitively determine whether the superior outcomes in period A result from the comprehensive intervention, favorable seasonal conditions, beneficial secular trends, participant selection, or some combination of these factors.

To strengthen causal inference, future investigations should employ individual randomization or, at minimum, implement time-stratified randomization where participants within each enrollment period are randomly assigned to different intervention intensities. Such designs would eliminate systematic period effects as alternative explanations for observed differences. In addition, the collection of objective activity measurements (accelerometry and GPS tracking) would enable direct validation of whether bioimpedance changes truly reflect differential physical activity patterns rather than other time-varying factors.

### *Statistical Approaches to Address Temporal Confounding*

While our primary analysis compared outcomes across the three temporally defined groups, several statistical approaches could potentially adjust for temporal confounding, though each has limitations. ANCOVA adjusting for baseline characteristics, season of enrollment, and secular time trends could reduce bias from measured confounders but would not address unmeasured time-varying factors. Propensity score matching or inverse probability weighting could balance measured baseline characteristics across periods but assumes no unmeasured confounding—an assumption we cannot verify.

More fundamentally, these statistical adjustments cannot fully eliminate the period effect problem because the intervention assignment is perfectly confounded with time; every participant in period A received comprehensive intervention, every period C participant received standard care, with no overlap. This perfect confounding prevents us from separating intervention effects from time effects even with sophisticated statistical methods. We acknowledge this limitation transparently and interpret our findings as suggestive associations requiring validation in randomized trials rather than definitive causal effects.

### *Additional Limitations*

Beyond temporal allocation, several additional limitations warrant acknowledgment. First, the single-center design limits geographic and healthcare system generalizability. Findings from this Japanese primary care clinic may not extend to populations with different demographic characteristics, healthcare structures, or cultural contexts. Second, our framework's population-specificity—requiring high limb-use asymmetry for left-arm reactance sensitivity—limits applicability to populations with different daily activity patterns or cultural practices. Validation in diverse populations is necessary.

Third, we lacked objective activity measurement for direct validation of the hypothesized mechanism linking bioimpedance changes to physical activity. While our framework posits that reactance changes reflect habitual activity patterns, we cannot definitively exclude alternative mechanisms such as dietary changes, medication adjustments, or other behavioral modifications that might independently affect both bioimpedance and glycemic control. Fourth, the 4-month follow-up may be insufficient to assess long-term sustainability or clinical outcomes beyond glycemic control, such as cardiovascular events or diabetes complications.

Fifth, our reliance on $HbA_{1c}$ target achievement as the primary outcome, while clinically relevant, represents a relatively short-term surrogate marker. Longer-term studies examining patient-centered outcomes (quality of life, diabetes complications, and health care use) would strengthen clinical relevance. Finally, we did not systematically collect data on potential adverse effects of increased physical activity (musculoskeletal injuries and hypoglycemia during exercise), limiting comprehensive benefit-risk assessment.



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### Future Work

Future work includes the following:

- Prospective, multicenter validation with preregistered analysis focusing on left-arm 50 kHz reactance.
- Mechanistic studies linking reactance changes to muscle composition, hydration, and activity patterns.
- Integration with digital self-management tools to operationalize reactance-guided coaching.

### Conclusions

This study establishes a validated digital bioimpedance tracking framework that transforms exercise compliance assessment from subjective reporting to objective, real-time measurement in primary care diabetes management. The population-specific approach—demonstrating that left-arm 50 kHz reactance provides optimal sensitivity in high-asymmetry populations—represents a practical step toward objective monitoring in precision digital health, offering evidence-based protocols for immediate clinical implementation using standard equipment.

The framework's integration of individual physiological responses with environmental data achieves 84% prediction accuracy, providing health care providers with acceptable performance in identifying patients likely to achieve glycemic targets. This capability enables evidence-based treatment optimization within the critical early intervention window, improving the efficiency and effectiveness of primary care diabetes management.

Most importantly, this research validates the concept of population-tailored digital biomarkers, challenging traditional approaches to health technology development and providing a foundation for culturally-adapted digital health solutions. The immediate implementability using FDA 510(k)-cleared equipment eliminates typical barriers to digital health adoption, enabling rapid scaling across health care systems.

Future integration with electronic health records, telemedicine platforms, and mobile apps could extend this framework's utility, supporting the evolution toward comprehensive, digitally-supported diabetes care that combines real-time monitoring with personalized intervention strategies. This represents a crucial step toward realizing the full potential of digital health technologies in chronic disease management.

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The data sets generated during and/or analyzed during the current study are not publicly available due to privacy and ethical restrictions related to participant confidentiality but are available from the corresponding author on reasonable request.

### Data Availability

Deidentified individual-level data, a data dictionary, and analysis code will be deposited in the Open Science Framework (OSF) upon acceptance. A persistent DOI will be provided in the published article.

### Authors' Contributions

AK conceived and designed the study, analyzed data, and drafted the manuscript. SO contributed to data collection and manuscript revision. TO supervised clinical aspects and contributed to manuscript revision. MEG contributed to study design, data interpretation, and manuscript revision. All authors approved the final version.

### Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional statistical analyses, sensitivity tests, and figures supporting the main findings.
[DOCX File, 452 KB - diabetes_v10i1e83768_app1.docx ]

Checklist 1
STROBE checklist.
[DOCX File, 49 KB - diabetes_v10i1e83768_app2.docx ]

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## Abbreviations

**API:** application programming interface
**AUC:** area under receiver operating characteristic curve
**BIA:** bioelectrical impedance analysis
**FDA:** Food and Drug Administration
**FDR:** false discovery rate
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**IPW:** inverse probability weighting
**OR:** odds ratio
**STROBE:** Strengthening the Reporting of Observational Studies in Epidemiology

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# A Culturally Tailored Physical Activity Intervention for Hispanic Adults Living With Type 2 Diabetes: Pre-Post Pilot Feasibility Study

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## Abstract

**Background:** Type 2 diabetes mellitus (T2DM) is a metabolic disease that affects over 38 million adults in the United States, who are disproportionately Hispanic.

**Objective:** This study describes the development and implementation of Salud Paso por Paso, a culturally tailored and linguistically appropriate intervention to increase engagement in physical activity (PA) for Hispanic adults living with T2DM.

**Methods:** Participants were enrolled in a 6-week pre-post pilot test of a culturally tailored intervention that included sessions covering different aspects of PA and T2DM. Participants were recruited at a local free clinic. Nonparametric paired-sample Wilcoxon signed-rank tests were used to examine differences between pre- and postintervention measures.

**Results:** Twenty-one participants were recruited, and 19 (90.5%) completed the intervention. Participants significantly increased average hours spent in moderate PA, by 3.16 hours (from 4.73, SD 3.79 minutes to 9.63, SD 6.39 minutes; $Z$=−3.52; $P$<.001), average steps per week (from 23,006.38, SD 14,357.13 steps to 43,000.81, SD 30,237.17 steps; $Z$=−2.79; $P$=.005), and minutes per week of PA (from 105.94, SD 72.23 minutes to 224.19, SD 167.85 minutes; $Z$=−3.36; $P$<.001).

**Conclusions:** Developing effective culturally tailored interventions that can ameliorate the deleterious effects of T2DM in Hispanic adults is an important strategy to promote health equity. The Salud Paso por Paso intervention is an effective way to promote PA in Hispanic adults living with T2DM.

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**KEYWORDS**

type 2 diabetes; physical activity; Hispanic adults; intervention; diabetes mellitus; metabolic disease; United States; lifestyle modification; pilot intervention; community-engaged; self-efficacy

## Introduction

Diabetes mellitus is a metabolic disease that affects approximately 38 million individuals in the United States [1]. Among individuals living with diabetes, over 90% are classified as having type 2 diabetes mellitus (T2DM) [1]. Risk factors for T2DM include age (45 years or older), having immediate family members with T2DM, having prediabetes, having a history of gestational diabetes, being of Hispanic/Latino descent, having overweight or obesity, and having a low level of physical activity (PA) [2]. Estimates show that T2DM prevalence in Hispanic individuals is approximately 10.3% (compared to 8.5% for non-Hispanic White individuals) [3]. Hispanic adults are disproportionally affected by T2DM and exhibit disparities in diabetes-related complications, including nephropathy, retinopathy, and amputations [4].

Lifestyle modification, including changes in PA, is one of the cornerstones to enhance health outcomes for people living with T2DM. Current PA guidelines state that for substantial health benefits, adults should engage in at least 150 minutes to 300 minutes a week of moderate-intensity aerobic PA, or 75 minutes to 150 minutes a week of vigorous-intensity aerobic PA [5]. Regular PA can reduce mortality risk among adults with T2DM by improving cardiovascular fitness, enhancing glycemic control, improving vascular function, and contributing to weight management [6,7]. Despite the benefits of regular PA, almost 32% of US adults with diagnosed T2DM are physically inactive, defined as engaging in less than ten minutes a week of moderate or vigorous activity [3]. Within ethnic minority populations, estimates show Hispanic adults having the highest prevalence of physical inactivity at 32.1% [8]. Evidence suggests that there is a wide variation in cultural tailoring of interventions, with strategies ranging from adapting previously evaluated



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interventions in Spanish, such as the Diabetes Prevention Program, to using a formalized community-engaged research approach to develop intervention content [9]. Despite recognizing that culturally tailoring interventions for implementation with Hispanic adults with T2DM may be effective, the heterogeneity of approaches to culturally tailoring interventions shows the need for more rigorous approaches [9]. Effective strategies are needed to promote moderate-intensity PA among Hispanic adults living with T2DM [10].

There is evidence suggesting intervention programs to prevent or delay T2DM onset are not readily accessible to ethnic and racial minorities, which may contribute to diabetes disparities [9]. Efforts to reach high-risk populations such as Hispanic adults with T2DM include the development of culturally tailored or adapted interventions [9]. Culturally tailored interventions involve more than linguistic translation of intervention components. Rather, cultural tailoring of interventions should include domains such as attention to family orientation and fostering a strong relationship with the health care provider, along with empowerment, a sense of control, and respect for religion and folk beliefs [11]. Additionally, to culturally tailor interventions, it is important to use principles of community engagement, as these are well suited to engage stakeholders from the population of interest [11]. Culturally tailoring intervention components such as literacy modifications and delivering interventions in appropriate community settings may be effective in modifying behavior in Hispanic populations [9]. Collectively, these data underscore the need for tailored and linguistically appropriate interventions among Hispanic adults living with T2DM [9]. Thus, the purpose of this study is to describe the development and implementation of Salud Paso por Paso (Health Step by Step), a culturally tailored and linguistically appropriate intervention designed according to principles of community engagement to enhance self-efficacy and increase engagement in PA among Hispanic adults living with T2DM.

## Methods

### Study Design, Sample Size, and Participant Recruitment

A six-week pre-post pilot test study was designed to examine the feasibility and preliminary acceptability of Salud Paso por Paso. Inclusion criteria included a confirmed diagnosis of T2DM by a health care provider, the ability to speak English or Spanish, and an ongoing sedentary lifestyle (ie, lying or sitting down with little to no exercise in the past 6 months) [12]. The recruitment period was from October 2019 through February 2020. The initial recruitment goal was to enroll 24 participants to account for attrition. The primary objective of this study was to assess the feasibility of the intervention. As such, no formal sample size calculations were made. However, there is evidence to suggest that a minimum of 12 subjects per group can be considered for pilot studies [13]. Participants were recruited through flyers and generalized announcements made at the recruitment site. Recruitment only occurred at the clinic. One of the particular characteristics of the clinic is that it is only open 2 days a week, in the afternoon. Additionally, the clinic closes for the week during holidays. While the recruitment time period spanned October 2019 to February 2020, there were 3 weeks when the clinic was not open due to holidays. Furthermore, due to holiday travel, there were decreased numbers of attendees of clinic sessions when the clinic was open.

### Ethical Considerations

Written informed consent was obtained from participants prior to study participation. Participants provided consent in the language of their choice (English or Spanish) using written consent documents. Participants had the opportunity to ask questions and obtain clarification regarding study components and study purpose. Participants received compensation in the form of gift cards (US $80) for their participation in the study. Data included in this study are deidentified to protect participant privacy and confidentiality. Approval for this study was obtained from the University of Missouri Institutional Review Board (2013903).

### Study Setting

The intervention was delivered at a free community clinic located within a neighborhood center complex in Tucson, Arizona. The neighborhood center complex is located next to a public bus transit center. Key stakeholders identified the location as a facilitator for participants to access clinic services. The clinic provides health care services to community members and is staffed by volunteer health care providers, including physicians, physician assistants, nurse practitioners, registered nurses, and certified diabetes educators. Additionally, PA activities were completed by using the current infrastructure of the neighborhood complex; this complex has ample space with sidewalks to facilitate walking. Participants were asked to walk around the neighborhood complex in the designated exercise areas and walking paths.

### Intervention Development

There were several efforts to culturally tailor the intervention component for this study. Input for development of the Salud Paso por Paso intervention was provided by community members and staff from the community-based clinic (ie, medical staff, nurse volunteers, and a diabetes nurse educator). Key stakeholders were identified through their roles at the clinic (eg, experienced care providers, long-term volunteers, clinic leaders, and long-term patients). Four informal meetings were held with key stakeholders from the clinic to solicit input for intervention development. Based on stakeholder feedback, the intervention was tailored to the participants' Hispanic background. Stakeholders identified prevalent participant characteristics that included Spanish as the primary language and lower levels of literacy. All study materials were modified for delivery in Spanish and the educational materials were reviewed and adapted to a fifth grade reading level. To increase ease of participant attendance at educational and PA sessions, the educational component of the intervention was delivered in the waiting room of the clinic, and the PA component of the intervention was performed around the neighborhood center complex.



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Intervention development was guided by social cognitive theory [14,15] to enhance self-efficacy for increasing PA in accordance with established guidelines from the American Diabetes Association [16] and American Heart Association [17]. The PA component of the intervention was purposefully modified for participants, with a goal of increasing walking incrementally to 150 minutes per week to reduce risk of injury. Table 1 provides an overview of the Salud Paso por Paso sessions and PA goals.



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**Table .** Intervention activities for physical activity (PA).

| Session | Duration | Components | Activities |
|---|---|---|---|
| 1. Changing PA behavior | 60 min | • Welcome to the Salud Paso por Paso study<br>• Discussion on motivation for participants to engage in PA<br>• Intervention orientation<br>• Materials provided to participants (eg pedometers, paper logs)<br>• PA recommendations based on American Heart Association guidelines<br>• Participant PA instructions for following week | • Demonstration of warm-up process for safely engaging in PA by principal investigator and participants (eg 5 minutes of walking at a casual pace)<br>• Participants instructed to engage in at least 5 minutes of walking at a casual pace for 5 days during this week |
| 2. Potential barriers to engaging in PA | 45 mins | • Group discussion of potential barriers to PA<br>• Group discussion on solutions to overcome potential barriers to PA<br>• Group discussion on ability to engage and maintain PA during last week<br>• Reviewed PA logs | • 5 minutes of walking at a casual pace<br>• Demonstration of moderate-intensity PA by principal investigator and participants for 5 minutes (eg brisk walking—at least 4 km per hour)<br>• Participants were instructed to engage in 5 minutes of walking at a casual pace and 5 minutes of moderate-intensity walking for 5 days during this week |
| 3. Motivation for PA | 45 mins | • Group discussion of participant motivators for PA<br>• Group discussion on strategies to remain motivated for PA<br>• Group discussion on ability to engage and maintain PA during last week<br>• Reviewed PA logs | • 5 minutes of walking at a casual pace by principal investigator and participants<br>• 10 minutes of moderate-intensity PA by principal investigator and participants<br>• Participants were instructed to engage in 5 minutes of walking at a casual pace and 10 minutes of moderate-intensity walking for 5 days during this week |
| 4. Potential setbacks | 45 mins | • Group discussion on potential setbacks that occur during PA behavior change<br>• Group discussion on how to deal with setbacks during PA behavior change<br>• Group discussion on ability to engage and maintain PA during last week<br>• Reviewed PA logs | • 5 minutes of walking at a casual pace by principal investigator and participants<br>• 15 minutes of moderate-intensity PA by principal investigator and participants<br>• Participants were instructed to engage in 5 minutes of walking at a casual pace and 15 minutes of moderate-intensity walking for 5 days during this week |
| 5. Family/social support | 45 mins | • Group discussion on potential sources of support during PA behavior change<br>• Group discussion on capitalizing on support from family and social networks during PA behavior change<br>• Group discussion on strategies to engage family and friends in PA<br>• Group discussion on ability to engage and maintain PA during last week<br>• Reviewed PA logs | • 5 minutes of walking at a casual pace by principal investigator and participants<br>• 20 minutes of moderate-intensity PA by principal investigator and participants<br>• Participants were instructed to engage in 5 minutes of walking at a casual pace and 20 minutes of moderate-intensity walking for 5 days during this week |



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| Session | Duration | Components | Activities |
|---|---|---|---|
| 6. A better future | 60 mins | • Group discussion on achievements and successes from participation in Salud Paso por Paso<br>• Group discussion on long-term sustainment of PA change<br>• Group discussion on ability to engage and maintain PA during last week<br>• Reviewed PA logs | • 5 minutes of walking at a casual pace by principal investigator and participants<br>• 25 minutes of moderate-intensity PA by principal investigator and participants<br>• Participants were instructed to engage in 5 minutes of walking at a casual pace and 25 minutes of moderate-intensity walking for 5 days during this week |

## Measures

PA outcomes were assessed by (1) 7-day PA recall at baseline and after the intervention, (2) self-efficacy for PA at baseline and after the intervention, (3) total number of steps per week, and (4) total minutes of PA per week per participant. Demographic and health characteristics, including acculturation scores, were collected at baseline to describe the study sample.

### *Weekly Exercise Logs and PA Recall*

Frequency, number of steps, and number of minutes spent in PA each week were recorded by participants using paper and pencil logs. Participants received a pedometer and instructions on how and when to wear the pedometer. The pedometer model was an Omron Alvita USB Pedometer (model HJ-322U). Participants were asked to record steps per day with the pedometer and minutes spent in PA and to bring the logs to each weekly session. The principal investigator administered the 7-Day Physical Activity Recall (7-Day PAR) paper questionnaire during the baseline and postintervention assessments. The 7-Day PAR measures time spent in PA, strength, and flexibility activities for the 7 days prior to questionnaire completion [18]. The 7-Day PAR has been validated for use with adults and has been translated into Spanish [19,20].

### *Self-Efficacy*

Participants completed the Self-Efficacy for Exercise Behaviors Scale (SEEBS) at baseline and after the intervention. The SEEBS scores were used to measure exercise self-efficacy. The SEEBS questions are divided by subscales for “making time for exercise” and “sticking to it.” Self-efficacy for participants was defined as the perception by the participant that they could engage in exercise behaviors. The SEEBS measures self-efficacy on a Likert scale from 1 to 4, with higher scores relating to higher self-efficacy, and it has been validated for use in Hispanic populations [21]. Lower SEEBS scores signify that participants believe they cannot accomplish the behaviors; conversely, higher SEEBS scores signify participants’ belief that they can accomplish the behaviors.

### *Acculturation*

Participants completed the Short Acculturation Scale for Hispanics (SASH). The SASH measures changes that Hispanic individuals experience in values, norms, attitudes, and behaviors when exposed to mainstream cultural patterns of the United States [22]. The scale measures acculturation on a 5-point Likert scale, with a value of 1 corresponding to “very Hispanic” and a value of 5 corresponding to “very American.”

### *Demographic Data and Health Information*

Age, sex, ethnicity, birthplace, marital status, educational level, income level, and additional health conditions were obtained through self-reporting.

### *Feasibility*

Feasibility was evaluated based on the ability to recruit participants, attendance at each weekly session, and completion of intervention components by participants, which included daily logs documenting PA. A meta-analysis found mean retention rates of 75% (SD 13%) for intervention groups and mean adherence rates of 61% (SD 21%) for PA studies [23]. For this study, retention and adherence goals were set at 80% due to the characteristics of the target sample. Potential participants for this study were people who spend time living and traveling between Mexico and Tucson, Arizona. Evidence suggests that current national- and state-level surveys in the United States and Mexico only capture information regarding stationary Mexican immigrant and returned migrant populations [24]. Some of the potential participants cited their inability to predict when they would be present in the United States as the main barrier to participating in this study. Due to the mobility of this sample of the population, the principal investigator determined the retention and adherence rates for the small sample size. The retention goal was for 20 participants to complete the intervention. The goal for participant intervention adherence, or attendance to weekly sessions and completion of PA logs, was to attend 5 of 6 (>80%) weekly sessions and complete 5 of 6 weekly PA logs.

## Data Collection

The principal investigator shared all aspects of the study with potential participants by meeting individually with them in a private area of the clinic. All data were collected using paper and pencil surveys. All participants received a health screening and physical examination, and they were cleared for study participation by a physician or nurse practitioner prior to participating in intervention and PA sessions. The first wave of intervention delivery occurred from the first week of March 2020 through the second week of April 2020. The second wave of intervention delivery occurred from the third week of April 2020 through the fourth week of May 2020. Notably, this is the time when the COVID-19 pandemic restrictions began in earnest in Arizona; these restrictions included a requirement for social



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distancing and masking and avoiding unnecessary exposure to other people in public.

### Statistical Analysis

Data were analyzed using SPSS Statistics (version 29; IBM Corp) and screened for normality, missing data, and outliers. Ranges, means, and SDs for demographic data, self-efficacy scores, and PA frequency were calculated at baseline and at intervention completion. Nonparametric paired-sample Wilcoxon signed-rank tests were performed to examine differences between pre- and postintervention measures on 7-Day PAR results, PA self-efficacy scores, self-reported steps per week, and self-reported minutes of PA per week.

## Results

### Characteristics of Study Participants

Twenty-four potential participants were screened between mid-October 2019 and February 2020. After recruitment was completed, 3 participants were unable to begin the study as they had to unexpectedly travel to Mexico for various reasons, including to provide care for family members. A total of 21 (88%) participants ultimately enrolled in the Salud Paso por Paso study. Participant characteristics are described in Table 2. These characteristics describe all participants who originally enrolled, as they provided demographic information at the beginning of the study. Briefly, participants ranged in age from 30 to 75 years (mean 53, SD 11.8 years). The majority (n=19, 90%) of participants were female, and most (n=16, 76%) were married. All participants except one identified Mexico as their country of origin. Most participants had an income level below US $35,000, with 9 participants reporting an income level less than US $15,000. Over half the participants had completed high school or had less than a high school education. Participants had lived in the United States from 3 months to 35 years (mean 14.9, SD 11.25 years). Over half the participants reported another chronic health condition in addition to T2DM. Participants had a mean SASH score of 1.53 (SD 0.744) at baseline, indicating a low level of acculturation.



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**Table .** Salud Paso por Paso participant demographic and health characteristics (n=21).

| Characteristics | | Values |
|---|---|---|
| Age (years), mean (SD) | | 53.0 (11.8) |
| Gender, n (%) | | |
| | Female | 19 (90) |
| | Male | 2 (10) |
| Ethnicity, n (%) | | |
| | Mexican | 20 (95) |
| | Dominican | 1 (5) |
| Marital status, n (%) | | |
| | Single/divorced | 4 (19) |
| | Married/widowed | 16 (76) |
| | No answer | 1 (5) |
| Yearly household income, n (%) | | |
| | <US $14,999 | 9 (43) |
| | >US $15,000-$34,999 | 4 (19) |
| | >US $35,000 | 2 (10) |
| | No answer | 6 (29) |
| Education level, n (%) | | |
| | Less than high school | 7 (33) |
| | High school | 7 (33) |
| | College | 6 (28) |
| | No answer | 1 (5) |
| Years living in the United States, mean (SD) | | 14.9 (11.3) |
| Primary language at home, n (%) | | |
| | Spanish | 21 (100) |
| Other chronic health conditions, n (%) | | |
| | Present (prediabetes, hypertension, other) | 12 (57) |
| | Not present or did not answer | 9 (43) |
| Short Acculturation Scale for Hispanics score, mean (SD) | | 1.53 (0.7) |

## Feasibility

Twenty-four participants were recruited over a period of 14 weeks, with 21 participants completing the initial intervention measures. Nineteen of 21 (90%) participants who enrolled in the study attended all weekly face-to-face intervention sessions. One participant attended the first week of the intervention but withdrew from the study due to work schedule conflicts. Another participant withdrew from the study in week 3 due to work schedule conflicts as well as the need to take care of a family member.

## 7-Day PAR Results

Participants significantly increased the average hours spent in moderate PA, by 3.16 hours (from 4.73, SD 3.79 to 9.63, SD 6.39 hours; $Z$=−3.52, $P$<.001). There were no significant results for vigorous PA or very vigorous PA (Table 3).



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**Table .** 7-Day Physical Activity Recall (PAR) results (n=16; not all participants were included due to the inability of some to recall end point activity).

| | | Hours, mean (SD; 95% CI) | *Z* score | *P* value |
|---|---|---|---|---|
| 7-Day PAR moderate | | | –3.52 | <.001 |
| | Baseline | 4.73 (3.79; 2.71 to 6.76) | | |
| | End point | 9.63 (6.39; 6.22 to 13.03) | | |
| 7-Day PAR vigorous | | | –0.54 | .59 |
| | Baseline | 1.75 (4.27; –0.52 to 4.02) | | |
| | End point | 1.17 (3.52; –0.70 to 3.05) | | |
| 7-Day PAR very vigorous | | | –1.0 | .32 |
| | Baseline | 0 (0; 0 to 0) | | |
| | End point | 0.06 (0.25; –0.07 to 0.20) | | |

## SEEBS Results

The preintervention SEEBS mean score for participants was 3.53 (SD 0.65), and the postintervention mean score was 3.6 (SD 0.42). Subscale scores before and after the intervention were similar for “making time for exercise” and “sticking to it” (Table 4). The mean score >3.5 suggests that all the participants had high self-efficacy to engage in exercise prior to starting the intervention. Overall, there were no significant differences before and after the intervention in self-efficacy scores ($Z$=−0.764; $P$=.44).

**Table .** Self-Efficacy for Exercise Behaviors Scale (SEEBS) results.

| | | Score, mean (SD; 95% CI) | *Z* score | *P* value |
|---|---|---|---|---|
| All SEEBS factors | | | –0.76 | .45 |
| | Baseline | 3.53 (0.65; 3.22 - 3.84) | | |
| | Postintervention | 3.60 (0.42; 3.40 - 3.80) | | |
| Making time for exercise | | | –0.231 | .82 |
| | Baseline | 3.65 (0.55; 3.38 - 3.91) | | |
| | Postintervention | 3.65 (0.39; 3.46 - 3.84) | | |
| Stick to it | | | –1.026 | .31 |
| | Baseline | 3.45 (0.74; 3.09 - 3.80) | | |
| | Postintervention | 3.57 (0.46; 3.35 - 3.79) | | |

## PA Steps and Minutes per Week

The participants significantly increased their average number of steps per weeks from 23,006.38 (SD 14,357.13) to 43,000.81 (SD 30,237.17; $Z$=−2.79; $P$=.005). Similarly, participants reported significant increases in the amount of time they engaged in PA per week, from 105.94 (SD 72.23) minutes at baseline to 224.19 (SD 167.85) minutes at week 6 ($Z$=−3.36, $P$<.001; Table 5).

**Table .** Steps and minutes of physical activity per week.

| | | Values, mean (SD; 95% CI) | *Z* score | *P* value |
|---|---|---|---|---|
| Steps | | | –2.79 | .005 |
| | Baseline | 23,006.38 (14,357.13; 15,356 - 30,656.75) | | |
| | End point | 43,000.81 (30,237.17; 26,888.56 - 59,113.06) | | |
| Minutes of physical activity | | | –3.36 | <.001 |
| | Baseline | 105.94 (72.23; 67.45 - 144.42) | | |
| | End point | 224.19 (167.85; 134.75 - 313.63) | | |



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## Discussion

### Principal Findings

The purpose of this pilot study was to examine the feasibility and preliminary effectiveness of a culturally tailored PA intervention, Salud Paso por Paso, in a group of Hispanic adults living with T2DM. Findings indicate adherence to the PA intervention was satisfactory in the priority population and participants showed a significant increase in steps and minutes of PA per week from before to after the intervention.

Participants in this study had low acculturation levels, reflecting the participants' strong identification with their Hispanic heritage. Low levels of acculturation have been associated with lower levels of self-rated health and lower use of medical services in Hispanic people [25]. However, participants in this study, despite lower levels of acculturation, successfully increased their PA from before to after the intervention. Participants in this study had high self-efficacy for exercise at baseline. Previous research indicates that higher self-efficacy for exercise is associated with increased PA [26]. In this context, participants may have had the desire and ability to engage in PA, but may not have had the opportunity to do so prior to enrolling in this study. Participants may have benefited from the structure and accountability provided through their participation in this study. It is notable that 19 participants (90%) completed the intervention, even considering the negative impact that the COVID-19 pandemic has had not only on conducting research, but on PA levels [27].

While participants showed increased engagement in PA, evidence suggests that the COVID-19 pandemic had a negative effect on PA, with a declining trend in PA engagement across participants from different countries [28]. This decline in PA engagement was also reflected in the United States, where Hispanic adults engaged in less PA when compared to White adults [29]. Participants in this study expressed interest in continuing with the intervention behaviors after the intervention ended. Some of the participants stated that they would be willing to enroll in a different study with a longer duration, as they perceived the 6-week intervention as ending quickly.

Modest increases in PA by participants helped improve adherence to PA recommendations at the completion of the study. The intervention was unique because it was delivered in the clinic and a neighborhood center complex, a location that was accessible and familiar for participants as this is where they typically seek health care services. Strengths of this research included its community-partnered approach and the researcher sharing the cultural and linguistic background of the participants. While the findings of this study are promising regarding increasing PA, there were limitations. This was a small, noncontrolled pilot study. A prospective randomized study with a longer duration is needed to further examine intervention efficacy. In addition, refinement of study materials as well as determining whether PA was maintained would strengthen the findings of a future iteration of this study. Another limitation is the potential negative impact the COVID-19 pandemic had on intervention fidelity. The intervention study began just 2 weeks before an executive order from the governor of Arizona recommended social distancing and mask precautions [30]. While PA was an approved activity under this order and all appropriate precautions (eg physical distancing) were maintained, many of the participants expressed concern about engaging in PA due to the increased risk of contracting COVID-19.

### Conclusions

The need for effective interventions that promote PA in Hispanic adults, and the general population of individuals living with T2DM, is considerable. As the Salud Paso por Paso intervention was being conducted, many participants expressed interest in learning more about other behaviors that can enhance T2DM outcomes, such as nutrition. Significant results for PA outcomes, specifically 7-Day PAR increases in moderate PA and increases in number of steps and PA minutes, support a prospective randomized controlled study to examine the efficacy of Salud Paso por Paso among Hispanic adults living with T2DM. Future research should include measures to examine the ability for long-term sustainment of PA improvements. Since this was a feasibility study, results from this study could inform the planning and completion of a randomized controlled trial for future research. Developing effective interventions that can ameliorate the deleterious effects of T2DM in Hispanic adults is an important strategy to promote health equity.

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### Conflicts of Interest

None declared.

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## Abbreviations

**7-Day PAR:** 7 Day Physical Activity Recall
**PA:** physical activity
**SASH:** Short Acculturation Scale for Hispanics
**SEEBS:** Self-Efficacy for Exercise Behaviors Scale
**T2DM:** type 2 diabetes mellitus

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# Coefficient of Variation to Assess the Reproducibility of Meal-Induced Glycemic Responses: Development of a Clustering Algorithm

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## Abstract

**Background:** Managing type 1 diabetes (T1D) requires maintaining target blood glucose levels through precise diet and insulin dosing. Predicting postprandial glycemic responses (PPGRs) based solely on carbohydrate content is limited by factors such as meal composition, individual physiology, and lifestyle. Continuous glucose monitors provide insights into these responses, revealing significant individual variability. The statistical clustering method proposed here balances the number of clusters formed and the glycemic variability of the PPGRs within each cluster to offer a clustering technique on which treatment decisions could be based.

**Objective:** This study aims to develop and evaluate a PPGR clustering method that identifies reproducible meal-specific glucose patterns in people with type 1 diabetes.

**Methods:** Blood glucose data from the OhioT1DM dataset were used to assess clustering of PPGR based on the coefficient of variability (CV) of glucose. Clustering was performed using statistical clustering, with each PPGR isolated into 48 data points per event. A CV threshold of <36% was used to define clinically similar clusters. This aimed to cluster PPGRs with minimal glycemic variability. The approach aims to enhance precision in analyzing postprandial glycemic dynamics, assessing cluster cohesion via standard deviation and CV within meal categories.

**Results:** The analysis revealed a reproducible set of PPGR clusters specific to meal types and individuals (mean [SD], 2.4 [1.8] for breakfast, 2.7 [0.9] for lunch, and 3.1 [1.0] for dinner), with the number of clusters varying across participants and meals in the dataset. Carbohydrate intake alone did not affect cluster formation, suggesting a complex relationship between meal composition and PPGR variability. However, certain individuals showed significant associations between carbohydrate intake and cluster formation for specific meals.

**Conclusions:** The meal-based glycemic clustering algorithm provides a promising framework for predicting PPGRs in people with type 1 diabetes, independent of carbohydrate intake. It emphasizes the need for personalized prediction models to optimize time in range and enhance diabetes management. Efforts to refine treatment strategies are crucial in reducing T1D-related complications.

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**KEYWORDS**

bolus targeting solution; meal-based PPGR clustering algorithm; postprandial glycemic response (PPGRs); PPGR clusters; reproducibility; type 1 diabetes (T1D)

## Introduction

Type 1 diabetes (T1D) is a chronic autoimmune disease that inhibits the production of insulin, preventing the intrinsic regulation of blood glucose (BG) [1]. The management of T1D focuses on the international consensus of achieving BG levels within the recommended target range of between 3.9 and 10 mmol/L at least 70% of the time [2], while consuming a balanced and varied diet [3]. The key to optimal insulin therapy is minimizing BG fluctuations after meals [4] (postprandial glycemic response [PPGR]) and keeping the BG within the target range [2,5]. PPGR management in people with T1D (PwT1D) is further complicated by the need to administer the appropriate dose of exogenous bolus insulin [6], which is commonly determined by the amount of carbohydrate present



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in the meal [7]. Current treatment strategies focus on carbohydrate-based insulin dosing where people with T1D are required to determine the amount of carbohydrates present in the meal to calculate the appropriate bolus insulin dose needed [8]. The intricate interplay of individual physiology, metabolism, behaviors, and the diverse nature of meals in the real world, which impact the PPGR, complicates effective insulin therapy management [9]. Despite efforts to refine carbohydrate-based insulin dosing strategies, factors beyond carbohydrate content significantly influence the PPGR, including fiber content, exercise, and metabolic factors [10-12], revealing a nuanced and complex landscape [3,13-16]. However, to optimize the PPGR and effectively keep BG levels in range, the bolus dosage and timing should factor in the speed at which the carbohydrates are absorbed, which is determined by other nutritional factors, such as amount of fat, protein, and fiber [17].

The use of continuous glucose monitors (CGMs) allows for a complete picture of the PPGR to a meal to be seen and analyzed [18]. It has been shown that PPGRs are reproducible within individuals (intraindividual) when exposed to meals of the same nutritional composition [5,15,19]. However, interindividual variability in PPGRs to identical meals has been noted in the literature [20,21], suggesting that individual characteristics influence the PPGR beyond what is expected from the meal itself [17,22]. However, this intraindividual reproducibility offers the potential for an effective PPGR self-management technique in T1D based on the learned response to the previous PPGR to a given meal [23]. Leveraging this repetitiveness of PPGRs, the ability to isolate PPGR clusters will allow for meal-based glycemic responses that exhibit similar patterns to be effectively grouped together. Being able to understand and predict how one might respond to a meal based on its composition, the physiology of the individual, and the lifestyle factors that influence BG levels allows for reduction in the burden of self-management and the potential to optimize meal and bolus planning [14,22,24].

Clustering PPGR data can reveal relationships between variables and uncover patterns in glycemic responses to meals, enabling tailored treatment interventions based on individualized PPGR profiles [14]. In this work, a statistical clustering approach was developed to balance the number of clusters with the glycemic variability within each cluster, using variability as a measure of internal cohesion. The coefficient of variability (CV) of glucose, which quantifies glycemic variability over time [25], was adopted as the primary parameter for assigning PPGR events to specific clusters. By constraining the CV within each cluster to below 36%, the method aims to identify repeated PPGR patterns for specific meals, potentially reducing hypoglycemia risk when applied to guide insulin therapy [25]. The balance between cluster quantity and clinically relevant measures of glycemic variability is particularly important given the individualized nature of PPGR responses, where the optimal number of clusters may differ between subjects. In evaluating various clustering strategies, conventional methods, including Time Series Means Clustering [26,27], standard partitioning methods [28,29], DBScan [30], and hierarchical clustering [31], proved unsuitable due to limitations in handling small datasets, irregular data densities, and the individualized nature of glucose response patterns. In contrast, the proposed CV-based clustering method is designed to overcome these limitations, providing a framework for analyzing personalized glucose response dynamics.

This work focuses on identifying the repetitive patterns of PPGRs elicited within specified meal categories (ie, breakfast, lunch, and dinner) and generates clinically similar PPGR clusters for people with T1D, which minimize the glycemic variability and have a low risk of hypoglycemic outcomes [25,32]. This will provide a categorization system that captures the reproducibility of everyday PPGR events, allowing for a personalized and adaptive BG prediction model that is based on unique PPGR events. This could be extrapolated to specific meals offering the ability to learn the appropriate meal-time insulin bolus (bolus targeting solution) to optimize the time in range (TIR).

The overarching aim is to utilize the PPGR clustering technique to provide a practical strategy for insulin therapy treatment adjustments, ultimately improving TIR for people with T1D.

## Methods

### Patient Data

This study evaluated whether PPGRs could be matched and clustered using the CV of the PPGR. Data were from the OhioT1DM dataset [23], comprising 8 weeks of CGM and self-reported lifestyle logs from 12 adults with T1D using insulin pump therapy and Medtronic Enlite CGM systems. CGM readings were taken every 5 minutes, alongside insulin dosages, heart rate, and timestamped dietary and lifestyle events. Data were aligned to a 24-hour clock and stratified by day and week. Despite its modest size [33], the dataset reflects real-world conditions and is widely used in T1D research [34]. Participant demographics are shown in Table 1.



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**Table .** Gender, age range, insulin pump, and insulin used along with the continuous glucose monitors (CGM) for each OhioT1DM participant as available from the dataset [23].

| ID | Gender | Age range (years) | CGM device | Pump and insulin used |
|---|---|---|---|---|
| 540 | Male | 20 - 40 | Medtronic Enlite | 630G (Humalog) |
| 544 | Male | 40 - 60 | Medtronic Enlite | 530G (Humalog) |
| 552 | Male | 20 - 40 | Medtronic Enlite | 630G (Humalog) |
| 567 | Female | 20 - 40 | Medtronic Enlite | 630G (Humalog) |
| 584 | Male | 40 - 60 | Medtronic Enlite | 530G (Novolog) |
| 596 | Male | 60 - 80 | Medtronic Enlite | 530G (Humalog) |
| 559 | Female | 40 - 60 | Medtronic Enlite | 530G (Novolog) |
| 563 | Male | 40 - 60 | Medtronic Enlite | 530G (Humalog 200) |
| 570 | Male | 40 - 60 | Medtronic Enlite | 530G (Humalog) |
| 575 | Female | 40 - 60 | Medtronic Enlite | 530G (Novolog) |
| 588 | Female | 40 - 60 | Medtronic Enlite | 530G (Novolog) |
| 591 | Female | 40 - 60 | Medtronic Enlite | 530G (Novolog) |

## Ethical Considerations

This study is an in silico analysis that relies exclusively on open-access, publicly available data obtained from recognized repositories. No new data were collected, and no interaction or intervention with human participants, animals, or identifiable private information occurred. As such, this research does not meet the criteria for “human subjects research” as defined by institutional and international ethical standards. Ethics approval was not required for this study as it utilized open-access, deidentified data available in the public domain. The analysis involved no direct or indirect contact with human participants or animals, and no identifiable personal data were used [35-39].

## Isolating PPGR Process

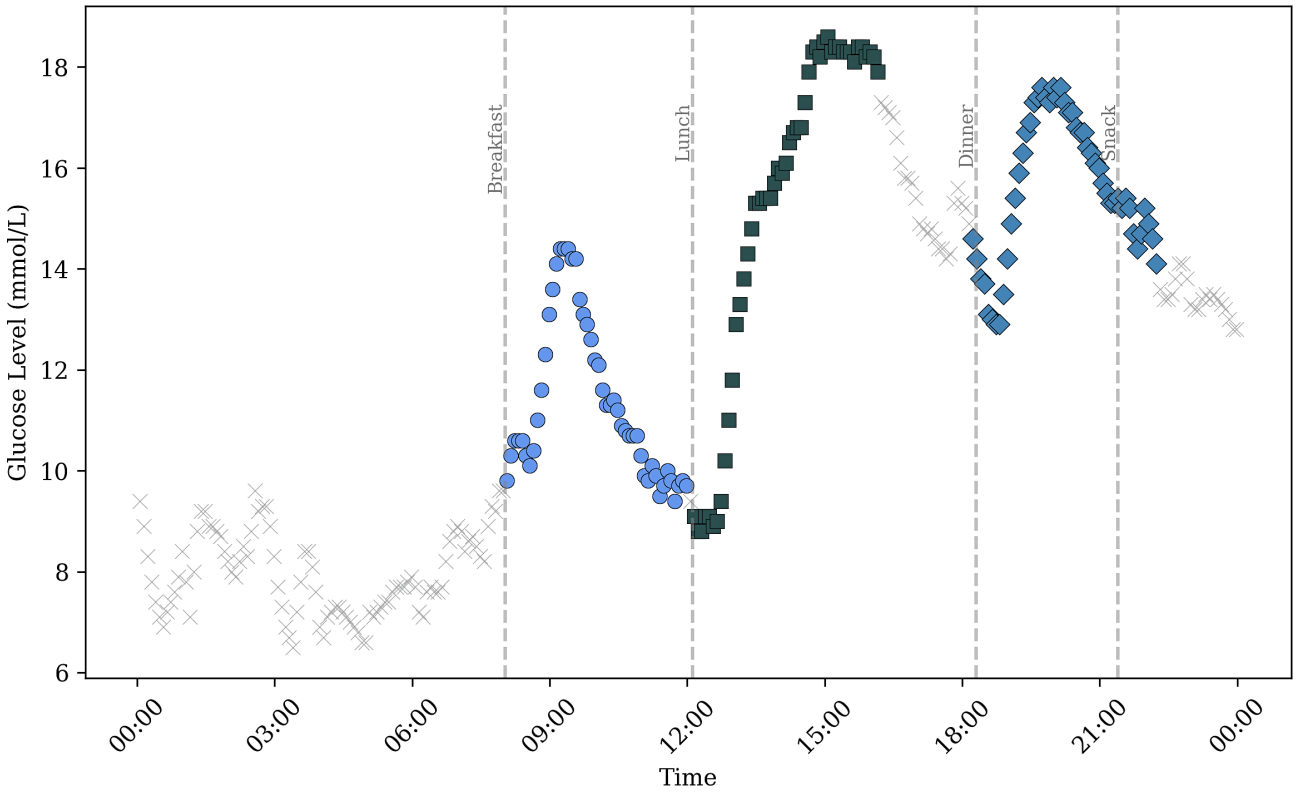
A PPGR was defined as a 4-hour window (48 readings) from self-reported mealtime or bolus insulin administration (see Figure 1). When mealtimes were missing, start times were imputed from matching events on the same weekday in other weeks, using the closest average timing. The 4-hour window was chosen to capture the full glycemic excursion, given that glucose in nondiabetics typically normalizes within 90 minutes [40], gastric emptying completes within 4 - 5 hours [41], and rapid-acting insulin (eg, Novorapid) peaks at 100 - 120 minutes when given 15 - 20 minutes before meals [42]. Events with <2 hours of CGM data (24 points) were excluded.

PPGRs were categorized as breakfast (06:00-10:00), lunch (10:00-14:00), snack (14:00-18:00), or dinner (18:00-22:00) in line with circadian and sociocultural eating patterns [41,43,44]. Additional carbohydrate intake within the 4-hour postprandial window was considered part of the original PPGR. A bolus is classified as meal-related if its start time falls within a tight window around a logged meal, specifically from 4 minutes before to 4 hours after the meal; boluses outside every such window are labeled corrections. Correction boluses are then summarized by the PPGR categorization bands (6-10, 10-14, 14-18, 18-22). Where bands did not have an isolated PPGR from a self-reported meal of mealtime bolus, the PPGR was isolated, and where the bands contained meal events, the bolus dose was confirmed to be a correction.



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**Figure 1.** Example of mealtime postprandial glycemic response (PPGR) isolation from a single day of blood glucose data from a single participant from the OhioT1DM dataset (544). The different colors and markers represent the distinct meal categories, “x” indicating unassigned BG data, “ ” indicating breakfast PPGR, “ ” the lunch PPGR and “ ” dinner PPGR. The dashed gray lines indicate the time of the self-reported meal consumption.




## Normalization of PPGR Events

To enable cross-comparison of glucose responses independent of absolute magnitude, each PPGR was normalized by centering it around its peak value. Specifically, the peak glucose reading within each 4-hour window was identified, and all other values were recalculated by subtracting this peak value. This process generated a normalized, peak-centered time series for each event, allowing for uniform trend analysis across individuals and events.

## Calculation of CV

The CV quantified variability by dividing the standard deviation of each isolated PPGR by the mean of all PPGRs for the same individual and meal category, then multiplying by 100 (Equation 1). This approach provided a normalized measure of glycemic variability contextualized within each person’s own physiological response patterns. A CV threshold of less than 36% was adopted as the criterion for acceptable variability, consistent with clinical literature associating lower CV values with reduced risk of hypoglycemia [25,45]. Given that one would expect the PPGR-specific CV to be significantly higher than the 24-hour CV, using the 24-hour threshold of 36% would ensure the internal cohesion of the PPGRs is tighter than the clinically recommended glycemic variability.

$$(1)\quad CVPPGR=(\sigma PPGR\mu PPGR)\times 100$$

- PPGR is the standard deviation of the isolated PPGR.
- $\mu$PPGR is the mean of all the PPGRs in the same meal category for that individual.

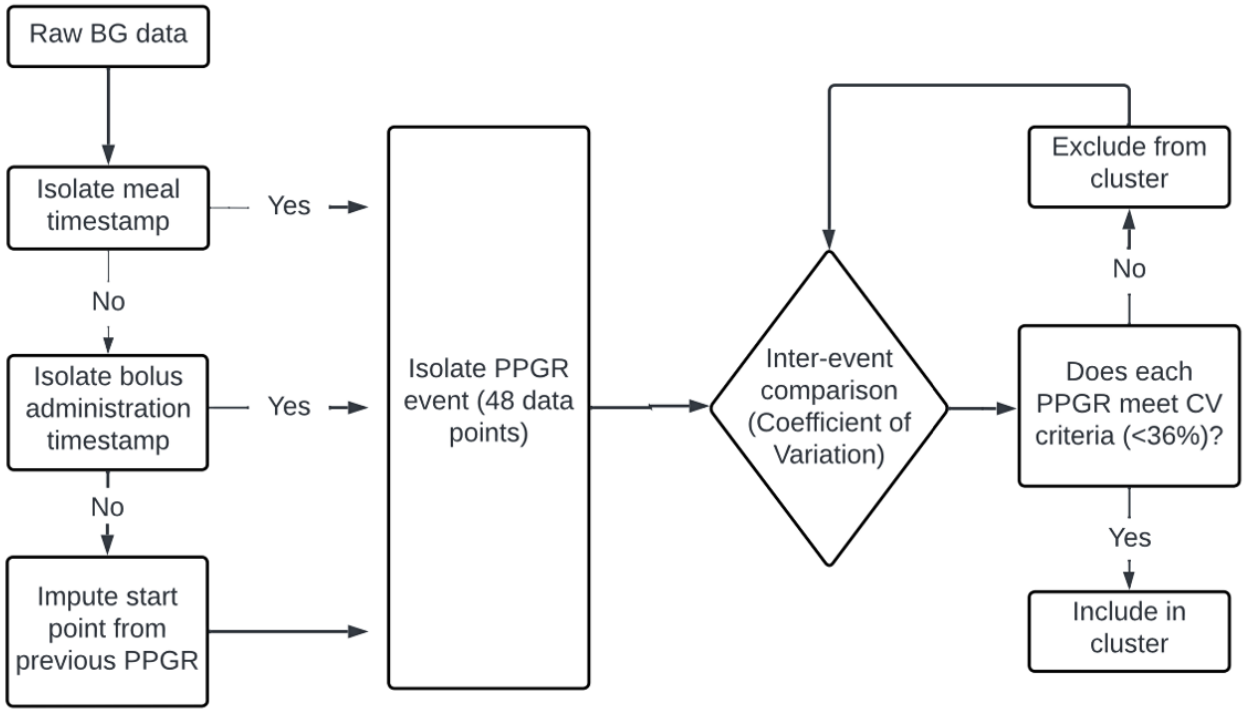
## Clustering of Postprandial Glycemic Responses

Each PPGR was treated as a unique time series and clustered within the specified meal categories. An iterative pairwise algorithm began with an unassigned PPGR and added other unassigned events if the cluster CV remained <36%. Clusters were expanded until no additional events could be included without exceeding the threshold. Unassigned events were reevaluated in later iterations; PPGRs eligible for multiple clusters were assigned to the largest cluster. Events failing all inclusion criteria were labeled outliers (Figure 2).



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**Figure 2.** Methodological framework for assessing the reproducibility of postprandial glycemic responses (PPGRs): an iterative coefficient of variability (CV)-based clustering approach. BG: blood glucose.




### Cluster Evaluation

Each cluster was evaluated using several statistical measures to assess internal consistency and clinical relevance. The standard deviation of glucose values within each cluster was used to estimate dispersion around the cluster mean. The standard error was calculated by dividing the standard deviation by the square root of the number of PPGR events in the cluster, providing a measure of the reliability of the cluster mean. An internal CV for each cluster was also computed, based on the combined glucose values of the cluster and the overall mean for the corresponding meal category. The total number of PPGRs per cluster was recorded to assess distribution across clusters and ensure adequate representation.

### Statistical Analyses

Sample size and power calculations used the TTestIndPower function from statsmodels in Python [46], targeting power=0.8 and α=.05 to minimize type I or II errors [47]. Within each meal category, one-way ANOVA tested for differences in mean carbohydrate intake between clusters.

### Tools and Software

Data preprocessing, normalization, and clustering were implemented in Python 3.10.7 [48] using Visual Studio Code 1.77.3 [49] and standard libraries. The 36% CV threshold, though derived from 24-hour glucose variability, was used to ensure PPGR clusters had tighter internal cohesion than recommended clinical variability limits.

## Results

The 12 participants in the OhioT1DM dataset generated 20635 PPGRs, which reflects the consolidation of 99121685 blood glucose data points. The meal-matched isolated PPGRs were subjected to the CV-based clustering technique outlined above. It was found that the available BG data formed a set number of PPGR clusters for each meal type, with breakfast having mean (SD) of 2.4 (1.8) clusters identified, lunch having 2.7 (0.9) clusters, and dinner having 3.1 (1.0) clusters. An example of the clusters formed across all meals for a single participant is represented in Figures 3-5 . This outlines the mean curve, standard deviation, and standard error of the cluster, in comparison to the standard error of the CGM device. The number of PPGR clusters present for each participant across the 3 meals, along with metrics and CV score, is outlined in Table 2, suggesting the reproducibility of PPGR events is specific to the individual and type of meal consumed. In the meal categories where the average CV is above 36%, this is due to the formation of outlier clusters, which contain individual PPGRs due to the PPGR-specific large CV. The cluster-specific metrics can be found in Table S1 in Multimedia Appendix 1. Along with the set number of PPGR clusters per meal type within each participant, there is variation in carbohydrate intake across meal type and individuals (Table 2). The individual cluster error across all clusters and all participants falls below the standard CGM error (0.8 mmol/L) [50] in all but 1 of the clusters formed, which was composed of outliers (563 lunch). The metrics for each isolated PPGR cluster, including the number of PPGRs isolated to each cluster, can be found in Table S1 (Multimedia Appendix 1).

When assessed on an individual basis, the distribution of carbohydrate intake was the same across all clusters in all meal categories barring 2 meals across 2 participants. For dinner in participant 563, the carbohydrates consumed had a significant effect on the cluster formation ($F(2,42) = 3.48$, $P=.04$) and lunch for participant 559 $F$ (2,59)=4.66, $P=.01$. With the OhioT1DM



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sample size of 12 participants, the analysis revealed an effect size (Cohen *d*) [51] of 1.1968. The effect size of 1.1968 observed in this study suggests that the intervention had a strong impact [52].

**Figure 3.** A sample of postprandial glycemic response (PPGR) clusters formed for a single participant. The plots reflect the mean blood glucose (BG) value of each formed cluster with the meal category breakfast, with indication of the standard deviation, error of the clustering technique, and the inherent error of the blood glucose sensor.

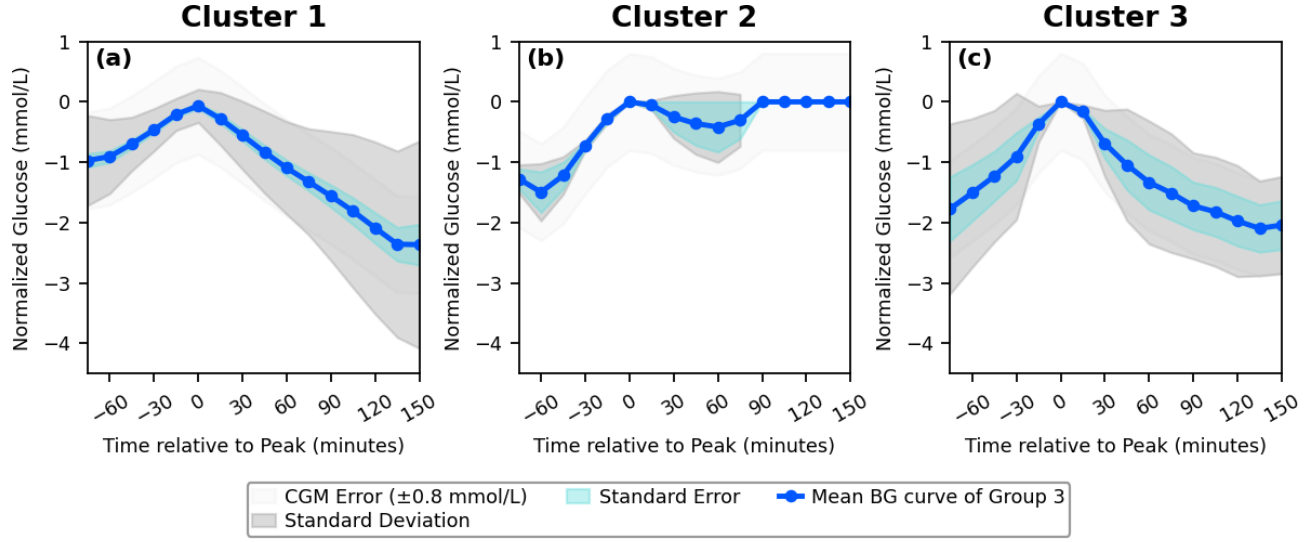
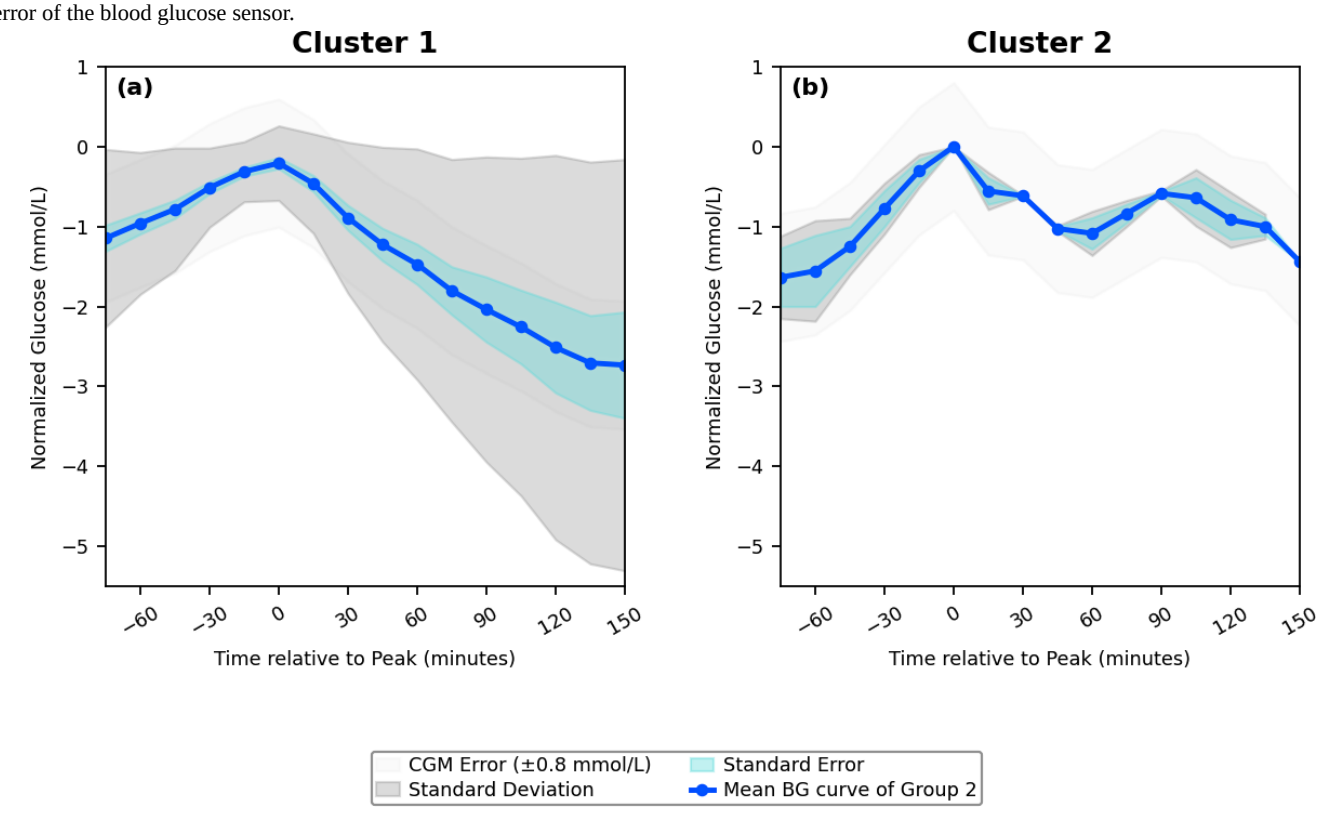


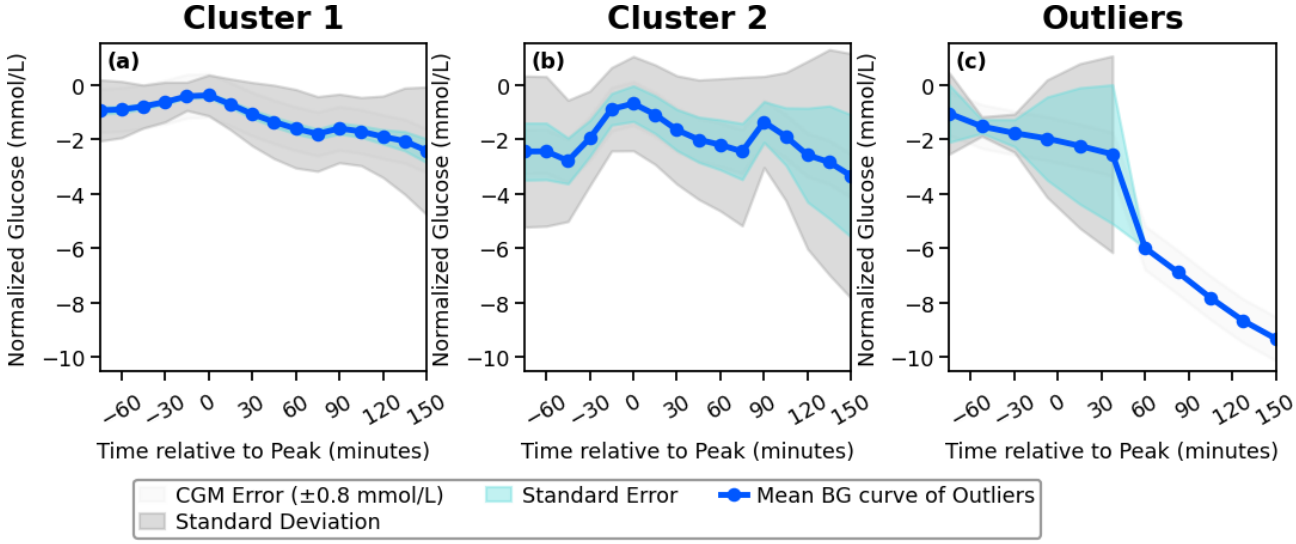

**Figure 4.** A sample of postprandial glycemic response (PPGR) clusters formed for a single participant. The plots reflect the mean blood glucose (BG) value of each formed cluster within the meal category lunch, with indication of the standard deviation, error of the clustering technique, and the inherent error of the blood glucose sensor.






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**Figure 5.** A sample of postprandial glycemic response (PPGR) cluster formed for a single participant. The plots reflect the mean blood glucose (BG) value of each formed cluster within the meal category dinner, including outliers (c), with indication of the standard deviation, error of the clustering technique, and the inherent error of the blood glucose sensor.






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**Table .** The average number of clusters formed for each meal category, along with the within-cluster metrics (standard deviation, standard error, and coefficient of variability [CV])[a].

| ID | Meal | Clusters formed | | | | | Outliers | | | | Statistical values | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Number of clusters formed | PPGRs[b] per cluster, mean (SD) | Peak BG[c] (mmol/L), mean (SD) | Internal cluster CV (%), mean (SD) | Avg. carb intake (g), mean (SD) | PPGRs in outlier cluster | Peak BG (mmol/L), mean (SD) | Internal cluster CV (%), mean (SD) | Avg. carb intake (g), mean (SD) | *F* test *(df)* | *P* value |
| 522 | Breakfast | 3 | 12.3 (15.3) | 9.1 (2.4) | 33.0 (2.5) | 49.1 (25.7) | N/A[d] | N/A | N/A | N/A | 0.64 (2, 23) | .53 |
| | Lunch | 2 | 32.0 (39.5) | 11.9 (4.9) | 23.3 (17.8) | 56.8 (33.3) | 1 | 9.4 (5.3) | 56.7 (0.8) | 15 (0.0) | 1.5 (1, 32) | .22 |
| | Dinner | 2 | 27.5 (24.7) | 7.8 (2.7) | 28.5 (3.7) | 47.3 (2.6) | 4 | 8.3 (3.8) | 45.9 (0.3) | __[e] | 0.09 (1, 30) | .07 |
| 540 | Breakfast | 3 | 16.7 (24.5) | 11.0 (4.0) | 28.8 (9.0) | 38.2 (33.9) | 5 | 7.7 (3.7) | 48.6 (0.2) | 55.0 (49.5) | 1.62 (1, 30) | .21 |
| | Lunch | 3 | 23.7 (26.3) | 9.7 (2.3) | 19.7 (4.8) | 60.6 (2.8) | 4 | 8.0 (3.6) | 45 (0.3) | 100.0 (0.0) | 0.66 (3, 29) | .58 |
| | Dinner | 4 | 16.5 (23.1) | 9.6 (108) | 31.4 (3.9) | 62.2 (15.6) | 10 | 8.0 (3.8) | 46.9 (0.2) | 20.5 (27.6) | 1.18 (4, 22) | .34 |
| 544 | Breakfast | 1 | 51.0 (0.0) | 9.7 (2.5) | 25.4 (0.1) | 41.1 (17.2) | N/A | N/A | N/A | N/A | Not performed due to one cluster formed | N/A |
| | Lunch | 2 | 27.5 (27.5) | 12.3 (3.1) | 29.4 (0.6) | 102.6 (4.9) | N/A | N/A | N/A | N/A | 0.61 (1, 52) | .44 |
| | Dinner | 1 | 75.0 (0.0) | 9.8 (3.1) | 31.8 (0.1) | 68.2 (38.2) | 3 | 9.5 (5.0) | 52.9 (0.4) | 93.9 (64.3) | 1.19 (1, 75) | .28 |
| 559 | Breakfast | 2 | 28.5 (34.6) | 8.5 (4.2) | 28.7 (8.6) | 31.3 (3.6) | 1 | 8.0 (0.0) | 52.6 (0.6) | 30.0 (0.0) | 0.56 (2, 55) | .57 |
| | Lunch | 2 | 29.5 (2.1) | 9.4 (3.3) | 29.4 (1.6) | 34.4 (3.2) | 3 | 9.9 (4.9) | 50 (0.4) | 3.0 (2.9) | 4.66 (2, 59) | .01 |
| | Dinner | 2 | 26.0 (19.7) | 10.4 (4.2) | 28.4 (1.4) | 42.0 (5.8) | 2 | 9.1 (5.0) | 54.6 (0.5) | 32.5 (17.6) | 1.08 (2, 51) | .35 |
| 563 | Breakfast | 6 | 10.2 (16.7) | 8.5 (1.7) | 33.4 (3.3) | 24.2 (9.7) | 4 | 11.1 (3.5) | 546 (0.4) | 36.0 (0.8) | 0.71 (6, 47) | .64 |
| | Lunch | 1 | 59.0 (0.0) | 9.1 (2.3) | 25.8 (0.04) | 29.9 (14.5) | 2 | 7.0 (4.0) | 52.9 (0.4) | 40.0 (0.0) | 0.48 (1, 47) | .49 |
| | Dinner | 2 | 37.0 (27.0) | 9.1 (2.4) | 26.5 (0.5) | 38.9 (10.3) | 4 | 8.6 (4.5) | 51.9 (0.3) | 20.0 (21.2) | 3.48 (2, 43) | .04 |
| 567 | Breakfast | 1 | 49.0 (0.0) | 9.3 (2.7) | 28.8 (0.1) | 72.6 (16.0) | 2 | 6.5 (2.8) | 51.3 (0.3) | — | Not performed due to one cluster formed | N/A |
| | Lunch | 3 | 20.7 (20.8) | 8.3 (1.7) | 31.1 (3.5) | 81.2 (9.5) | 5 | 9.5 (6.2) | 65.4 (0.4) | 87.0 (0.0) | 1.48 (2, 8) | .28 |
| | Dinner | 2 | 35.0 (46.7) | 12.3 (2.7) | 33.2 (2.5) | 83.2 (0.0) | 2 | 9.7 (5.1) | 52.8 (0.5) | 110.0 (0.0) | 0.73 (1, 5) | .43 |



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| ID | Meal | Clusters formed | | | | | Outliers | | | | Statistical values | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Number of clusters formed | PPGRs[b] per cluster, mean (SD) | Peak BG[c] (mmol/L), mean (SD) | Internal cluster CV (%), mean (SD) | Avg. carb intake (g), mean (SD) | PPGRs in outlier cluster | Peak BG (mmol/L), mean (SD) | Internal cluster CV (%), mean (SD) | Avg. carb intake (g), mean (SD) | *F* test *(df)* | *P* value |
| 570 | Breakfast | 1 | 51.0 (0.0) | 13.0 (3.5) | 26.6 (0.1) | 101.4 (39.1) | N/A | N/A | N/A | N/A | Not performed due to one cluster formed | N/A |
| | Lunch | 3 | 17.0 (23.4) | 7.4 (2.9) | 29.4 (5.8) | 125.2 (16.0) | N/A | N/A | N/A | N/A | 0.84 (2, 46) | .44 |
| | Dinner | 3 | 23.0 (34.6) | 9.4 (5.1) | 24.0 (9.8) | 113.7 (27.3) | 1 | 5.5 (2.2) | 39.4 (0.3) | 125 (0.0) | 0.94 (3, 65) | .43 |
| 575 | Breakfast | 1 | 57.0 (0.0) | 4.6 (0.2) | 4.4 (0.0) | 40.8 (13.9) | N/A | N/A | N/A | N/A | Not performed due to one cluster formed | N/A |
| | Lunch | 1 | 90.0 (0.0) | 4.6 (0.2) | 3.8 (0.0) | 38.9 (23.1) | N/A | N/A | N/A | N/A | Not performed due to one cluster formed | N/A |
| | Dinner | 1 | 108.0 (0.0) | 4.6 (0.2) | 4.0 (0.0) | 44.9 (27.2) | N/A | N/A | N/A | N/A | Not performed due to one cluster formed | N/A |
| 584 | Breakfast | 3 | 17.6 (22.9) | 11.6 (5.7) | 27.4 (2.9) | 59.3 (1.2) | N/A | N/A | N/A | N/A | 0.59 (2, 32) | .56 |
| | Lunch | 2 | 24.0 (31.1) | 7.3 (3.1) | 23.4 (12.8) | 57.6 (3.4) | N/A | N/A | N/A | N/A | 0.56 (1, 27) | .46 |
| | Dinner | 2 | 41.0 (48.1) | 12.1 (2.7) | 30.2 (4.4) | 55.9 (5.8) | 2 | 7.1 (3.8) | 54.3 (0.5) | 60.0 (0.0) | 0.34 (2, 50) | .71 |
| 588 | Breakfast | 1 | 55.0 (0.0) | 9.8 (2.4) | 14.9 (4.0) | 14.8 (3.9) | N/A | N/A | N/A | N/A | Not performed due to one cluster formed | N/A |
| | Lunch | 2 | 37 (46.7) | 12.3 (5.0) | 28.9 (1.0) | 37.9 (0.6) | 2 | 16.2 (7.1) | 43.8 (0.7) | 39.0 (17.0) | 0.01 (2, 73) | .99 |
| | Dinner | 3 | 39.3 (21.9) | 9.7 (2.1) | 25.8 (5.1) | 37.0 (1.1) | 4 | 8.9 (4.1) | 46.2 (0.3) | 31.3 (14.4) | 0.04 (3, 114) | .99 |
| 591 | Breakfast | 1 | 66.0 (0.0) | 7.5 (2.6) | 34.5 (0.1) | 28.5 (11.4) | 7 | 8.0 (4.8) | 60.4 (0.3) | 30.1 (16.3) | 12 (1, 71) | .73 |
| | Lunch | 2 | 34.5 (30.4) | 7.4 (2.7) | 33.2 (3.1) | 32.6 (7.1) | 3 | 8.9 (4.8) | 53.3 (0.4) | 32.3 (8.1) | 2.39 (2, 68) | .099 |
| | Dinner | 2 | 43.5 (44.5) | 7.4 (2.9) | 28.7 (0.4) | 30.3 (1.8) | 5 | 7.0 (4.0) | 56.4 (0.3) | 45 (14.5) | 1.92 (2, 81) | .15 |



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| ID | Meal | Clusters formed | | | | | Outliers | | | | Statistical values | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Number of clusters formed | PPGRs[b] per cluster, mean (SD) | Peak BG[c] (mmol/L), mean (SD) | Internal cluster CV (%), mean (SD) | Avg. carb intake (g), mean (SD) | PPGRs in outlier cluster | Peak BG (mmol/L), mean (SD) | Internal cluster CV (%), mean (SD) | Avg. carb intake (g), mean (SD) | *F* test (*df*) | *P* value |
| 596 | Breakfast | 1 | 64.0 (0.0) | 8.9 (3.0) | 33.6 (0.1) | 25.4 (6.7) | N/A | N/A | N/A | N/A | Not performed due to one cluster formed | N/A |
| | Lunch | 1 | 7.0 (0.0) | 7.9 (2.8) | 35.4 (0.0) | 24.4 (15.0) | 3 | 8.1 (4.4) | 53.6 (0.4) | 18 (15.7) | 0.53 (1, 106) | .47 |
| | Dinner | 2 | 50.0 (66.5) | 6.5 (2.7) | 30.1 (3.2) | 26.6 (0.8) | N/A | N/A | N/A | N/A | 0.68 (2, 92) | .51 |

[a]The ANOVA results (*F* value [degrees of freedom], *P* value) compare the effect of the average carbohydrate intake and the cluster formation.

[b]PPGRs: postprandial glycemic responses.

[c]BG: blood glucose.

[d]N/A: not applicable.

[e]—: average carbs not known.

# Discussion

## Principal Findings and Comparison With Previous Works

In this study, data from 12 people with T1D were analyzed. Each participant contributed 9900 BG measurements, which were used to generate and cluster over 200 isolated PPGRs per person. CV-based clustering identified stable, participant-specific PPGR patterns, averaging 2.4 for breakfast, 2.7 for lunch, and 3.1 for dinner with most cluster errors below the CGM's intrinsic error. Carbohydrate intake was largely consistent within clusters, with significant variation in only 2 of 36 meal-participant combinations. The large effect size (Cohen $d$=1.20) underscores the robustness of this approach. These findings demonstrate the intraindividual reproducibility of the PPGRs within a meal category under free-living conditions in people with T1D, highlighting the possibility to predict the PPGR to a given meal in an individual, a concept already validated in healthy individuals [15] and people living with type 2 diabetes [5]. Using PPGR clusters to highlight how an individual responds to a specific meal type provides insight into the overall meal metabolism without requiring onerous additional information from the people with T1D. This could outline appropriate insulin doses for each PPGR cluster that would optimize TIR. Enhancing the PPGR clustering framework presented here without increasing the burden of disease management, through the utilization of meal tags associated with each PPGR event, could ease the burden of nutrition reporting.

Using the CV as a clustering metric for PPGRs is clinically advantageous because a PPGR-specific CV would be expected to be significantly higher than a 24-hour CV, meaning that applying the 24-hour clinical threshold of 36% ensures tighter internal cohesion than the recommended glycemic variability limit. In a comparative analysis, k-means clustering with dynamic time warping produced moderate cohesion, with 50% (6/12) of participants forming clusters across at least 1 time-of-day period when set to 3 clusters (59% of these meeting the CV threshold) and 58% (7/12) when set to 4 clusters (61% meeting the threshold). By contrast, our proposed method achieves markedly superior performance: in all clusters containing more than 1 PPGR, 100% meet the clinical CV threshold, and cluster formation covers all meal categories for every participant, ensuring both clinical relevance and complete coverage.

In the dataset observed within this work, carbohydrate intake alone does not typically predict which cluster a corresponding PPGR would align to, highlighting the importance of overall meal composition and the physiological factors of the individual in determining the PPGR outcome. In those meals where the average PPGR clusters do not meet the target CV, there is a large discrepancy in the number of PPGRs isolated to each cluster, with many of the clusters resulting from outliers that skew the average CV (as seen in Table S1 in Multimedia Appendix 1). Outliers are to be expected given the real-world setting of the dataset.

The limitations of using carbohydrate alone to predict the PPGR are evident and reflect the known limitations of carbohydrate counting, with studies showing a 20% mean error in carbohydrate estimates in people with T1D [53]. The complexity of carbohydrate-based insulin dosing is compounded by the varying rates of glucose absorption from different types of carbohydrates or meals with multiple components, making them nutritionally complex [53,54]. The absorption of digestible carbohydrates in comparison to simple glucose, known as the glycemic index (GI), is well researched [4,20,54]; however, when used in the real world, with complex mixed meals, the prediction of the PPGR using solely GI has shown low precision [13,55]. The unpredictable interaction of several factors, dietary



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and otherwise [56-58], contributes to the complexity and interpersonal nature of the management of the PPGR [59].

The number of clusters formed per meal type varies with time of day, highlighting the significant impact of meal timing on the PPGR. The PPGR response to meals with the same nutritional breakdown, consumed at different times of day, is expected to be greater during the night versus during the day [60]. Current treatment guidelines considering insulin-to-carbohydrate ratios, which fluctuate throughout the day, support the argument that carbohydrate content alone should not dictate the PPGR [61,62]. This enhances the argument reflected in this work that carbohydrate content of a meal alone should not be the only determining factor of the PPGR [59,63]. The work here suggests that the PPGR is decided by a combination of the complete nutritional intake and the individual's physiology, which is supported by the intraindividual PPGR reproducibility to identical meals shown in 800 people [15]. Overall, this highlights the need for the development of a personalized prediction model based on unique PPGR events [58].

Meal timing, along with nutritional composition, has a marked effect on the PPGR [17,24,63], resulting in meals of identical nutritional profiles eliciting different PPGRs when consumed at different times of day (ie, breakfast vs dinner). The treatment relevance of the reproducibility of a PPGR to similar meals at a similar time of day is exacerbated by the fact that habit is a proven driver of food consumption [64,65], both in the type of food and in portion size [66]. To enhance this identified habitual human nature, people with T1D are encouraged to "establish a routine" in the early stages after diagnosis [40]. These factors that enhance the repetitive nature of PPGRs offer the possibility to streamline treatment plans through clustering the PPGRs based on pattern recognition. The traditional treatment strategies of carbohydrate-based insulin dosing have limitations, especially for the case of high fat, high protein foods, which are consistently problematic to manage, along with breakfast cereals possibly due to the high fiber and sugar content [67]. It has been indicated that a person with T1D will use previous experience as a determinant for the bolus dose needed to cover a meal [68]. The optimal indicators of the PPGR in a person with T1D are the carbohydrate and fat content of a meal [20,69]. However, reporting multiple macronutrients compounds the burden on people with T1D, increasing the likelihood of reporting errors. Due to the complexity of PPGR prediction, along with the limitations of carbohydrate counting as a predictor alone, it has been reported that the bolus insulin dose needed to cover the meal consumed was inaccurately estimated in 64% of cases [70]. Therefore, assigning PPGRs to clusters based on an individual's unique response to a meal would simplify treatment planning and reduce the reliance on determining meal carbohydrate content. The presented PPGR-focused clustering algorithm offers an alternative to traditional evaluation methods, such as area under the curve based on GI, which fail to capture individual physiological responses to meals [59].

The clear establishment of PPGR clusters reflects the recurrent behaviors of people with T1D, potentially offering clinical insights for insulin dose decisions and treatment adjustments to optimize TIR. Utilizing PPGR clusters to predict BG values from the PPGR of a previously consumed meal could offer a reduction in patient anxiety and diabetes burden, due to the foreknowledge of upcoming glycemic fluctuations, ultimately easing the management of T1D. Although this work investigates real-world scenarios, the outcomes are supported by the discernible correlation between PPGRs shown to standardized meals [71]. The assessment of CGM data for patterns shows that interday similarities tend to be higher in older people with T1D [18], which reflects the population in the Ohio dataset used here, whose average age is in the range of 30.9 - 56.4 years. The presence of repeatable PPGRs in the real world, as seen in this work, may be attributed to factors such as insulin utilization and the habitual nature of dietary intake and lifestyles. This habitual nature of people's eating patterns, along with the encouraged ritualistic nature of disease management in T1D, will allow the use of PPGR clusters to enhance a feedback loop to better predict BG levels. The work presented here provides an initial framework for prediction that is independent of the initial BG level and not solely reliant on identifying the amount of carbohydrates consumed, suggesting a more physiological-based glycemic response to food. A bolus targeting solution algorithm based on the PPGR-focused clustering algorithm presented here would allow for an insulin adjustment plan to optimize time in range for each isolated PPGR cluster.

## Limitations and Future Work

This study presents a PPGR clustering method that incorporates the full 4-hour BG profile, enabling reduced glycemic variability and contextual insights into individual responses to specific meal types. While promising, limitations include reliance on self-reported meals including carbohydrate intake, which is prone to consistent under- or overreporting within individuals [72], and omission of insulin dose, insulin-on-board, and carbohydrates-on-board, all of which influence PPGR. The dataset was derived from multiple clinical studies with nonstandardized insulin regimens, and insulin sensitivity was treated as an independent variable. Future work will address these factors by incorporating dose, timing, and administration data to improve modeling accuracy.

Even with reproducible PPGR clusters, translating findings into insulin dosing strategies remains complex due to the highly individualized nature of bolus timing and dose optimization [3,73]. In both research datasets (eg, OhioT1DM) and real-world contexts, inconsistent meal logging presents challenges. To mitigate this, we propose a meal-tagging mechanism to link PPGRs via pattern recognition rather than precise carbohydrate counts (Lubasinski et al, unpublished data, 2025) [68], enabling clusters to form based on similar nutritional profiles. This will reduce reporting burden, align with natural logging habits, and provide proactive predictions for upcoming meals, including tailored bolus recommendations aimed at optimizing TIR while lowering cognitive load.

Limitations also include a small sample size, reducing statistical power and generalizability. This work is exploratory and should be interpreted with caution due to potential sampling bias. Broader validation is essential, and our methodology has already been applied to a larger public dataset [74] and replicated in



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follow-up work (Lubasinski et al, unpublished data, 2025). Future multicenter studies with more diverse populations are recommended to strengthen statistical power, enable subgroup analysis, and support the development of scalable, individualized glycemic prediction and adaptive insulin dosing models.

## Conclusions

The clinically relevant and safe PPGR clustering technique developed in this study categorizes PPGRs into distinct PPGR clusters based on the participants' unique response to a meal. This offers a framework for a more personalized and adaptable way to manage PPGRs, independent of initial BG levels or carbohydrate consumption. The reproducibility of PPGRs offers clinical significance through insights for insulin dosing decisions and treatment adjustments to optimize TIR, which may indicate priming insulin doses to flatten the PPGR spike. This will alleviate patient anxiety by providing advance knowledge of glycemic fluctuations and by learning from the past behaviors and outcomes within each cluster. Notably, this work challenges the conventional notion that carbohydrate intake alone determines PPGRs. In summary, we found that PPGRs are reproducible, resulting from a complex interplay of an individual's unique physiology and their overall nutritional intake, underscoring the need for personalized prediction models.

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The authors would like to acknowledge the OhioT1DM dataset [23] for providing invaluable data that facilitated the analysis conducted in this study. The availability of this dataset greatly contributed to the depth and rigor of our research, and we express our gratitude to the creators and contributors of the OhioT1DM dataset for their efforts in making it publicly accessible.

## Data Availability

All data supporting the findings of this study are available within the paper and its Supplementary Information. The code for our study can be found on GitHub [75].

## Authors' Contributions

Conceptualization: NL, HT, PWN, SH.
Data interpretation: NL, HT, PWN, SH.
Methodology and formal analysis: DP.
Writing, original draft: NJL.
Writing, review & editing: NL, HT, PWN, SH.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Breakdown of each of the clusters formed within each meal category per participant.
[DOCX File, 31 KB - diabetes_v10i1e68821_app1.docx ]

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## Abbreviations

**BG:** blood glucose
**CGM:** continuous glucose monitor
**CV:** coefficient of variability
**GI:** glycemic index
**PPGR:** postprandial glycemic response
**PwT1D:** people with T1D
**T1D:** type 1 diabetes
**TIR:** time in range



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# Toward a Personalized Basal Tuner for Detecting Basal Rate Inaccuracies in Type 1 Diabetes Mellitus Without Meal Data: Algorithm Development and Retrospective Validation Study

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## Abstract

**Background:** Basal rate (BR) adjustment is crucial for managing type 1 diabetes mellitus, accounting for 30% to 50% of total daily insulin needs. All current closed-loop systems revert to the user's usual pump BR (known as manual mode) in the event of closed loop failure. Furthermore, access to closed-loop systems remains relatively low in low- and middle-income countries and among those without suitable health insurance. Accurately adjusting the BR remains challenging, leading to hypo- or hyperglycemia, and research on optimizing the BR is limited.

**Objective:** This study proposed an adaptive algorithm that uses continuous glucose monitoring data to identify BR inaccuracies without requiring meal intake information.

**Methods:** The OhioT1DM dataset formed the basis for implementing this methodology. Each composite day was generated by excluding bolus insulin profiles lacking meal intake information and by calculating hourly blood glucose (BG) relative levels along with their corresponding reliability measures, enabling assessment of deviations from the recommended BR (ie, a BG relative change of 0 mg/dL). Both a noninferiority analysis and a classification precision metric were used to assess the practicality of this approach compared to using meal data.

**Results:** Data from 12 participants showed noninferiority of the no-meal method: using a 20% noninferiority margin on absolute BG relative change, 9 of 12 participants met the criterion (1-sided $P<.05$). Classification precision was 73.9% (139/188) of meals correctly classified on average per participant (SD 11.8%; 95% CI 67.2%-79.7%). The daily cumulative BG average was 200.6 mg/dL (SD 61.7 mg/dL; 11.1 mmol/L, SD 3.4 mmol/L; 95% CI 161.4–239.8 mg/dL), with peak values reaching 270.15 mg/dL (14.99 mmol/L). Furthermore, 99.3% (286/288) of the BG relative values (SD 0.5%; 95% CI 97.5% - 99.8%) that were unaffected by external factors were associated with incorrect BR settings, with deviations ranging from −25.5 to 46 mg/dL (−1.58 to 2.59 mmol/L).

**Conclusions:** Current strategies to optimize BR settings are inadequate, and our approach of a personalized basal tuner (PBT) helps better analyze BR without relying on meal intake information. Indeed, without an optimally set BR, in the event of the closed loop reverting to manual mode, patients may be exposed to persistent hypo- or hyperglycemia, leading to safety and efficacy issues. Future work will focus on generating BR recommendations through the application of this algorithm in clinical practice to assist clinicians in setting BR in low- and middle-income countries, where closed-loop systems are not prevalent, to help increase time in range.

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**KEYWORDS**

personalized basal tuner; PBT; meal detection; adaptive basal insulin; blood glucose management; type 1 diabetes mellitus; T1DM



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## Introduction

### Background

The current state of the art in insulin delivery is automatic insulin delivery, also known as closed-loop systems [1]. In real-world settings—such as with the open source loop system—these have been shown to improve both glycemic control and quality of life [2]. However, all existing closed-loop systems revert to the user's preset pump basal rate (BR) manual mode in the event of system failure. Specific closed-loop systems also use the pump BR for other reasons, such as serving as an integral part in the control algorithm functionality (Tandem t:slim) [3] or as a safety backup (reverting to manual mode) if the user has been hyperglycemic for a set time (Omnipod 5) [4].

While high-income countries are transitioning to closed-loop systems, those in low- and middle-income countries (LMICs) and without suitable health insurance have limited access to closed-loop systems [5,6]. Therefore, without an optimally set BR, a closed-loop system reverting to manual mode may expose patients to persistent hypo- or hyperglycemia, compromising both safety and efficacy. This is particularly crucial as basal insulin contributes approximately 30% to 50% of total daily insulin use in individuals with type 1 diabetes mellitus (T1DM) [7,8].

Recent evidence indicates that insulin requirements, including BR, do not always follow predictable circadian or clinically assumed patterns, with unexpected deviations occurring as frequently as expected ones [9]. Such variability underscores the need for regular assessment and adjustment of BR settings to ensure stability across different operational modes and clinical contexts. Accordingly, the proposed algorithm is clinically relevant in several scenarios: (1) when a closed-loop system fails and reverts to manual mode; (2) in devices that incorporate fixed basal profiles as part of their control strategy (eg, the Tandem t:slim); (3) when safety protocols trigger a manual mode reversion after sustained hyperglycemia (eg, the Omnipod 5); and (4) in settings where closed-loop technology is unavailable due to cost, insurance coverage, or regulatory constraints, such as in many LMICs. In all these cases, an accurately set BR remains essential for maintaining glycemic stability.

### Challenges in BR Optimization

Traditionally, establishing BR has involved a series of fasting tests, each lasting 6 to 12 hours and conducted at different times of the day. The results are used to fine-tune, retest, and record BR settings. While effective, this method can be challenging for both patients and clinicians [10] and is less commonly used in routine practice, where adjustments are often made based on continuous glucose monitoring (CGM) or finger-prick blood glucose (BG) values. Once the initial BR is determined, the clinician's recommendations remain unchanged for several months between clinic visits. This approach is particularly concerning for children and adolescents, whose physiological needs evolve rapidly, making it difficult to ensure that their requirements are adequately adjusted and addressed [11-14].

### Objective

The objective of this study was to evaluate whether accurate assessment of basal insulin rates can be achieved without requiring meal information. Using 45 days of CGM and basal insulin delivery data, the algorithm generates a composite 24-hour basal profile designed to support stable and safe glycemic control, particularly in scenarios in which a closed-loop system fails and reverts to manual mode. Current guidelines recommend a time in range (TIR) of at least 16.8 hours per day (70%), corresponding to BG levels between 70 and 180 mg/dL (3.9 - 10 mmol/L) for that proportion of time [15,16]. While this work focused on demonstrating the nonnecessity of meal data for such assessments, the application of these results to guide BR adjustments will be addressed in future research.

### Related Work

Several studies have explored strategies to set up basal insulin delivery for improved glycemic control in individuals with T1DM. Run-to-run adaptive control strategies using model predictive control dynamically adjust basal insulin based on daily glycemic patterns to enhance glucose stability and reduce hypoglycemia risk [17]. Similarly, iterative learning control has been applied to optimize basal insulin in multiple daily injection therapy, leveraging historical BG data to personalize and refine dosing over time [18]. Additionally, a multivariate learning framework has been proposed for artificial pancreas systems, allowing for continuous adaptation of basal insulin rates in response to individual variability and long-term changes in glycemic behavior [19]. Finally, a multiagent reinforcement learning method has been used to adjust both basal and bolus insulin dosing [20].

### Study Contribution

Unlike methods that depend on complex models and real-time adjustments, the personalized basal tuner (PBT) algorithm provides a simpler, more practical solution for evaluating BR without the need for meal data. Additionally, updating calculations on a 45-day basis may improve the performance of certain closed-loop systems that incorporate BR as a key component of their algorithms. This approach could also enhance the safety of these systems when reverting to manual mode. Furthermore, it supports clinicians in LMICs, where closed-loop systems are less common, by aiding in BR adjustments to improve TIR and better manage BG fluctuations unrelated to meal intake.

### Aim and Hypothesis

The primary aim of this study was to develop and evaluate an algorithm capable of identifying and removing BG excursions caused by mealtime insulin boluses without requiring meal information. The hypothesis was that this approach would be noninferior and reasonably precise compared with methods using meal data, thereby supporting its use in scenarios in which meal information is unavailable or unreliable.



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## Methods

### Ethical Considerations

This study used the OhioT1DM dataset [21], originally collected under Institutional Review Board approval at Ohio University (National Institutes of Health grant 1R21EB022356). Access to the dataset requires a data use agreement signed between Ohio University and the requesting institution, as stated in the dataset descriptor. In this work, access was provided to the research team at the University of Manchester under such an agreement, and all records were fully deidentified before release. As this was a secondary analysis of anonymized data, no additional ethics approval was required locally in accordance with University of Manchester policy on the use of anonymized secondary data.

### Participants

This study used data from 12 adults with T1DM included in the OhioT1DM dataset [21]. For each participant, approximately 45 consecutive days of CGM, insulin delivery, and self-reported life event information were available. Participant demographics are summarized in Table 1. Although the cohort was modest in size, each record provided a rich multimodal profile that included CGM, insulin therapy, and contextual events. This level of longitudinal detail supports reproducible analyses and methodological development despite the limited number of participants.

**Table .** Demographic characteristics of participants in the OhioT1DM dataset relevant to the personalized basal tuner algorithm.

| ID | Sex | Age group (y) | Pump model | Cohort year[a] | Activity reported[b] |
|---|---|---|---|---|---|
| 540 | Male | 20 - 40 | 630G | 2020 | No |
| 544 | Male | 40 - 60 | 530G | 2020 | No |
| 552 | Male | 20 - 40 | 530G | 2020 | No |
| 567 | Female | 20 - 40 | 630G | 2020 | No |
| 584 | Male | 40 - 60 | 530G | 2020 | No |
| 596 | Male | 40 - 80 | 530G | 2020 | No |
| 559 | Female | 40 - 60 | 530G | 2018 | Yes |
| 563 | Male | 40 - 60 | 530G | 2018 | Yes |
| 570 | Male | 40 - 60 | 530G | 2018 | Yes |
| 575 | Female | 40 - 60 | 530G | 2018 | Yes |
| 588 | Female | 40 - 60 | 530G | 2018 | Yes |
| 591 | Female | 40 - 60 | 530G | 2018 | Yes |

[a]The dataset includes patients from different cohorts and with different pump models.

[b]"Activity reported" indicates whether the participant provided physical activity data.

### Materials

Each participant's dataset includes 20 distinct variables viewable through the open-source OhioT1DM Viewer (Ohio University) [21]. For the scope of this study, the following specific variables were extracted and analyzed for each individual: BG, BR, bolus insulin doses, meal data, and baseline step count.

### Main Algorithm

The current algorithm functions as a sequential pipeline designed for the analysis of T1DM data, with distinct stages designed to identify inaccuracies in historical BR (Figure 1).

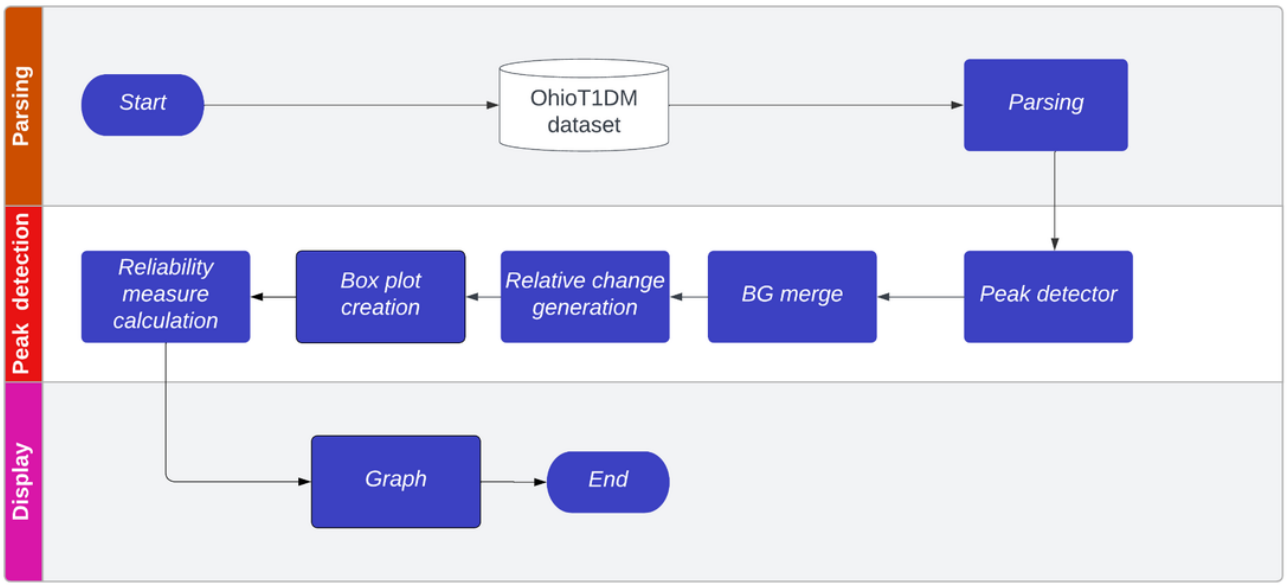
The first stage involves parsing CGM and insulin delivery data, which are downloaded from the corresponding devices. The second stage applies a peak detection algorithm to filter out BG readings influenced by meal intake, preserving readings from fasting periods as much as possible. The primary goal is to remove meal-related peaks even when the meals are not recorded. This process is applied to all historical data, and relative changes in BG are then calculated on an hourly basis to quantify deviations from the optimal target of 0 mg/dL, which serves as the conceptual baseline. In clinical practice, once the clinician determines the optimal basal insulin dose, it is expected that fasting glucose will remain stable or show minimal deviation. Afterward, box plots are generated to analyze and visualize the distribution of BG relative changes. Finally, a metric based on the number of data points is calculated to assess the reliability of the obtained values. The final stage focuses on displaying results and evaluating the findings (see the Results and Discussion sections for further reference).

In summary, this variant of the algorithm takes a different approach by avoiding the necessity of meal information. Instead, it leverages historical data to characterize BG peaks, effectively removing them and, thus, providing clear BG readings unaffected by external factors such as meals or mealtime insulin bolus delivery. This method offers an approach to evaluating BR in historical BG readings adaptable to any patient.



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**Figure 1.** The developed algorithm is organized into 3 stages: one focused on preprocessing blood glucose (BG) data, another focused on peak detection and evaluation of basal rate (BR), and the final stage focused on display and analysis. The main objective was to highlight and evaluate aspects related to BR.




## Peak Detection Analysis

Peak detection serves the purpose of identifying and removing the influence of mealtime insulin bolus on BG levels in reaction to meal metabolism. The process commences with the examination of the BG information available for each sampled patient as a function of date and time (algorithm 1 in Textbox 1). Meal information in this study was used for annotation purposes (ie, to evaluate whether the BG peaks found were due to meals).

**Textbox 1.** Peak detection algorithm (algorithm 1).

Require: N ← BG files sorted by date;

for i in len(N) do

Apply low-pass filter to $N_i$ to avoid noise;

$\{P_1, P_2, P_3, ..., P_i\}$ ← peaks;

$\{W_1, W_2, W_3, ..., W_i\}$ ← widths of peaks

Obtain percentiles 95th of peak heights and widths;

for j in len($\{P_1, P_2, P_3, ..., P_i\}$) do if $P_j$ or $W_j \geq$ P95

then

$T_{ini} \leftarrow T_{Peak\ j} - 1hr$; ▷ Obtain initial times to remove.

$T_{f\ in} \leftarrow T_{Peak\ j} + 3hrs$; ▷ Obtain final times to remove.

if $T_{f\ in} \geq 23:59:59$ then

$T_{f\ in} \leftarrow T_{f\ in} - 00:00:00$; ▷ Obtain value to be removed next day.

Read $N_{i+1}$ file;

CleanBGFile ← Cut BG values ∈ $(00:00:00, T_{f\ in})$;

end if

end if

CleanBGFile ← Cut BG values ∈ $(T_{ini}, T_{f\ in})$

end for

end for

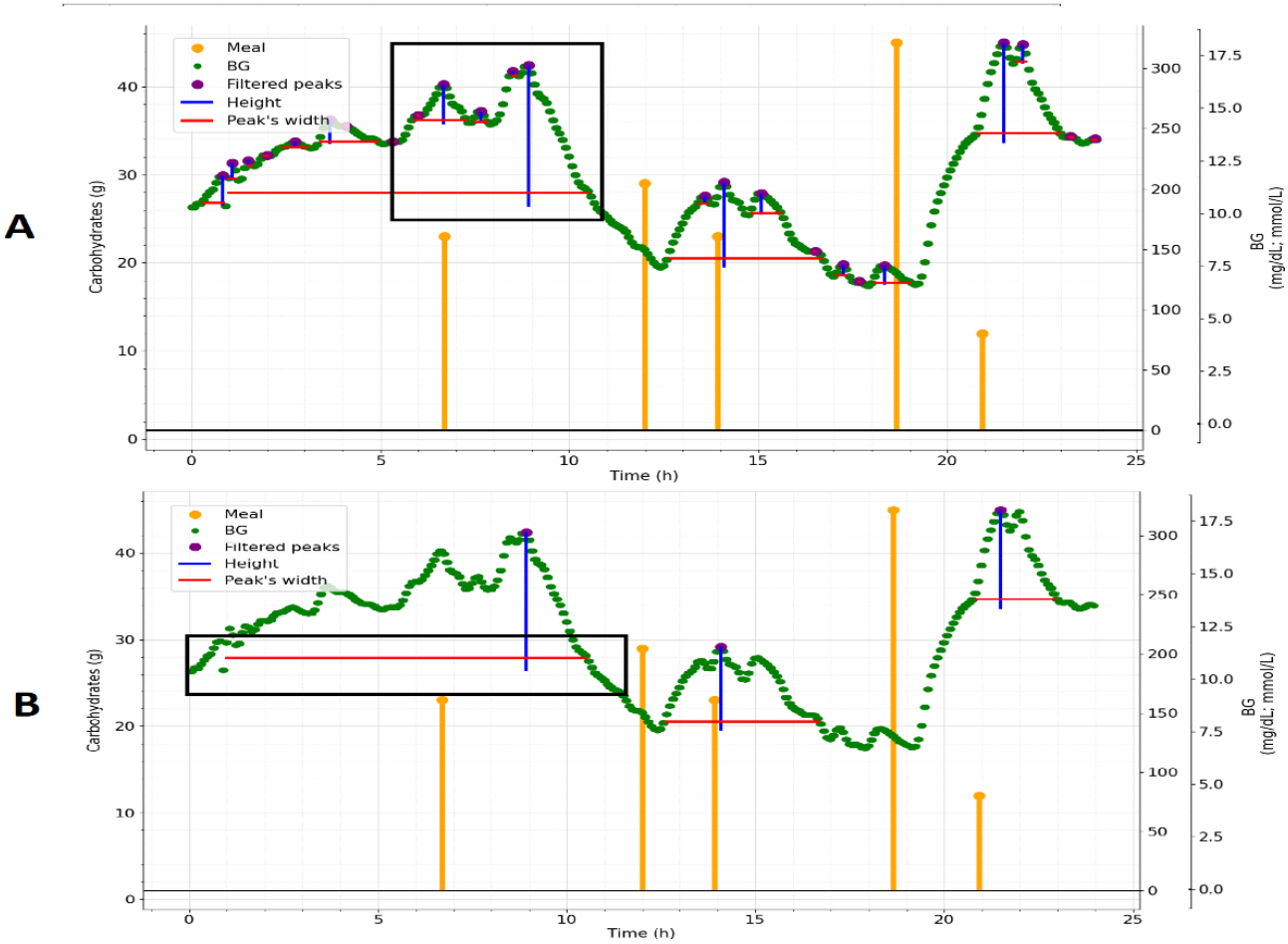
Algorithm 1 is specifically crafted to process BG data associated with a patient. In each iteration, the algorithm uses a low-pass filter to eliminate potential inaccuracies from reading errors in a CGM system. Once the filter is applied to the data, algorithm



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1 takes on the task of detecting what is considered a BG peak for this study. This involves using algorithms for peak detection, height calculation, and width estimation, all based on standard signal processing techniques. The peak's height (mg/dL) is calculated geometrically by measuring height relative to neighboring minima. Once the minima on each side of the peak are located, the height corresponding to the deeper valley is selected. The width (hours) is determined via linear interpolation at a specified height [22]. After identifying all peaks, an outlier detection method leveraging either height or width is used to pinpoint peaks potentially associated with meal intake. A threshold corresponding to the 95th percentile is established to filter out peaks likely linked to meals. The outcome of this process is illustrated in Figure 2, where panel A displays all detected peaks and panel B shows the filtered peaks following the application of the threshold. Similar approaches for outlier detection using peak characteristics such as height and width have been discussed in the literature, including robust regression and outlier detection methods [23], anomaly detection techniques [24], and event detection with outlier handling in biological time-series data [25]. Research shows that different macronutrients (carbohydrates, proteins, and fats) affect glucose peak profiles in distinct ways. Carbohydrates typically cause a rapid rise in BG, leading to a sharp increase followed by a quick, often asymmetrical decline. In contrast, proteins and fats slow gastric emptying and glucose absorption, resulting in a more delayed and flatter peak. These observations suggest that glucose peak curves are better modeled using skewed distributions such as log-normal or gamma distributions rather than the traditional symmetric Gaussian curve [26]. Furthermore, one study indicated that glucose use begins soon after a meal, with peak glucose use and insulin action typically occurring within 3 to 4 hours after a meal [27]. Therefore, for this study, if peaks were identified, a 4-hour window was excluded from the BG readings around each peak time (extending from 1 hour before to 3 hours after the peak).

**Figure 2.** (A) This example illustrates a series of purple peaks identified by the algorithm over a single day. (B) After applying the outlier detector with threshold criteria based on the 95th percentile for width (hours) and height (mg/dL), only the peaks that meet these criteria are removed. In both examples, widths are shown in red, and heights are shown in blue. Meal information is highlighted in orange, offering visual guidance to help the reader better understand the phenomena evaluated by the algorithm. BG: blood glucose.

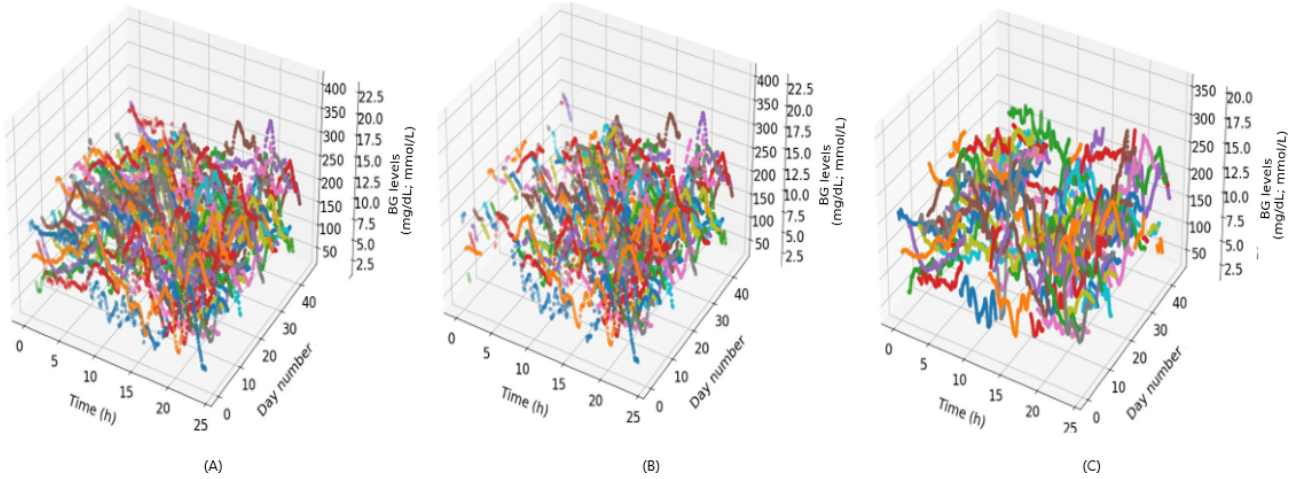



If the temporal subtraction extends into the early hours of the subsequent day, this adjustment is carried over to the following reading. Consequently, the outcome is daily BG data in which any regions influenced by significant peaks in BG are effectively removed. It is essential to acknowledge that this step may be susceptible to inaccuracies as there could be instances in which peaks are not precisely obtained and some peaks may be attributed to factors other than meals. The effect of removing BG peaks using algorithm 1 is illustrated in Figure 3.



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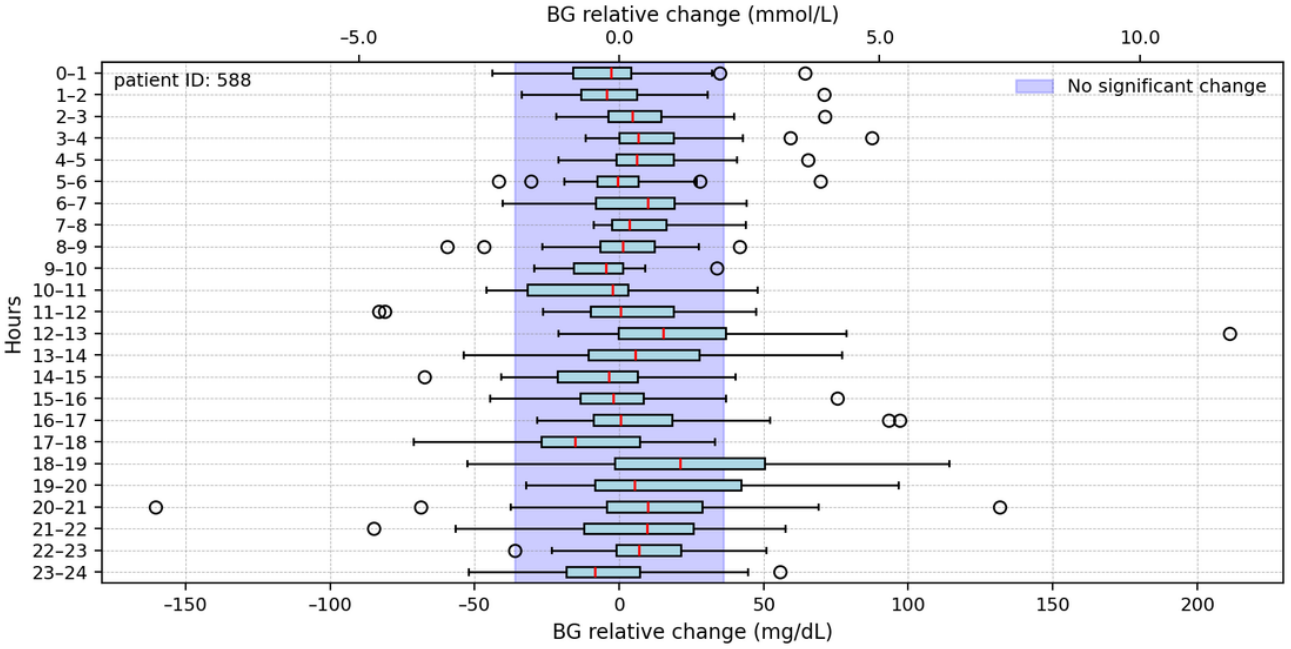
**Figure 3.** Example application of algorithm 1: (A) 45 blood glucose (BG) readings for patient ID 588 over a day; (B) segments of BG readings removed due to external influences; and (C) remaining BG levels after removal, representing periods without external interference.




After removing BG intervals influenced by meal absorption, the algorithm consolidates the results into a unified table using a 24-hour pivot structure with 1-minute increments. This approach is selected to accommodate the irregular intervals at which measurements are recorded—typically every 5 minutes. The primary objective is to create a comprehensive daily composite, which serves as input for calculating BG relative change values.

Once the cleaned BG data are consolidated, they are divided into 24 one-hour segments for more detailed and thorough analysis. This segmentation aims to assess the stability of BG levels throughout the day. The underlying hypothesis is that, if the start and end points show no significant change, indicated by a relative BG change of 0 mg/dL (0 mmol/L), the BR is considered appropriate, and no further adjustments are needed. However, if differences are detected, further evaluation is required to determine the significance of these changes. The results of implementing this approach are shown in Figure 4.

**Figure 4.** Hourly box plots depicting relative changes showcase the median distribution's behavior over a composite 24-hour period. Values outside the blue-shaded range indicate greater fluctuations during those time slots; however, this range is intended solely for visualization purposes. BG: blood glucose.




The blue shading in Figure 4 represents a fixed range of –36 to +36 mg/dL (–2 to +2 mmol/L), serving as a visual reference for hourly fluctuations in relative BG levels. However, as the computation of box plots depends on the number of data points within each interval, some intervals exhibiting substantial variability require further analysis to assess the accuracy of these values.

To address this, a personalized reliability measure—based on the number of data points—was incorporated into the analysis. Percentiles were used as thresholds determined through exploratory analysis of the hourly data, with the 50th and 70th percentiles identified as points of notable separation in the dataset [28]. The resulting composite day representation illustrates relative changes in BG categorized using a 3-level reliability measure, as shown in the Peak Detection Analysis



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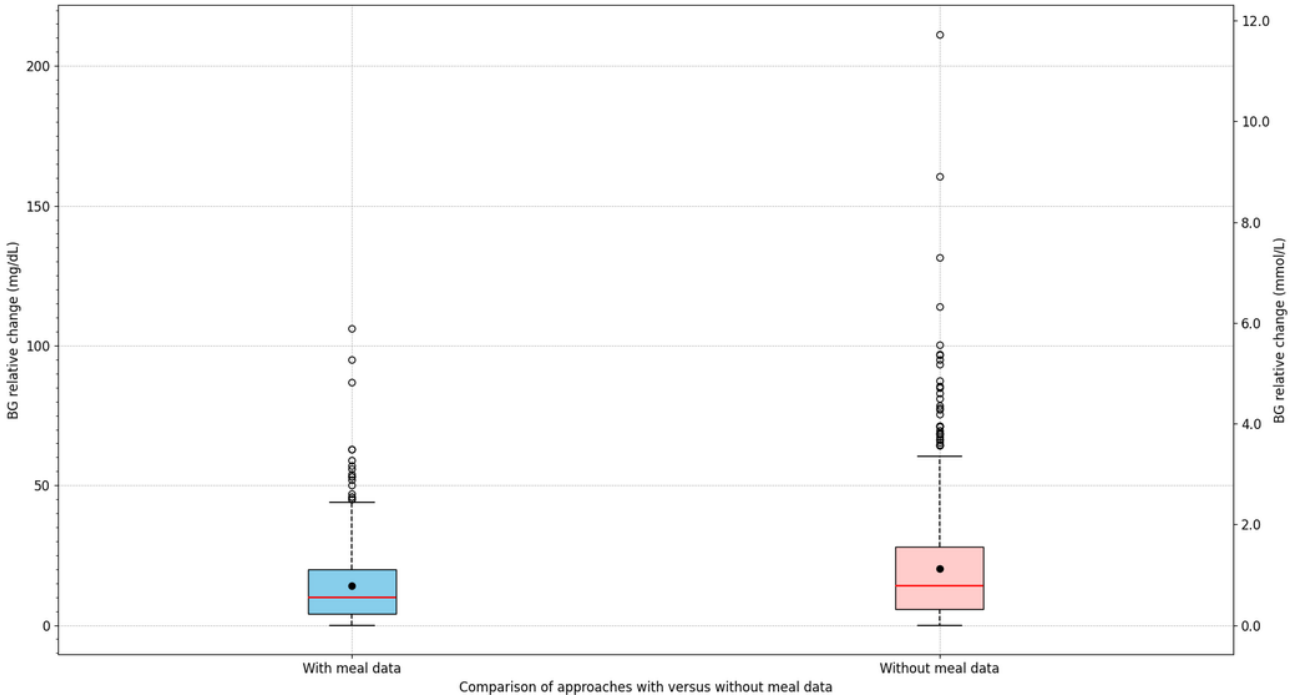
Results section, and is intended to evaluate the current deviation of the BR.

Finally, to assess whether this procedure serves as a viable alternative to the use of meal data, 2 tests were conducted. First, a noninferiority test was conducted to evaluate whether the cumulative deviation of BG relative changes captured by this method was comparable to that obtained using meal information. This metric was chosen because BG deviations are critical for assessing the current state of BR. Second, precision was calculated to measure the accuracy with which the method classified peaks as meal-related events. An interindividual analysis was also conducted to identify general patterns across participants.

### Noninferiority Test

To determine whether the peak detection algorithm can be used as an alternative to traditional meal announcements, it was compared against historical meal data. Specifically, once a meal was announced, the subsequent 4 hours of BG data were excluded from the analysis, as recommended in prior studies [26,27]. The new method must demonstrate noninferiority by exhibiting comparable cumulative BG relative level deviations. As BG relative levels can fluctuate above and below the target value of 0 mg/dL, the absolute value of the deviation was used. A comparative distribution of BG deviations is shown in Figure 5.

**Figure 5.** Box plot comparing the deviation in blood glucose (BG) between the method using meal data and the peak detection algorithm.




### Precision

To further evaluate the method's performance, precision was calculated to determine the proportion of detected peaks that were correctly attributed to meal events [29]. The analysis assessed whether the peak detection algorithm correctly identified a BG peak associated with a meal event occurring within a flexible window, from 1 hour before the estimated base starting point (defined as peak-width/2) to 1 hour after the peak. This window was defined based on exploratory data analysis, which revealed variability in the timing and quality of meal annotations (see the Precision Results section). The 95% CIs for these proportions were calculated using the Wilson score method.

### Interindividual Analysis

To identify general patterns across participants, the BG relative change data from all individuals were pooled into a single dataset, and each 24-hour composite day was divided into 1-hour intervals. For each interval, values were classified into 1 of 3 categories: excessive insulin (<0 mg/dL), insufficient insulin (>0 mg/dL), or optimal insulin (±0 mg/dL). For each category, the range (minimum and maximum), the average daily cumulative value, and the peak value across all participants were computed. Additionally, variance was compared between the excessive and insufficient insulin categories to assess consistency in glycemic deviations. The proportion of inappropriate BR settings was calculated as the number of hourly intervals classified as "excessive" or "insufficient" insulin divided by the total number of hourly intervals (n=288) after excluding periods influenced by meals.

## Results

### Overview

The results of the analysis are structured into 4 key stages of evaluation. First, the phenomena observed in all patients were identified and described, highlighting the detected patterns (see the Peak Detection Analysis Results section). Second, the noninferiority test was conducted for each individual to evaluate the safety of using this methodology compared with using meal data (see the Noninferiority Test Results section). Third, the precision of the method was assessed (see the Precision Results



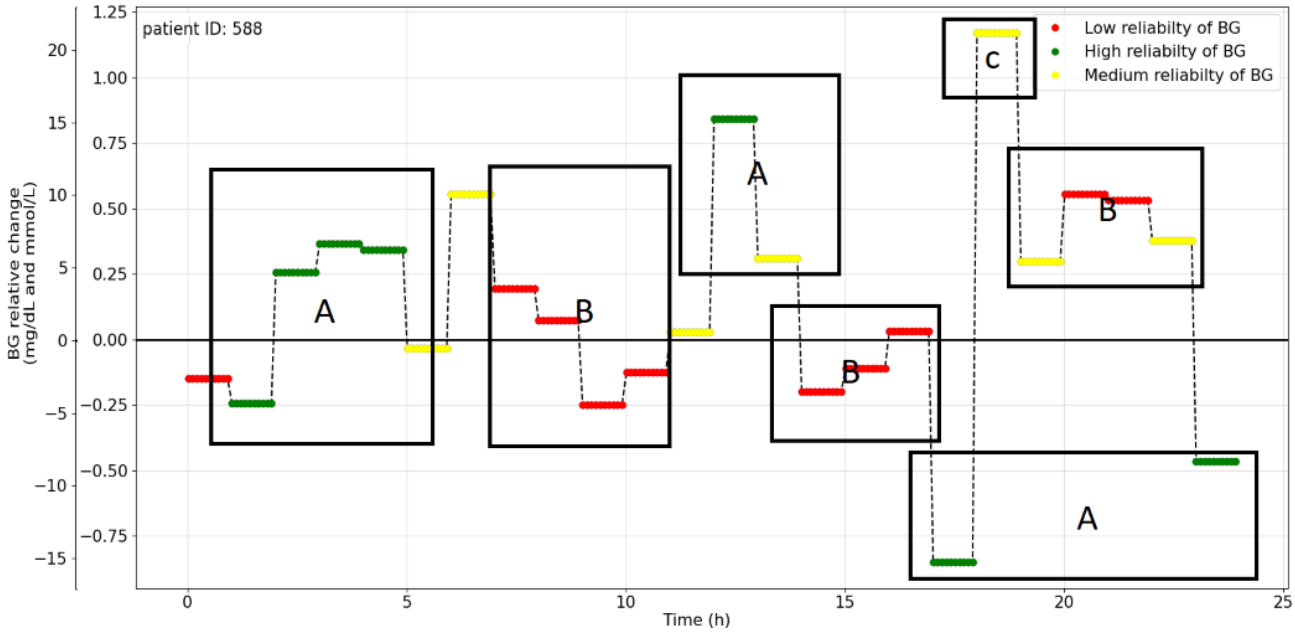
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section). Finally, an interindividual analysis was conducted to evaluate the general state of BR across participants and whether they shared a common issue with their actual BR (see the Interindividual Analysis Results section). This 4-stage approach enabled a deeper understanding of the findings and their implications.

## Peak Detection Analysis Results

The analysis of BG relative levels across multiple patients revealed consistent patterns of reliability issues in the BG data. For most patients, higher reliability in BG relative changes was observed during early-morning hours, periods between meals, and late-night intervals. In contrast, mealtimes were associated with lower reliability, often accompanied by the presence of outliers. Patient ID 588 in Figure 6 serves as a representative example, where "A" shows BG levels with high reliability during early hours and between meals, "B" shows low-reliability BG values around mealtimes, and "C" highlights occasional outliers during periods of low reliability.

**Figure 6.** Blood glucose (BG) relative changes and reliability for the patient with ID 588. "A" indicates that BG levels demonstrated high reliability during early hours and periods between meals. "B" indicates that low-reliability BG values were observed around mealtimes. "C" indicates that occasional outliers were observed during periods of low reliability.




## Noninferiority Test Results

The results of the noninferiority test, which compared the level of deviation from optimal BG levels for each individual using this method and meal data, are shown in Table 2. There is no accepted standard for the noninferiority margin, but for this analysis, a threshold of 20% was established as a reasonable starting point. Using this margin, the majority of participants satisfied the noninferiority test. This indicates that the cumulative deviation of BG relative values as a metric was not worse when comparing this method to using meal information.

**Table .** Results of the noninferiority test for each participant in the OhioT1DM dataset.

| ID | *t* test (*df*) | *P* value |
|---|---|---|
| 540 | 3.381 (460) | <.001 |
| 544 | –4.510 (980) | <.001 |
| 552 | 3.673 (1025) | <.001 |
| 567 | 4.344 (263) | <.001 |
| 584 | 6.955 (1336) | <.001 |
| 596 | 0.591 (854) | .277 |
| 559 | 0.663 (1101) | .254 |
| 563 | 3.345 (1299) | <.001 |
| 570 | –2.219 (983) | .013 |
| 575 | –7.310 (1080) | <.001 |
| 588 | –3.192 (1140) | <.001 |
| 591 | –1.396 (915) | .081 |



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## Precision Results

The results, summarized in Table 3, indicate precision values ranging from 46.8% (88/188) of meals to 84% (158/188) of meals, with an average of 73.9% (139/188; SD 11.8%) of meals correctly classified per participant (95% CI 67.2% - 79.7%, calculated using the Wilson score method) when low-quality data, denoted by the "1" in the "low quality" column, were excluded. Notably, missing data (ie, instances in which no meal events were annotated in the dataset) impacted precision outcomes as the absence of reference points prevented meaningful comparisons.

**Table .** Summary of precision across multiple individuals. Low-quality data significantly impacted performance as the large proportion of missing information negatively affected the results[a].

| ID | Precision (%) | Low quality[b] | Missing meal files, n/N (%) |
|---|---|---|---|
| 540 | 56 | 1 | 29/46 (63) |
| 544 | 71 | 0 | 3/41 (7) |
| 552 | 47 | 1 | 15/38 (39) |
| 567 | 47 | 1 | 36/47 (77) |
| 584 | 49 | 1 | 12/46 (26) |
| 596 | 79 | 0 | 9/46 (20) |
| 559 | 73 | 0 | 7/42 (17) |
| 563 | 63 | 0 | 4/46 (9) |
| 570 | 73 | 0 | 6/41 (15) |
| 575 | 81 | 0 | 4/46 (9) |
| 588 | 84 | 0 | 1/46 (2) |
| 591 | 70 | 0 | 6/46 (13) |

[a]Precision values ranged from 47% (88/188) to 84% (158/188) of meals, with an average of 74% (139/188) of meals in the filtered dataset.

[b]Low quality: binary indicator; 1=low-quality data, 0=high-quality data.

## Interindividual Analysis Results

Figure 7 shows that 99.3% (286/288) of the BG relative values (SD 0.5%; 95% CI 97.5% - 99.8%) fell into the categories of either insufficient or excessive insulin, presenting a stark contrast to the relatively sparse occurrences of optimal insulin levels, averaging approximately 0.166 hours per day across the study group.

Figure 8 shows that BG relative levels seemed to exhibit diverse patterns when either too little or too much insulin was administered, with noticeable variations among individuals, ranging from −28.5 to 46.7 mg/dL (−1.58 to 2.59 mmol/L). Data analysis indicates that, on average, individuals show lower variability when more insulin than optimal is administered compared to other dosing conditions. When computing the daily cumulative average from the data of all individuals, the analysis revealed an average value of 200.6 mg/dL (SD 61.7; 11.1 mmol/L, SD 3.4; 95% CI 161.4–239.8 mg/dL), with peak values reaching 270.15 (SD 14.99) mmol/L.



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**Figure 7.** Histogram illustrating the distribution of hours during which individuals experienced insufficient, excessive, or optimal insulin levels, corresponding to blood glucose relative values that were below or above the optimal target or at the optimal target, respectively. Across 12 participants (24 hours each; total=288 values), 99.3% (286/288; SD 0.5%) of the values fell into the categories of either insufficient or excessive insulin. Optimal insulin levels were rare, averaging approximately 0.166 hours per day across the study group.

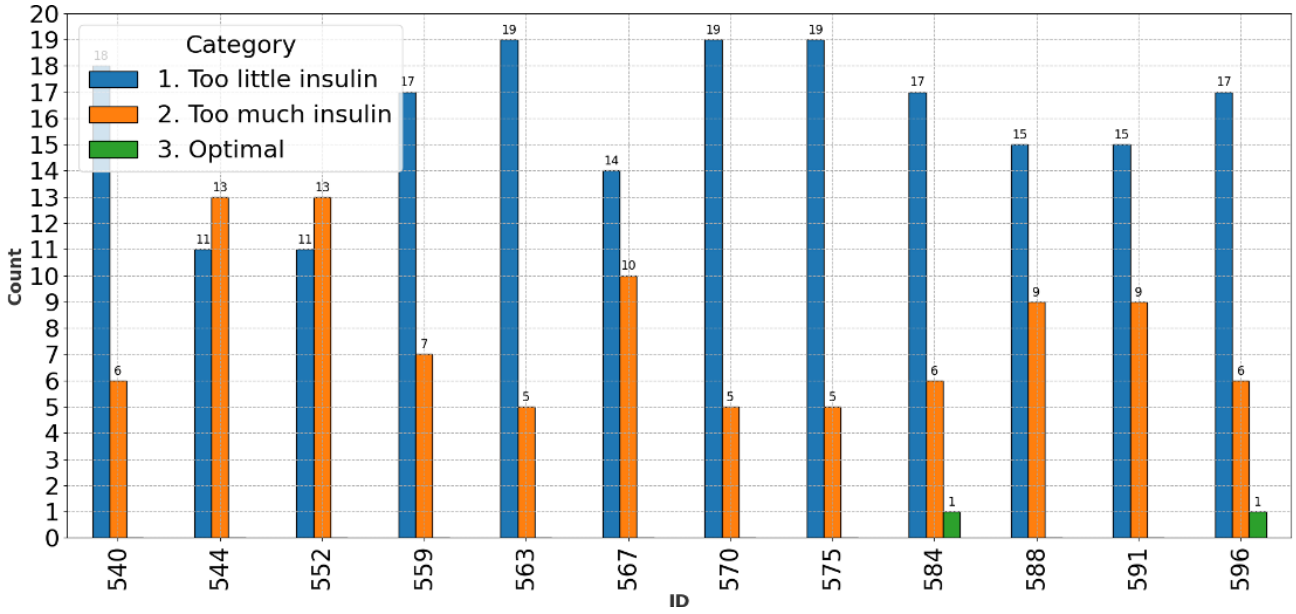
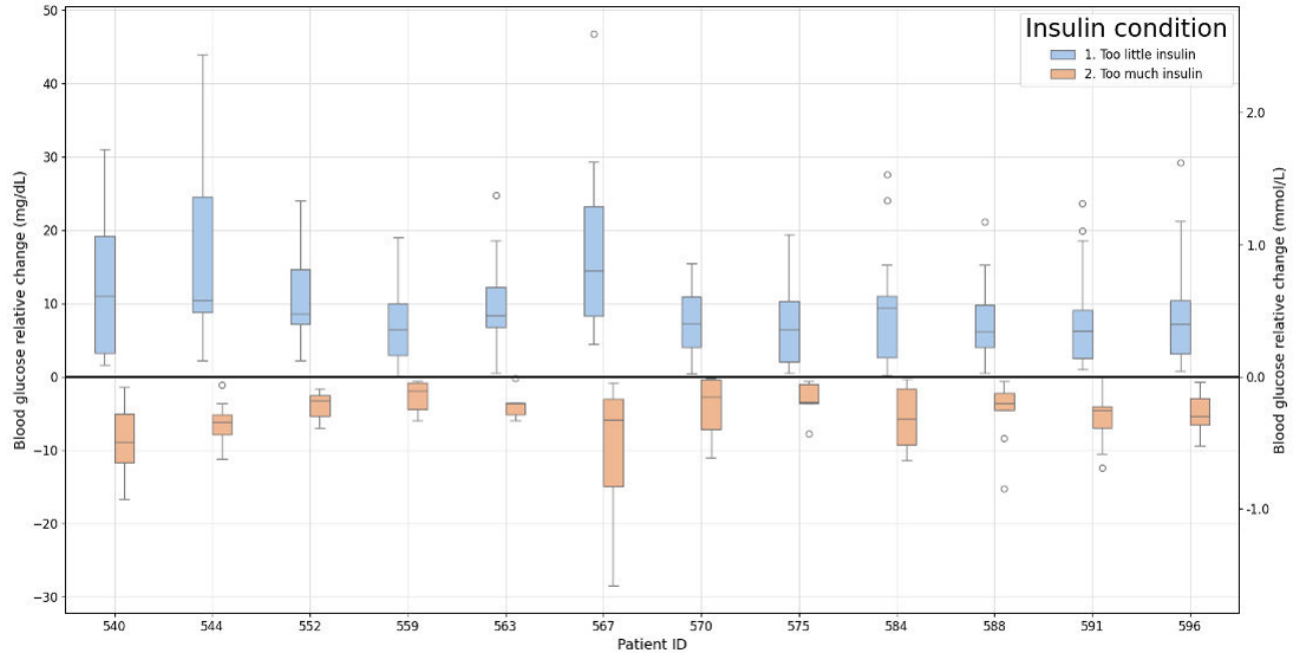



**Figure 8.** Box plots showing blood glucose relative levels under conditions of insufficient and excessive insulin administration, with interindividual variability ranging from −28.5 to 46.7 mg/dL (−1.58 to 2.59 mmol/L). Daily cumulative averages across all individuals revealed a mean of 200.6 (SD 61.7) mg/dL (11.1, SD 3.4 mmol/L; 95% CI 161.4–239.8 mg/dL), peaking at 270.15 (SD 14.99) mmol/L.




## Discussion

### Principal Results

This study introduced a meal-independent approach for assessing the adequacy of BR using historical CGM and insulin delivery data. Unlike prior work focused on BR as an input for BG prediction models, our method directly evaluates BR performance over time and identifies when adjustments are needed.

Peak detection analysis across participants revealed consistent patterns in data reliability—higher reliability was generally observed during early-morning hours, between meals, and late at night, whereas mealtimes tended to show lower reliability and more frequent outliers.

Using a predefined 20% noninferiority margin on absolute BG relative change, the no-meal method showed comparable behavior to the meal-based approach in 9 of 12 participants (1-sided $P$<.05). These findings indicate that the method may achieve comparable performance without relying on meal information, although individual differences and data variability may explain the few nonsignificant results. Precision averaged 73.9% (139/188) of meals correctly classified per participant



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(SD 11.8%; 95% CI 67.2% - 79.7%), indicating reasonable accuracy in excluding meal-related BG excursions.

Interindividual analysis showed that 99.3% (286/288) of BG relative values (SD 0.5%; 95% CI 97.5% - 99.8%) fell into the excessive or insufficient insulin categories, with deviations ranging from −25.5 to 46 mg/dL (−1.58 to 2.59 mmol/L). These findings highlight the prevalence of suboptimal BR settings and suggest that the proposed approach could support BR adjustments without the burden of collecting meal data, reducing patient effort and device-related strain [30] and supporting future calibration in both closed-loop and stand-alone pump use.

Although CGM-derived glucose trends formed the primary analytical focus, basal insulin delivery data were central to interpreting these results. The composite 24-hour BG profile for each participant was generated directly from their CGM data, and relative BG changes were assessed in the context of BR. Given that 99.3% (286/288; SD 0.55%) of the BG relative values fell into the excessive or insufficient categories rather than the optimal 0 mg/dL range, these deviations strongly indicate that the current BR configurations were inadequate. In this way, insulin delivery data were not only included but also essential for linking glucose deviations to inaccuracies in BR setup.

### Comparison With Prior Work

Extensive research in BG prediction for T1DM has been conducted in recent years [31]. Approaches have ranged from data-driven models to physiological models and combinations of both, often using advanced machine learning techniques, related algorithms, or mathematically complex differential equations [32,33]. This work contributes to that body of knowledge by introducing an algorithm that may help assess whether current BR settings are appropriate without requiring meal data. This is clinically relevant because incorrect BR inputs—whether in closed-loop systems that revert to manual mode or in stand-alone insulin pumps—can lead to inaccurate adjustments and suboptimal BG management.

Previous research efforts have predominantly revolved around BR as an input variable rather than it being the central subject of investigation. Few studies have tackled this challenge directly. Certain works have applied clustering methods, grouping new patients based on characteristics such as age or diabetes duration [34]. Several studies have used traditional machine learning methods for prediction tasks [35]. However, test outcomes have been suboptimal [36]. Recent research [37,38] has documented the effective performance of automatic insulin delivery systems in real-world operation. While they offer significant clinical benefits, these systems still have calibration challenges and emerging cybersecurity considerations [5].

In addition to the previous examples, some studies have examined the characterization of BR profiles. Such studies have examined the previously noted variables [10,39-41] alongside factors including the dawn phenomenon and age-related effects on these profiles. However, these studies do not provide guidance on how to accurately determine the appropriate BR for an individual, nor do they address how these rates may change over time for the same person.

In the landscape of meal detection research, the consulted examples hinge on the computation of rates of change using sophisticated mathematical approaches such as Kalman filters [42-45] or the validation of probabilistic methods through testing in in silico environments [46-48].

### Limitations

This work acknowledges several limitations. First, it relies on the assumption that mealtimes align with the attributes defined in the methodology—specifically, that BG peaks exceed the 95th percentile for either width (hours) or height (mg/dL). Second, the dataset was constrained by a limited sample size (N=12) and its demographic characteristics and data quality, which inherently impacts the precision and generalizability of the analysis. Third, the algorithm has only been evaluated on the dataset used for its development; therefore, validation in independent external datasets will be necessary to establish robustness and applicability across broader populations. Finally, while this study did not assess the clinical significance of the observed variations and changes in BG levels, this will be comprehensively addressed in future clinical investigations.

### Conclusions

This paper highlights the preliminary potential of the proposed algorithm, which relies solely on CGM data to approximate the timing of meal-related glucose excursions. By excluding these instances, the algorithm may help provide a clearer assessment of relative BG deviations and the current state of BR. These findings should be interpreted cautiously as preliminary evidence, and validation in larger and independent cohorts will be required before any clinical application can be considered. Therefore, future work will focus on refining the method and assessing its utility for supporting BR adjustments aimed at reducing BG deviations and extending TIR, particularly in LMICs, where advanced systems are less common.

## Acknowledgments

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## Data Availability

The dataset used in this study, OhioT1DM, was collected at Ohio University and is publicly available online [50]. All code supporting the findings of this study is openly available at Zenodo [49].



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## Authors' Contributions

SH and DGG conceived the study. DGG contributed to the development of the algorithm and to drafting the manuscript. All authors contributed to the study design, data analysis, and interpretation of the results and critically reviewed and approved the final version.

## Conflicts of Interest

None declared.

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## Abbreviations

**BG:** blood glucose
**BR:** basal rate
**CGM:** continuous glucose monitoring
**LMICs:** low- and middle-income countries
**PBT:** personalized basal tuner
**T1DM:** type 1 diabetes mellitus
**TIR:** time in range

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# Managing Exercise-Related Glycemic Events in Type 1 Diabetes: Development and Validation of Predictive Models for a Practical Decision Support Tool

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## Abstract

**Background:** Exercise is an important aspect of diabetes self-management. Patients with type 1 diabetes frequently struggle with exercise-induced hyperglycemia and hypoglycemia, decreasing their willingness to exercise.

**Objective:** We aim to build accurate and easy-to-deploy models to forecast exercise-induced glycemic events in real-world settings.

**Methods:** We analyzed free-living data from the Type 1 Diabetes Exercise Initiative study, where adults with type 1 diabetes wore a continuous glucose monitor (CGM) while performing video-guided exercises (30-minute exercises at least 6 times over 4 weeks), along with concurrent detailed phenotyping of their insulin program and diet. We built models to predict glycemic events (blood glucose ≤54 mg/dL, ≤70 mg/dL, ≥200 mg/dL, and ≥250 mg/dL) during and 1 hour post exercise with variables from 4 data modalities, such as demographic and clinical (eg, glycated hemoglobin; CGM (blood glucose value and their summary statistics); carbohydrate intake and insulin administration; and exercise type, duration, and intensity. We used repeated stratified nested cross-validation for model selection and performance estimation. We evaluated the relative contribution of the 4 input data modalities for predicting glycemic events, which informs the cost and benefit for including them in the decision support tool for risk prediction. We also evaluated other important aspects related to model translation into decision support tools, including model calibration and sensitivity to noisy inputs.

**Results:** Our models were built based on 1901 exercise episodes for 329 participants. The median age for the participants was 34 (IQR 26 - 48) years. Of the participants, 74.8% (246/329) are female and 94.5% (311/329) are White. A total of 182/329 (55.3%) participants used a closed-loop insulin delivery system, while the rest used a pump without a closed-loop system. Models incorporating information from all 4 data modalities showed excellent predictive performance with cross-validated area under the receiver operating curves (AUROCs) ranging from mean 0.880 (SD 0.057) to mean 0.992 (SD 0.001) for different glycemic events. Models built with CGM data alone have statistically indistinguishable performance compared to models using all data modalities, indicating the other 3 data modalities do not add additional information with respect to predicting exercise-related glycemic events. The models based solely on CGM data also showed outstanding calibration (Brier score ≤0.08) and resilience to noisy input.

**Conclusions:** We successfully constructed models to forecast exercise-induced glycemic events using only CGM data as input with excellent predictive performance, calibration, and robustness. In addition, these models are based on automatically captured CGM data, thus easy to deploy and maintain and incurring minimal user burden, enabling model translation into a decision support tool.

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**KEYWORDS**

type 1 diabetes; exercise-induced glycemic events; continuous glucose monitoring; predictive modeling; decision support tool; hypoglycemia; hyperglycemia



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## Introduction

Exercise refers to intentional physical activity, such as aerobic, resistance, or high-intensity interval training [1]. It has many benefits, including improving overall health and longevity [2]. However, patients with type 1 diabetes (T1DM) often struggle to meet recommended exercise guidelines (≥150 minutes of moderate activity per week) [3]. One contributing factor is that exercise can cause significant glycemic variability, with strenuous exercise causing exercise-associated hyperglycemia and subsequent postexercise hypoglycemia resulting from heightened postexercise insulin sensitivity [4]. Fear of exercise-associated glycemic variability presents a significant barrier to regular physical activity in adults with T1DM [5]. On the other hand, exercise is an important aspect of diabetes self-management. Less exercise during the COVID-19 pandemic was associated with poorer glycemic control in people with T1DM and type 2 diabetes [6]. Glycemic management peri-exercise presents an ongoing challenge for patients with T1DM. To address the needs of patients, we aim to develop models and decision support tools that predict glycemic events safely and accurately with minimal user burden.

As indicated in several recent reviews and meta-analyses [7-10], many studies have explored predicting glycemic events (hypo- and hyperglycemia) using statistical and machine learning methods and demonstrated good predictive performances. However, there is evidence that a general-purpose glycemic event prediction model has reduced performance when applied to high-activity conditions [11]. A smaller set of studies focused on the prediction of glycemic event risk specifically during and post exercise [12-16] reported highly promising results. The studies using data collected from highly structured clinical studies with controlled meal intake and exercise programs achieved very strong to near-perfect predictivity for hypoglycemia (blood glucose <70 mg/dL) during and post aerobic exercise [12,13]. Studies using data collected in real-world free-living conditions reported highly promising predictivities, ranging area under the receiver operating characteristic curve (AUROC) from 0.79 to 0.84, for predicting hypoglycemia during and post exercise [15,16].

Building on prior work, we aim to address important remaining questions related to model translation into a decision support tool for exercise-related glycemic event risk prediction. Specifically, we used the T1DEXI adult dataset and constructed models to predict a larger set of glycemic events, including hypoglycemia (≤54 mg/dL and ≤70 mg/dL) and hyperglycemia (≥200 mg/dL and ≥250 mg/dL) both during and post exercise, expanding the outcome, that is, blood glucose ≤70 mg/dL during exercise, previously examined in the study by Bergford et al [16]. There are three study goals: (1) to build high-quality predictive models for exercise-induced glycemic events using data from various modalities, including patient demographics, clinical data, CGM, carbohydrate and insulin intake, and exercise characteristics; (2) to assess the contributions of the different data modalities for predicting glycemic events to inform cost-benefit trade-offs for model deployment; and (3) to refine predictive models with the aim of minimizing user input while remaining a decision support tool for effective management of glycemic events.

## Methods

### Study Cohort

We used data from the Type 1 Diabetes Exercise Initiative (T1DEXI) study [17]. The T1DEXI was a real-world study of at-home exercise in adults with T1DM, where adult participants were randomly assigned to complete 6 structured aerobic, interval, or resistance exercise sessions over 4 weeks. Each exercise was approximately 30 minutes, consisting of a 3-minute warm-up and cool-down. In addition to study exercises, participants also continued their typical forms of daily physical activity. Information regarding carbohydrate intake was collected through the T1DEXI app. Insulin dosing information was extracted from the insulin pump. Continuous glucose monitoring (CGM) data were collected using Dexcom G6 sensors (1 measurement every 5 minutes). Diabetes history, glycated hemoglobin $A_{1c}$ ($HbA_{1c}$), and demographics were self-reported and collected via a portal.

### Analysis Design

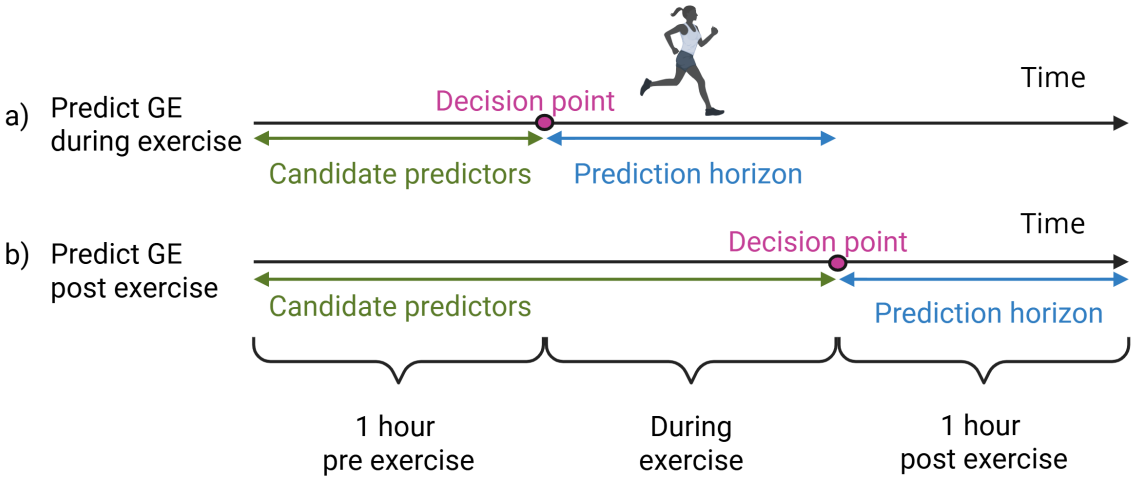
#### *Overall Design*

Figure 1 illustrates the analysis design. We designed our model to assess the risk for hypoglycemic events at two critical decision points (Figure 1) for managing exercise-related glucose events for patients with T1DM (as marked by purple dots in Figure 1): (1) prior to the start of the exercise to evaluate the risk of glycemic events during exercise using data collected from 1-hour pre-exercise (Figure 1A) and (2) right after the completion of the exercise to evaluate the risk of glycemic events for the 1-hour post exercise using data collected from 1-hour pre-exercise and during exercise (Figure 1B). With glycemic event risk estimated accurately at these decision points, patients can make adjustments, for example, to their exercise plan and carbohydrate and insulin intake, to avoid glycemic events accordingly. Data from various data modalities were considered as candidate predictors, including patient demographics, clinical, CGM, carbohydrate and insulin intake, and exercise characteristics.



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**Figure 1.** Design of analytical experiments. Subparts (A) and (B) represent the designs for predicting glycemic events during and post exercise, respectively. GE: glycemic events.




### *Targets of Interest*

Our targets of interest are binary variables representing the occurrence of glycemic events during and 1 hour post exercise. Specifically, we examined 4 glycemic events, including severe hypoglycemia (glucose ≤54 mg/dL), hypoglycemia (glucose ≤70 mg/dL), hyperglycemia (glucose ≥200 mg/dL), and severe hyperglycemia (glucose ≥250 mg/dL). Each of the 4 glycemic events was assessed separately during the exercise and postexercise period, resulting in 8 outcomes.

### *Candidate Predictors*

We extracted and constructed the following data elements as candidate predictors. All candidate predictors and their construction are listed in Table S1 in Multimedia Appendix 1.

1. Demographic data: Age, race, and sex.
2. Clinical data: Height, weight, and BMI at the beginning of the study. Most recent $HbA_{1c}$ prior to the study period. Out of the 329 participants in our study, 318 reported an $HbA_{1c}$ within 12 months of the start of the study.
3. CGM data: For predicting during exercise glycemic events, we used CGM data 1 hour pre-exercise (Figure 1A). For predicting postexercise glycemic events, we used CGM data 1 hour pre-exercise and during exercise. Up to 12 raw CGM readings prior to the decision point, as well as the minimum, maximum, mean, SD, and coefficient of variation of the CGM reading from the appropriate time period, were constructed and used as candidate predictors.
4. Carbohydrate and insulin intake: For predicting glycemic events during exercise, we used carbohydrate and insulin intake data 1-hour pre-exercise (Figure 1). For predicting postexercise glycemic events, we used carbohydrate and insulin intake data 1 hour pre-exercise and during exercise. We used the total amount of carbohydrates in grams from the appropriate time period and the total insulin intake, including both basal and bolus insulin, from the appropriate time period.
5. Exercise data: The study arm (aerobic, interval, or resistance exercise), the self-reported exercise intensity, and the exercise time of day were included as candidate predictors. The time of day of exercise was determined by the time of day of the start of exercise, split into the categories morning, afternoon, and night. Morning, afternoon, and night were defined as the periods of time between 5 AM and noon, between noon and 5 PM, and between 5 PM and 5 AM, respectively. For predicting postexercise glycemic events, we also included self-reported exercise duration as a candidate predictor for postexercise glycemic event prediction.

## Overview of Models and Analysis

To address the three goals mentioned above, we conducted three sets of analyses.

1. To achieve our first goal, that is, building high-quality predictive models for exercise-induced glycemic events using all available data, we built predictive models for all 8 outcomes of interest using variables from all data modalities, including patient demographics, clinical data, CGM data, carbohydrate and insulin intake, and exercise characteristics.
2. To achieve our second goal, that is, assessing the contribution of different data modalities for predicting glycemic events, we built models for all 8 outcomes of interest using data from each of the following 4 data modalities individually: patient demographics and clinical data, CGM data, carbohydrate and insulin intake, and exercise characteristics.
3. To achieve our third goal, that is, refining predictive models with the aim of clinical translation, we explored various methods to improve different aspects of model translation, including building models with variables that are easier to measure, enhancing model calibration, and assessing model performance with noisy data.

## Data Processing

To ensure sufficient data were available for each data modality to enable the comparison among data modalities (the second study goal), we included participants who had at least 80 recorded carbohydrate intakes, 6000 CGM reads, and 200 insulin intakes over the 4-week period (Figure S1 in Multimedia Appendix 1 shows the distribution of number of carbohydrate



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intakes, number of CGM reads, and number of insulin intakes). We did not include participants that are on multiple daily injections. Regarding exercise events, we only included study exercises (ie, the video-guided exercise as part of the TIDEXI study), since the types of exercise were well defined. To be able to compute candidate predictors, we included exercise events that had at least 10 CGM measurements 1 hour pre-exercise, 2 CGM measurements during exercise, and 10 CGM measurements 1 hour post exercise. Of the 2021 total number of exercises, 120 were filtered out with the criterion described above, resulting in 1901 exercise events. Of the 1901 exercise events, 1895 had more than 4 CGM readings. The median number of CGM readings per exercise was 6 (IQR 4-6 readings; spanning 30 minutes). The final dataset included 1901 exercise events from 329 participants.

## Methods for Predictive Modeling

### *Model Selection, Performance Estimation, and Validation*

We conducted model selection and performance estimation using stratified 5-fold nested cross-validation (NCV). The inner loop of the NCV was used to select the best classifier, feature selection method, and hyperparameter combinations while the outer loop evaluated the performance of the selected models. The NCV procedures were repeated 4 times to reduce the variation associated with splitting the data into 5 folds. In our primary analysis, exercise episodes were randomly distributed into the folds of the NCV, which means that different exercise episodes from the same participant could appear in both training and testing folds. We also conducted a sensitivity analysis where multiple exercise episodes from the same individual were included in the same NCV fold to account for person-specific effects (results are similar to our primary analysis and reported in Tables S2 and S3 in Multimedia Appendix 1).

### *Feature Selection*

For feature selection, we used all features, support vector machine recursive feature elimination [18], and generalized local learning, parent children (GLL-PC with the conditioning set size parameter K=1, 2, or 3) [19]. In theory, GLL-PC can select a parsimonious set of variables while retaining maximal information content regarding the prediction target. GLL-PC has also been shown to be highly successful in real-world applications [19,20].

### *Classification*

We considered the following classifiers: logistic regression, random forest (with mtry=sqrt [number of variables], number of trees=500), and support vector machines with a polynomial kernel (with polynomial degree paramter $P$=1, 2, and the box constraint parameter C=0.1, 1, 10).

### *Missing Values*

Treatment for missing values was incorporated into the modeling pipeline to ensure that imputation on the validation data was performed according to the distribution of the training data, preventing information leakage. Missing values for non-CGM predictor variables were handled using median imputation. Missing CGM values were replaced with the last nonmissing observation carried forward if available, or the next value carried backward otherwise. If multiple CGM values were missing consecutively, the missing value will be progressively carried forward or backward, if possible. For example, in the following sequence of measurements $\{t_0, t_1, t_2, t_3, t_4, t_5\}$, if $t_2$, $t_3$, $t_4$ are missing, they will all be imputed with the value of $t_1$, that is, the last nonmissing observation carried forward in time. We ensured that observations from the prediction horizon (ie, during exercise or post exercise) were never carried backward to be used as features. The percentage of missing CGM values ranged from 0% to 20% across different exercise events, with 99.5% of events having at most 10% missing CGM data.

### *Performance Metric*

We used the AUROC, sensitivity, and specificity to evaluate the predictive performance of the models. All performance metrics were estimated within the NCV pipeline to obtain unbiased estimates. To estimate sensitivity and specificity in each fold of the outer loop, we first determined the thresholds in the inner loops that maximized the J-index (J=sensitivity+specificity–1). To compare the sensitivity and specificity of our model to prior literature, we applied thresholds to match the sensitivity of the previously reported models. We then calculated the sensitivity and specificity on the outer loop fold using the mean of these thresholds. We used the Brier score to evaluate model calibration.

### *Information Content Analysis*

To examine the predictive performance of the 4 different data modalities in the dataset (demographics and clinical data, CGM data, carbohydrate and insulin intake, and exercise characteristics), we trained classifiers on each modality individually and compared the predictive performance to the model trained with all features.

## Methods for Improving Model Translation to Decision Support Tools

### *Models With Low Complexity for Deployment and User Burden*

When translating models to decision support tools, the complexity of constructing, diagnosing, and maintaining the tool is a key consideration. Models that include variables collected from different sources entail a more complex decision support tool. This complex decision support tool is more prone to failure in real-world settings and requires more resources to maintain. In addition, variables from data sources that are not automatically captured (eg, carbohydrate intake) need to be manually inputted, resulting in increased user burden. We compare models using all 4 data sources to assess whether models based on single, easy-to-acquire data sources performed similarly to models using multiple data sources (ie, the information content analysis from the “Information Content Analysis” section).

### *Model Performance With Noisy Data*

To assess the robustness of our models to noise in CGM data at prediction time, we added Gaussian noise of different levels to the outer loop testing data and evaluated the predictive performance. This approach mimics real-world conditions where



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CGM measurements may contain more noise than the data used for training the model. An issue with potential noise in CGM measurements has been documented. A recent study by Skroce et al [21] demonstrated that the average CGM noise is up to 15% mean absolute relative difference across all exercise intensities investigated when compared to capillary glucose. We considered 4 different noise levels, where Gaussian noise with a mean of x and SD of p was added to each CGM measurement, with x being the original CGM value and p representing noise levels of (5%, 10%, 15%, and 20%). This corresponds to mean absolute relative differences of 4%, 8%, 12%, and 16%, respectively.

### *Model Calibration*

The close correspondence between model-predicted risk and observed risk is crucial for deploying the model in a real-world setting [22]. Deviations of predicted risk from the actual risk can lead to model misinterpretation and misuse. Therefore, we evaluated the calibration of our models using the Brier Score [23]. To potentially improve model calibration, we applied isotonic regression, Platt scaling, and spline calibration [24] to recalibrate the model predictions.

### *Analysis Tools*

Analyses were conducted using custom scripts in MATLAB 2023b (MathWorks) and R version 3.5.0 (R Foundation for Statistical Computing).

### Ethical Considerations

This study is based on deidentified, publicly available data and is not human subjects research.

## Results

### Participant and Exercise Characteristics

Table 1 shows characteristics of participants. The median age for the 329 participants was 34 (IQR 26 - 48) years. The majority of participants were female (246/329, 74.8%) and White (331/329, 94.5%). The median $HbA_{1c}$ was 6.5% (IQR 6.1% - 7.0%). The median BMI was 24.8 (IQR 22.86 - 27.46). A total of 326 (>99%) patients were on fast- or rapid-acting insulin, while the remaining 3/329 (<1%) patients were on short-acting insulin. Notably, 18/329 (5.5%) participants were additionally taking metformin. A total of 18,329 (55.3%) participants used a closed-loop insulin delivery system, while the remaining 147/329 (44.7%) participants used a pump without a closed-loop system. The median duration of T1DM was 16 (IQR 10.75 - 24) years. The median total daily insulin dose was 37.3 (IQR 28.06 - 47.96) units. There were similar numbers of participants in each exercise intervention group: 122/329 (34%) in the aerobic training group, 113/329 (34.3%) in the interval training group, and 104/329 (31.6%) in the resistance training group. Over the 4 weeks of the study, the median number of exercise events per participant was 6 (IQR 4 - 6).



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**Table .** Participant characteristics reported as median and IQR for continuous variables, and count and percentage for discrete variables.

| Variable name | Descriptive statistics |
|---|---|
| Age (years), median (IQR) | 34 (26-48) |
| Sex, n (%) | |
| Male | 83 (25.2) |
| Female | 246 (74.8) |
| Race, n (%) | |
| White | 311 (94.5) |
| Black | 1 (0.3) |
| Asian | 5 (1.5) |
| American Indian or Alaska Native | 1 (0.3) |
| Other | 5 (1.5) |
| Number of medications, median (IQR) | 2 (2-2) |
| Insulin delivery method, n (%) | |
| Closed-loop | 182 (55.3) |
| Pump without closed-loop | 147 (44.7) |
| Hemoglobin $A_{1c}$ (%), mean (SD) | 6.56 (0.66) |
| Number of participants per exercise type, n (%) | |
| Aerobic | 122 (34) |
| Resistance | 104 (31.6) |
| Interval | 113 (34.3) |
| Number of exercises per participant, median (IQR) | 6 (5-6) |
| Number of peri-exercise glycemic events per participant, median (IQR) | |
| ≤54 during exercise | 0 (0-0) |
| ≤70 during exercise | 0 (0-0) |
| ≥200 during exercise | 1 (0-1) |
| ≥250 during exercise | 0 (0-0) |
| ≤54 post exercise | 0 (0-0) |
| ≤70 post exercise | 0 (0-1) |
| ≥200 post exercise | 1 (0-1) |
| ≥250 post exercise | 0 (0-0) |

## Characteristics of Exercise Events

Table 2 summarizes the characteristics of exercise events. Of the 1901 exercise events included in the analysis, the median duration was 30 (IQR 22 - 30) minutes, with on average 12.4% (SD 14.7%) of missing CGM measurements during the exercise, ranging from 0% to 66.7%. Similar numbers of exercise episodes were observed for each exercise type, with 649 aerobic exercises, 659 interval exercises, and 593 resistance exercises. A total of 596 (27.8%) of the 1901 exercises started in the morning. Severe hypoglycemia during and post exercise was observed, and morning exercise was less frequent. Only 0.17% of morning exercises resulted in hypoglycemic events (≤54 mg/dL) during exercise, compared to 1.23% observed during exercises at other times of the day ($\chi^2_1$=4.1; *P*=.04). Severe hypoglycemia (≤54 mg/dL) post exercise occurred in 1.84% of morning exercises, compared to 4.75% at other times of the day ($\chi^2_1$=8.5; *P*=.003). There was no statistically significant difference in the likelihood of hypoglycemic events (≤54 mg/dL) across different exercise types ($\chi^2_2$=2.1; *P*=.35).



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**Table .** Exercise characteristics reported as median and IQR for continuous variables, and count and percentage for discrete variables.

| Variable names | | During exercise | | | | Post exercise | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Hypoglycemia | | Hyperglycemia | | Hypoglycemia | | Hyperglycemia | |
| | Total | ≤54 | ≤70 | ≥200 | ≥250 | ≤54 | ≤70 | ≥200 | ≥250 |
| Number of exercise events, n (%) | 1901 | 17 (0.9) | 88 (4.6) | 286 (15) | 76 (4) | 73 (3.8) | 255 (13.4) | 315 (16.6) | 92 (4.8) |
| Exercise duration (minutes), median (IQR) | 30 (22-30) | 30, (30-30) | 30 (24.5-30) | 30 (22-30) | 30 (22-30) | 30 (22-30) | 28 (22-30) | 30 (22-30) | 30 (24.5-30) |
| Number of morning exercises, n (%) | 529 | 1 (0.2) | 15 (2.8) | 77 (14.6) | 14 (2.6) | 11 (2.1) | 60 (11.3) | 92 (17.4) | 25 (4.7) |
| Number of evening exercises, n (%) | 780 | 10 (1.3) | 48 (6.2) | 129 (16.5) | 36 (4.6) | 41 (5.3) | 127 (16.3) | 136 (17.4) | 40 (5.1) |
| Number of aerobic exercises, n (%) | 649 | 3 (0.5) | 30 (4.6) | 102 (15.7) | 22 (3.4) | 27 (4.2) | 97 (14.9) | 104 (16) | 35 (5.4) |
| Number of interval exercises, n (%) | 659 | 7 (1.1) | 32 (4.9) | 91 (13.8) | 31 (4.7) | 28 (4.2) | 92 (14.0) | 111 (16.8) | 27 (4.1) |
| Number of resistance exercises, n (%) | 593 | 7 (1.2) | 26 (4.4) | 93 (15.7) | 23 (3.9) | 18 (3) | 66 (11.1) | 100 (16.9) | 30 (5.1) |

## Models Forecasting Exercise-Related Glycemic Events

We built a set of models using variables from all available data modalities, including patient demographics and clinical data, exercise characteristics, CGM data, and insulin and carbohydrate intake data. The forecasting performance for all glycemic events during and after exercise was excellent, with mean AUROC values ranging from 0.880 to 0.992 (Table 3). The AUROCs for predicting glycemic events during exercise were generally higher compared to those for postexercise prediction. It is worth noting that, although the modeling process had access to all 28 variables (for during-exercise predictions) or all 35 variables (for postexercise predictions) from the 4 data modalities (patient demographics, clinical data, CGM data, and carbohydrate and insulin intake), feature selection was performed to optimize predictive performance. This process resulted in models that used only a subset of the available variables, as shown in Table 3. The number of variables selected in each model varied from 2 to 35. We included model coefficients or variable importance of all models in Table 3 and Table S4 in Multimedia Appendix 1.



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**Table .** Predictive performances of models using data from all four modalities for each glycemic event at different prediction horizons (measured by area under the receiver operating characteristic curve) and number of predictors from each data module that was selected into the model by feature selection.

| Glycemic event | AUROC[b] | Number of predictors | | | | |
|---|---|---|---|---|---|---|
| | Mean (SD) | Total | CGM[a] | Clinical and demographics | Exercise | Carbohydrate and insulin |
| During | | | | | | |
| Hypo | | | | | | |
| ≤54 | 0.880 (0.057) | 28 | 17 | 7 | 2 | 2 |
| ≤70 | 0.907 (0.009) | 8 | 7 | 0 | 1 | 0 |
| Hyper | | | | | | |
| ≥200 | 0.987 (0.001) | 2 | 2 | 0 | 0 | 0 |
| ≥250 | 0.992 (0.001) | 2 | 2 | 0 | 0 | 0 |
| Post | | | | | | |
| Hypo | | | | | | |
| ≤54 | 0.902 (0.007) | 8 | 7 | 1 | 0 | 0 |
| ≤70 | 0.892 (0.006) | 14 | 14 | 0 | 0 | 0 |
| Hyper | | | | | | |
| | 0.901 (0.006) | 35 | 22 | 7 | 2 | 4 |
| ≥200 | | | | | | |
| ≥250 | 0.924 (0.003) | 13 | 11 | 1 | 0 | 1 |

[a]CGM: continuous glucose monitoring.

[b]AUROC: area under the receiver operating characteristic curve.

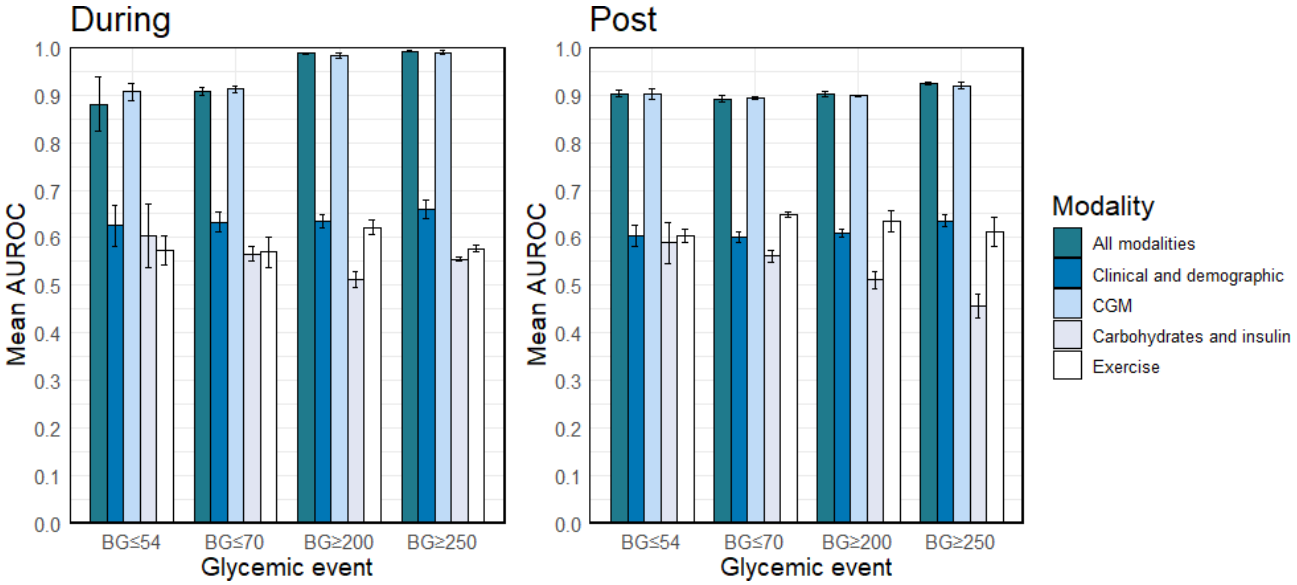
## Models Built Using Only CGM Data

To determine the predictive capability of individual data modalities, we developed models using each data modality separately. Figure 2 summarizes the performance of these models. The left panel shows glycemic events during exercise, and the right panel represents glycemic event post exercise. The height and error bar of the bar plots represent the mean and SD of AUROC. As shown in Figure 2 and Table S2 in Multimedia Appendix 1, the models constructed with the CGM data resulted in excellent AUROC ranging from 0.894 to 0.989. The predictive performance of these models was not statistically significantly different from models using all data modalities for any glycemic event outcomes ($P$>.05). Other data modalities showed low predictive power (mean AUROCs ≤0.659), with significantly lower performance compared to the full model ($P$<.01). When considered collectively, these results indicate that incorporating patients' demographic traits, clinical condition, carbohydrate and insulin consumption, and exercise variables, such as timing and type, fails to furnish additional information regarding exercise-induced glycemic events beyond what is provided by the CGM data.



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**Figure 2.** Predictive performances for the models using data from individual data modalities compared to models that use all 4 modalities for each Glycemic Event. AUROC: area under the receiver operating characteristic curve; BG: blood glucose; CGM: continuous glucose monitor.




We included the CGM-only model parameters or variable importance in Table S5 in Multimedia Appendix 1, and we compared the performance of the CGM-only models with models trained on a single CGM measurement in Table S8 in Multimedia Appendix 1. We also included an executable version of these models.

## Deployment Advantages of Models Using Only CGM Features

### *Deployment Complexity and User Burden*

The CGM-only model is preferable for deployment due to its high predictive performance and lower complexity of deployment. As stated previously, for all 8 glycemic outcomes, the model with all data modalities did not perform statistically significantly better compared to the CGM-only model, indicating the glycemic outcomes can be predicted equally well with and without the other variables, such as demographics, clinical variables, carbohydrate and insulin, and exercise characteristics. This is advantageous for model deployment. Since CGM data is automatically captured, it can be easily fed into the prediction model without user intervention, reducing the burden on patients. In contrast, real-world carbohydrate data is difficult to measure accurately, and collecting this data incurs an additional burden on patients. Data from insulin pumps are automatically documented, but extracting and integrating insulin pump data also adds additional complexity to a decision support tool for forecasting glycemic events.

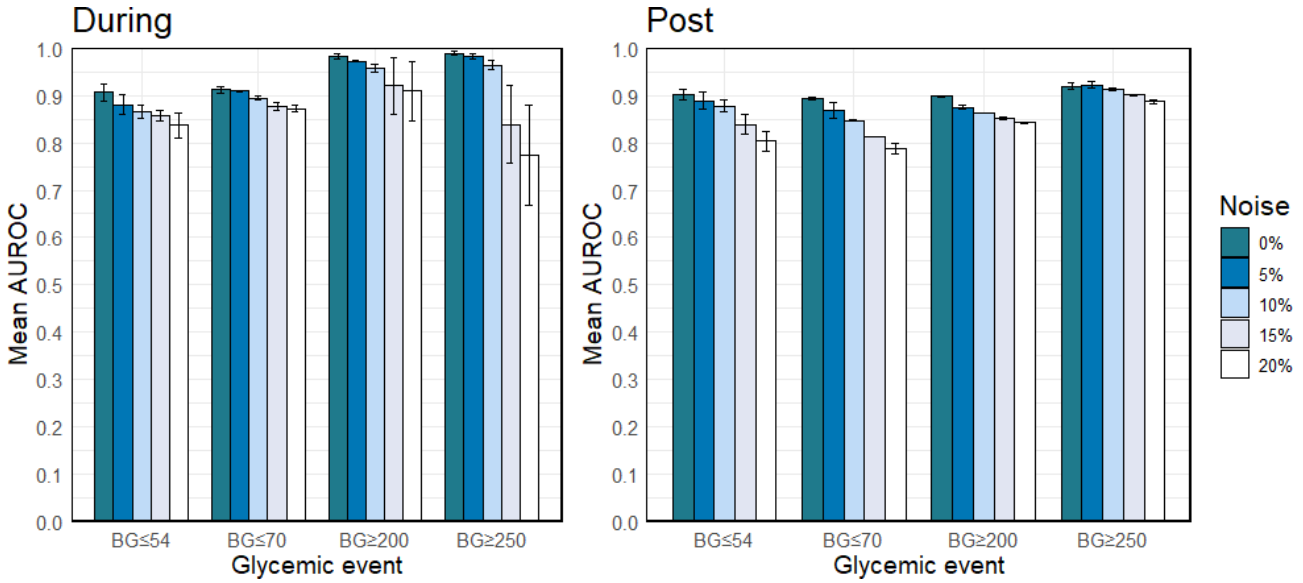
### *Noise Tolerance*

Another consideration of model deployment is the impact of measurement noise in CGM data. Different individuals' CGM measurements often exhibit varying levels of noise, influenced by factors such as sensor calibration, activity level, and pressure on the sensor [21,25-28]. We empirically assessed the performance degradation of our models under different levels of noise (5%, 10%, 15%, and 20%) to the CGM data at prediction time (Figure 3 and Table S3 in Multimedia Appendix 1). In Figure 3, the left panel shows glycemic events during exercise, and the right panel represents glycemic events post exercise. The height and error bar of the bar plots represent the mean and SD of the AUROC. As expected, increased noise led to a reduction in model performance. However, the degradation was generally moderate, except for predicting hyperglycemia (blood glucose ≥250 mg/dL) during exercise, where a decrease in AUROC of 0.216 was observed with 20% noise. For the other 7 out of the 8 glycemic events across different prediction horizons, the decreases in AUROC were small to moderate (<0.12) even when up to 20% noise was added.



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**Figure 3.** Predictive Performance (area under the receiver operating characteristic curve) of Model using only continuous glucose monitoring features with different amounts of added noise in the continuous glucose monitoring features data. AUROC: area under the receiver operating characteristic curve; BG: blood glucose.




We also examined whether models built with additional data modalities (beyond CGM) demonstrated greater resilience to added noise (Table S3 in Multimedia Appendix 1). We found no statistically significant difference in the AUROCs between the CGM-only models and those incorporating additional data modalities. This suggests that the CGM-only model has a similar level of noise tolerance compared to the more complex models using multiple data sources, further supporting the use of the CGM-only model in real-world settings due to its simplicity and robustness.

### *Sensitivity, Specificity, and Calibration*

Model sensitivity, specificity, and calibration are crucial factors for determining how and when a model should be applied in real-world settings. Table 4 presents the sensitivity, specificity, and calibration results of the CGM-only model. Sensitivity and specificity are influenced by the threshold used to binarize the continuous model predictions. We report the mean and SD from the NCV outer loop for sensitivity and specificity using a threshold that maximized the J-index in the inner loop of the NCV. Generally, our models showed good sensitivity (>0.76, except for hypoglycemia ≤54 mg/dL) and high specificity (>0.80 for all outcomes). In comparison with other studies, our models demonstrated similar or better sensitivity at equivalent specificity levels (Table S6 in Multimedia Appendix 1).

**Table .** Sensitivity, specificity, and calibration results of the continuous glucose monitoring features–only models.

| Event type | Sensitivity, mean (SD) | Specificity, mean (SD) | Brier score, mean (SD) | |
|---|---|---|---|---|
| | | | Without recalibration | With recalibration |
| During | | | | |
| Hypo | | | | |
| ≤54 | 0.667 (0.193) | 0.893 (0.065) | 0.017 (0.008) | 0.006 (0.003) |
| ≤70 | 0.770 (0.014) | 0.909 (0.011) | 0.035 (0.009) | 0.034 (0.010) |
| Hyper | | | | |
| ≥200 | 0.931 (0.005) | 0.943 (0.039) | 0.040 (0.034) | 0.029 (0.006) |
| ≥250 | 0.905 (0.022) | 0.978 (0.003) | 0.010 (0.000) | 0.011 (0.004) |
| Post | | | | |
| Hypo | | | | |
| ≤54 | 0.799 (0.047) | 0.802 (0.016) | 0.033 (0.005) | 0.033 (0.011) |
| ≤70 | 0.787 (0.018) | 0.825 (0.012) | 0.077 (0.001) | 0.072 (0.014) |
| Hyper | | | | |
| ≥200 | 0.762 (0.019) | 0.867 (0.014) | 0.075 (0.001) | 0.080 (0.009) |
| ≥250 | 0.790 (0.010) | 0.899 (0.024) | 0.028 (0.001) | 0.023 (0.006) |



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We also evaluated the Brier score for model calibration before and after applying different calibration methods (Table 4). The models achieved excellent calibration performance without additional calibration methods (Brier score <0.1 for all models). Applying calibration techniques did not significantly improve calibration for any of the glycemic outcomes (adjusted $P$>.05). Table 4 shows the Brier scores before and after applying the isometric regression. Results using Platt and spline calibration methods are similar and reported in Table S7 in Multimedia Appendix 1.

## Discussion

### Principal Findings

This study has made several key contributions. First, we leveraged a large and comprehensive dataset capturing free-living exercise episodes of participants with T1DM and built high-quality predictive models for exercise-induced glycemic events. These models used data from multiple modalities, including patient demographics, clinical data, CGM data, carbohydrate and insulin intake, and exercise characteristics. The predictive performance of our models for all examined exercise-induced glycemic events was excellent, with mean AUROCs >0.880 (SD 0.057). Second, we empirically assessed the information content of individual data modalities. Our results showed that the predictive performance of models using only CGM data was statistically indistinguishable from models incorporating variables from all data modalities. This suggests that a high-quality and cost-effective decision support tool can be built solely based on CGM data, resulting in cost savings. Third, we demonstrated the CGM-based models' good calibration and robustness to noisy inputs, in addition to excellent predictive performance. Our CGM-based models have strong potential to be translated into a decision support tool that is easy to deploy and maintain, offering support for patients with T1DM.

### Comparison to Prior Work

This study is among the few that focus on predicting exercise-induced glycemic events for the adult T1DM population in nonlaboratory settings using a large sample size. Our models demonstrated similar performances for exercise-related glycemic events compared to previously reported studies [12-16] (Table S4 in Multimedia Appendix 1). We made additional contributions by building models for a larger variety of outcomes.

### Strength

A major strength of this study is that we assessed and refined the models for translating into decision support tools that are accurate, robust, and easy to deploy and maintain, while minimizing the burden on patients. To the best of our knowledge, this is the first study to examine multiple crucial aspects of model translation into decision support tools for managing exercise-related glycemic events in T1DM.

### Limitations

The first limitation relates to the dataset. We choose to derive our models based on the T1DEXI, since it is one of the largest and most comprehensive datasets available that studies glucose control peri-exercise in the real-world setting. Despite its comprehensiveness, the T1DEXI population is relatively young (median age 34, range 18-69, IQR 26-48 years) years and predominantly White, which may limit the generalizability of the models to the broader clinical T1DM population. Similarly, the exercise episodes in the T1DEXI were relatively uniform in duration and self-reported intensity, which may not reflect the full diversity of real-world exercise activities. The second limitation relates to the types of variables examined related to participants and exercise episodes. Although our findings suggest that CGM data alone contains similar predictive information compared to all 4 data modalities examined, including additional information, such as sleep data, more detailed dietary information, and physical activity data from accelerometers could enhance model performance and robustness. These data elements were either not available in T1DEXI or difficult to construct from available data due to lack of standardized methods. Third, while our models successfully flag exercise episodes that are more likely to result in glycemic events, they do not currently suggest specific interventions to mitigate these risks.

### Future Directions

To address the first 2 limitations mentioned previously, future work can validate models developed in this study and develop new models de novo based on data that is more comprehensive and from a more diverse population. To address the third limitation, computational causal modeling techniques [29] can be applied to a dataset containing a wide range of potentially modifiable causal factors for glycemic events. This approach can uncover personalized intervention strategies to reduce glycemic events both in the acute period during and after exercise, as well as over a longer time horizon. Further, we empirically demonstrated that models using CGM data only have statistically indistinguishable performance compared to models using data from all modalities (Figure 2, Table S2 in Multimedia Appendix 1). This phenomenon is related to the Rashomon effect and target information equivalence, that is, there are often a multitude of models with optimal and near-optimal performance [30,31]. Future work can dissect and catalog the information-equivalent variables for glycemic events. This can potentially lead to both improved mechanistic understanding of glycemic events and their care [30,32-34].

### Conclusion

We developed multiple predictive models for exercise-induced glycemic events, achieving excellent predictive performance. Notably, the models using automatically captured CGM data exhibited strong performance, are well-calibrated, are cost-effective, and are robust to noisy input data. These models can be translated into a high-performance and easy-to-deploy decision support tool. This study marks an important first step toward creating a practical decision support tool for managing exercise-induced glycemic events in patients with T1DM.



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## Acknowledgments

This manuscript is based on research using data from the Type 1 Diabetes EXercise Initiative (T1DEXI) Study that has been made available through Vivli, Inc. Vivli has not contributed to or approved, and is not in any way responsible for, the contents of this publication.

## Data Availability

The data is available on the Vivli Platform Repository (ID: T1-DEXI; dataset name: Type 1 Diabetes EXercise Initiative (T1DEXI): The Effect of Exercise on Glycemic Control in Type 1 Diabetes Study. The data package can be requested at clinical research data repository [35].

## Authors' Contributions

SM, RC, LC, and MC contributed to conceptualization, writing–original draft, and writing–review & editing. SM, RC, and LC performed data curation and visualization. RC handled formal analysis and validation. SM and RC designed the methodology and software. SM was involved in project administration. SM and LC provided supervision.

## Conflicts of Interest

MAC has received consulting fees from Glooko and research support from Dexcom and Abbott Diabetes Care. LC has an investigator initiated grant from DEXCOM for product only.

Multimedia Appendix 1
Visualizations of data availability and results from additional experiments.
[DOCX File, 174 KB - diabetes_v10i1e68948_app1.docx ]

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## Abbreviations

**AUROC:** area under the receiver operating characteristic curve
**CGM:** continuous glucose monitoring
**GLL-PC:** generalized local learning, parent children
**$HbA_{1c}$:** glycated hemoglobin $A_{1c}$
**NCV:** nested cross-validation
**T1DEXI:** Type 1 Diabetes Exercise Initiative
**T1DM:** type 1 diabetes mellitus

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# Assessing the Clinical Feasibility of the DiaFocus System for Integrated Personalized Management of Type 2 Diabetes: 6-Month Pilot Cohort Study

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## Abstract

**Background:** Type 2 diabetes (T2D) is a complex, chronic condition that requires ongoing management. An important aspect of effective diabetes management is shared decision-making between the person with diabetes and the health care professionals (HCPs) to tailor individual treatment plans. Personal health technologies can play a crucial role in this collaborative effort by providing tools for monitoring, communication, and education.

**Objective:** This study aims to test the clinical feasibility of DiaFocus, a mobile health system developed for adults with T2D.

**Methods:** This was a single-arm, prospective, 6-month pilot study in a clinical outpatient setting at Steno Diabetes Center Copenhagen, Denmark. The DiaFocus system includes an app for the participants and a web portal for the HCPs. The system collects diabetes-related data, including participant-reported lifestyle surveys, sensor-based measures on physical activity, and participant-selected focus areas, aiming to support communication and shared decision-making at clinical visits. Participants were eligible if they were ≥18 years old, diagnosed with T2D≥12 months, spoke Danish, and had a smartphone (iOS 13+ or Android 8.0+). For each participant, 3 visits and 1 telephone call were scheduled during the 6-month study period. The DiaFocus system's acceptability and feasibility were assessed through retention rates, app usage, participant feedback, and by the CACHET Unified Method for Assessment of Clinical Feasibility (CUMACF) questionnaire. The clinical outcomes were assessed by the following questionnaires: Diabetes Distress Scale (DDS), Perceived Competence for Diabetes (PCDS), Diabetes Treatment Satisfaction Questionnaire (DTSQs+c), hemoglobin $A_{1c}$ levels, and body weight.

**Results:** A total of 17 participants with T2D were included in the study, 15 completed the study, and data were analyzed on an intention-to-treat basis. The median age was 68 (IQR 56-72) years, 12 (71%) were males, the median diabetes duration was 18 (IQR 11-21) years, and the median hemoglobin $A_{1c}$ was 59 (IQR 49-68) mmol/mol. Participants found the DiaFocus system feasible to support diabetes management despite technical problems, and they valued the ability to set focus areas. The most common focus areas were "blood glucose" (n=10, 59%) and "exercise" (n=9, 53%), but areas such as "sleep" and "mood" were also used. The CUMACF questionnaire showed that 90% (9/10) of the participants had very favorable views of how easy the system is to understand, learn, and use, and 80% (8/10) of the participants agreed or strongly agreed that the system was useful. Feedback was generally positive, indicating participants would use a refined version. Despite these findings, no statistically significant changes in clinical outcomes were observed throughout the study period using the DiaFocus system.

**Conclusions:** This pilot study demonstrated that the DiaFocus system is clinically feasible and acceptable for users with T2D, although there is a need for optimization of app functionality and stability.

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**KEYWORDS**

mHealth; mobile health; digital health system; digital platform; type 2 diabetes; diabetes mellitus; diabetes management; feasibility; pilot study; shared decision-making; chronic condition; monitoring; communication; adult; Denmark; diabetes treatment; diet; exercise; medication; smoking; stability



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## Introduction

### Background

Type 2 diabetes (T2D) is a chronic disease that affects many aspects of daily life, and managing diabetes can be challenging for individuals with T2D. It is well established that optimal disease management can lead to fewer diabetes-related complications and decreased mortality [1,2]; yet, many struggle to reach diabetes treatment goals [3]. Medical treatment of T2D includes a wide range of oral and injectable therapeutics. However, factors beyond medication can impact blood glucose levels, such as stress, physical activity, concomitant diseases, and sleep disturbances [4-6]. Accordingly, diabetes self-management education and support are crucial parts of optimal diabetes management, involving a combination of lifestyle modifications, medication management, and self-care strategies [7]. Personal health technology has been highlighted as a possible way to improve T2D self-management by providing more personalized, data-driven care. In addition, it has the potential to empower individuals with T2D to gain deeper insight into and manage their condition more efficiently, while also supporting collaboration between the health care professional (HCP) and the individual with diabetes [8,9].

### Prior Work

An integrated personalized diabetes management (iPDM) approach has previously been described [10,11]. In short, the iPDM approach consists of a structured, 6-step process that uses digital tools and aims to support collaborative diabetes care and shared therapeutic decision-making. Using this approach, the iPDM-ProValue study program, which included 907 persons with insulin-treated T2D in Germany, demonstrated improved glycemic control and treatment satisfaction [11]. A secondary analysis from the iPDM-ProValue study program further demonstrated that both patients and HCPs perceived a benefit in using digital tools in a structured manner [12].

DiaFocus is a novel smartphone-based system based on the principles of the iPDM approach [13]. The DiaFocus system includes an app for the participants and a web portal for HCPs. The system is designed to collect diabetes-related data, including participant-reported outcomes, sensor-based measures on physical activity, and participant-selected focus areas, aiming to support communication and shared decision-making between the HCP and the person with diabetes. The technical feasibility of using the DiaFocus app for T2D management was assessed in a 6-week pilot study with 12 participants [13]. This study showed that participants found the DiaFocus approach and system useful and usable for diabetes management and that most patients would use such a system, if available, as part of their treatment. Feedback from the participants in this study was used to adjust the system.

### Goal of This Study

In this clinical pilot study, we aimed to test the clinical feasibility of the DiaFocus system and to provide preliminary evidence of effectiveness. The study was conducted in a clinical outpatient setting for 6 months.

## Methods

### Study Design

This clinical pilot study was a single-arm, prospective, 6-month cohort study. We used a convergent study design (mixed methods approach) where quantitative and qualitative data were collected to explore the participants' experience using a shared decision solution containing an app for the participants and a web portal for HCPs.

### Study Participants and Recruitment

Participants were recruited from the outpatient clinic at Steno Diabetes Center Copenhagen (SDCC) in Denmark by their HCPs. Participants were preselected based on inclusion criteria. Participants were eligible if they were ≥18 years, diagnosed with T2D more than 12 months ago, treated at the outpatient clinic at SDCC for at least 12 months, understood and spoke Danish, and had a smartphone (with an operating system of at least iOS version 13 for Apple devices and version 8.0 Oreo for Android devices). Exclusion criteria were severe visual impairment or other conditions not compatible with participation (judged by the investigators). For persons interested in study participation, a subsequent consultation was scheduled and spoken and written information was given by the investigators.

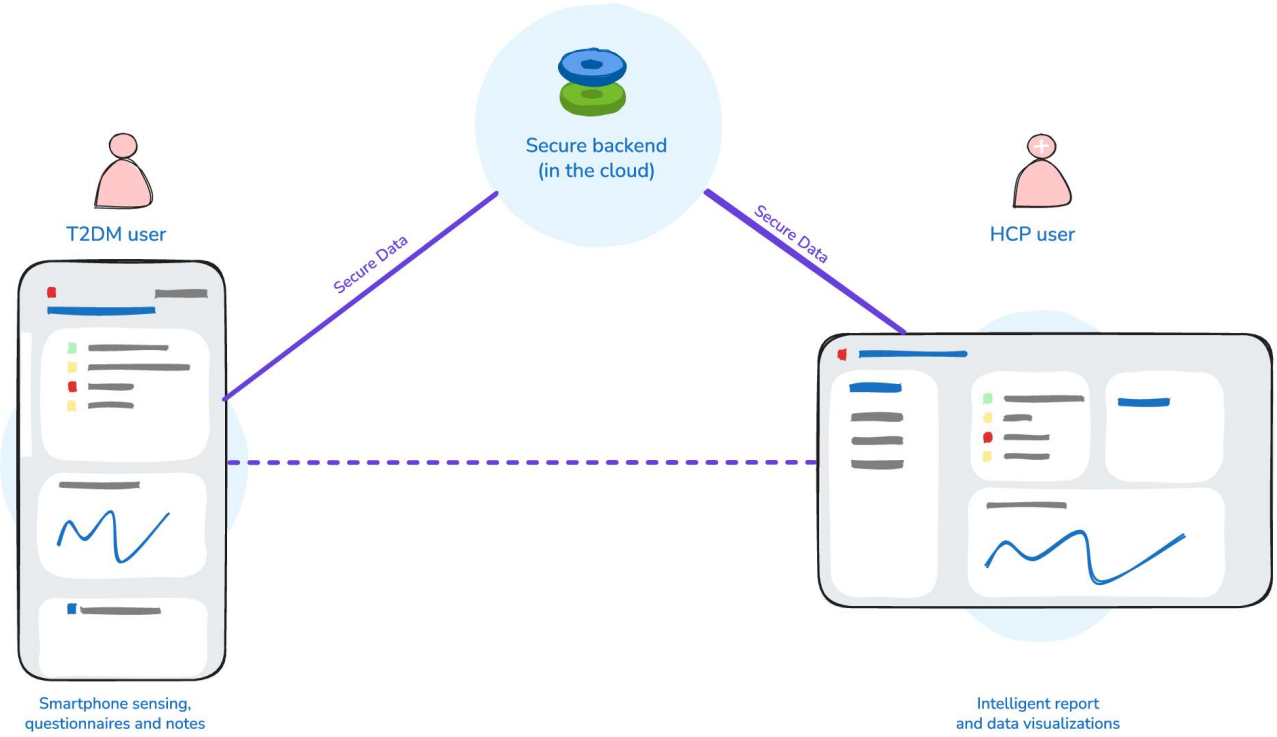
### System Description

The DiaFocus system used to support the iPDM cycle [10,11] consists of a mobile app used by the participant and a web portal used by the HCPs (Figure 1), sharing data via a secure backend server [13].



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**Figure 1.** The DiaFocus system. HCP: health care professional; T2DM: type 2 diabetes mellitus.

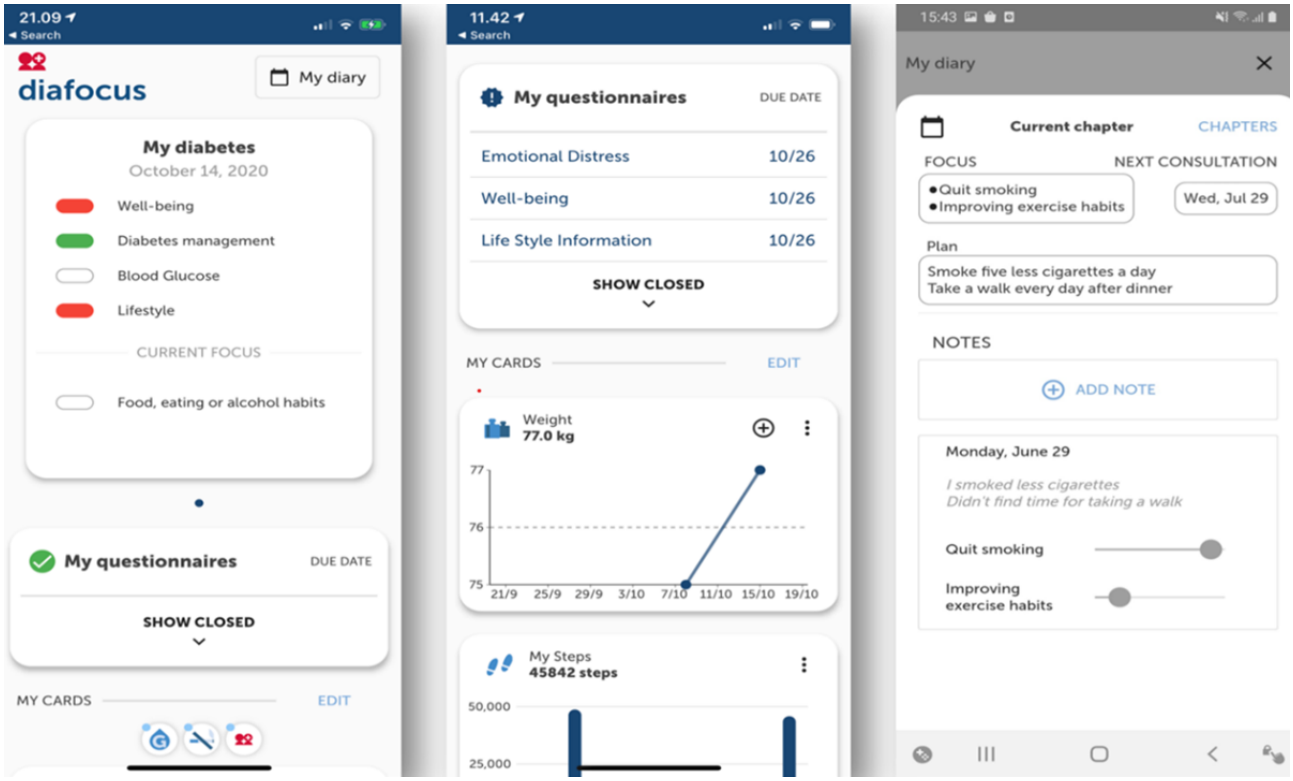



The DiaFocus app was installed on the participant's own smartphone and used for collecting three types of data: (1) patient-reported health and lifestyle measures such as blood glucose level, smoking, and alcohol consumption; (2) standardized questionnaires such as the World Health Organization Well-being Index (WHO-5) [14]; and (3) automatic collection of sensor data from the phones onboard sensors, such as the step counter. The type of lifestyle measures and questionnaires was adapted to the focus areas of the patient, an approach called "adaptive assessment," which worked in the following manner. All participants were prompted to answer the WHO-5 questionnaire and 2 questions on problems with diabetes. Depending on the answers hereof, additional questionnaires on sleep, anxiety, and depression were triggered. At each visit to the diabetes clinic, the participants created a new chapter and registered one or more focus areas. The participants could choose as many focus areas as they wanted and had the opportunity to continue or change focus areas at each visit. Some focus areas were prespecified (blood glucose measurements, diet, activity, and smoking); however, participants could also add a focus area of their own. The participants were subsequently able to track progress related to this area; if the participant and HCP, for example, decided to focus on reducing smoking, the participant could subsequently track and monitor daily smoking habits. At the next clinical visit, data collected through the phone, including responses to agreed questionnaires, were then aggregated and shown as a report on the web portal, which formed the basis for the following discussion and renewed focus area and target setting. The design of the DiaFocus system and the "adaptive assessment" approach are described in more detail elsewhere [13]. An example of a smartphone screen and part of a web portal report is shown in Figures 2 and 3. Figure 2 shows the health status (left), the list of pending questionnaires and data visualization (middle), and the editing of a chapter (right).



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**Figure 2.** The user interface of the DiaFocus app.






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**Figure 3.** Example of a patient report from the web portal.




## Study Procedures

Three visits and one telephone call were scheduled for each participant during the study period. The 3 visits were carried out in extension of the participants' regular clinical visits at baseline (visit 1), after 3 months (visit 2), and after 6 months (visit 3) according to the iPDM process. The 6-month study period allowed for the evaluation of 2 iPDM cycles, enabling adjustment of the process individually if needed.

At the baseline visit, participants were screened for eligibility, and after giving oral and written informed consent, initial baseline data were collected. The DiaFocus app was installed on the participant's own smartphone, the app was introduced to the participant, initial focus areas were set up for the participant, and the baseline questionnaires were completed. The participants were encouraged to use the app regularly at home. A telephone call was scheduled 2 weeks after the participants' first visit. The purpose of the call was to ensure that the app was operational and that the participants understood



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how to use the app. At visits 2 and 3, the HCP reviewed and assessed the data uploaded from the app together with the participant. Accordingly, the individual diabetes management plan was adapted, and future focus areas were planned through shared decision-making.

Blood samples were collected to analyze hemoglobin $A_{1c}$ ($HbA_{1c}$), blood glucose, creatinine, estimated glomerular filtration rate, and lipid profiles at baseline, and a urine sample was analyzed for albumin/creatinine ratio. $HbA_{1c}$ level was measured at visits 2 and 3. Participant-reported outcomes were measured at baseline and visit 3 using the following questionnaires: Diabetes Distress Scale (DDS) [15-17], Perceived Competence for Diabetes (PCDS) [18,19], and Diabetes Treatment Satisfaction Questionnaire (DTSQs+c) [20].

## Outcome Measures

### *Clinical Feasibility*

Assessment of the acceptability and feasibility of the DiaFocus system was measured by retention of participants in the study, the use of the DiaFocus app, willingness to share selected focus areas, and feedback from the participants during and after the study. While behavioral changes were primarily captured through self-report and usage data, these were not assessed using blinded evaluators, given the nature of the study and its feasibility design. To assess the perceived clinical feasibility of the DiaFocus system, participants who had indicated they would accept being contacted after the last visit were asked to respond to the CACHET Unified Method for Assessment of Clinical Feasibility (CUMACF) questionnaire [21]. The CUMACF questionnaire measures a system's perceived usefulness and usability if the tested system were to become available to the participants. As a result, any technical issues or glitches particular to the present implementation therefore receive less emphasis. It is overall divided into five sections, measuring (1) Health Expectancy (do the participants perceive using the system could help attain health benefits), (2) Effort Expectancy (would the system be perceived to be easy to use), (3) Social Influence (how important would others be expected to find it to be using the system), (4) Facilitating Conditions (would the needed organizational and technical infrastructure be in place for using the system), and (5) Behavioral Intention (would the participants intend to use the system). The degree to which the participants agree or disagree with each statement is a measure of their expectations toward the system. A Danish version of the questionnaire was used with the study participants; the equivalent English version (Table S2) can be found in the Multimedia Appendix 1. In addition to the CUMACF questionnaire, the participants were also invited to give feedback and comments, including suggestions for future versions of the app. This took place as part of a follow-up phone call after all participants had completed the study. One of the researchers (PB) in random order contacted the 12 participants who had expressed interest in being contacted subsequently. One did not respond to multiple calls, and another excused themselves. The remaining 10 participants replied to the CUMACF questionnaire and additionally provided comments and feedback. No call lasted more than 1 hour. Participants' feedback and comments were reviewed and grouped into broader categories to summarize key areas according to the overall themes addressed in the CUMACF questionnaire.

### *Clinical Efficacy*

The efficacy of the DiaFocus system was assessed by participant-reported outcomes. The primary clinical outcome was a change in diabetes-related distress from baseline to visit 3 (measured by the DDS). DDS includes a focus on self-management and physician-related distress. DDS consists of 17 items on a 6-point scale [15-17]. Secondary outcomes were change in PCDS, change in DTSQs+c (Table S1 in Multimedia Appendix 1), and change in $HbA_{1c}$ levels and body weight.

## Statistical Analyses

Due to the nature of the study being a feasibility design, no sample size was calculated. We aimed to assess feasibility and gather preliminary data to inform the design of a future, larger-scale trial. We chose a recruitment window of 12 months and were able to include 17 participants. This number was considered adequate to assess our feasibility objectives. Analyses comparing changes from baseline to end of study were performed using the *t* test for parametric data and Wilcoxon rank-sum test for nonparametric data. The chi-square or Fisher exact test was used for categorical data. The analyses followed the intention-to-treat principle, and no adjustments were made for multiple comparisons.

All statistical analyses were done using SAS Enterprise Guide version 8.3 (SAS Institute Inc). Data are presented as median (IQR) or mean (SD) unless otherwise stated. A 2-sided *P* value of ≤.05 was considered statistically significant.

## Ethical Considerations

The study was carried out in accordance with the Declaration of Helsinki after approval by the Regional Scientific Ethics Committee (H-20040944) and the data protection agency (P-2020 - 1055). Informed consent was obtained from all participants before participation. Written patient information was given along with the brochure: "Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt" (Rights of study subjects in a health science research project). The investigator ensured that the potentially eligible participants were adequately informed about the study rationale and design, in written and spoken words. Before signing the consent form, the person was given a minimum of 24 hours to reconsider. Potentially eligible participants were informed that they, at any time, could withdraw their informed consent without having consequences for their future treatment. All information on study participants was protected according to the law on the processing of personal data and the law of health. Data were kept using REDCap (Research Electronic Data Capture; Vanderbilt University), a secure web-based app designed to support research data capture. All personally identifiable information on paper was kept in a locked filing cabinet in a double-locked office. All data were deidentified before any data analysis. The study participants did not receive any compensation for being in the study.



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## Results

From February 2021 to April 2022, a total of 18 potential eligible participants with T2D were screened. There was one screen failure due to severe nephropathy not compatible with study participation. Two participants dropped out during the study due to technical problems with the app; accordingly, 15 completed the study, and data from all 17 participants were analyzed. The median age was 68 (IQR 56-72) years, 12 (71%) were males, the median diabetes duration was 18 (IQR 11-21) years, and 10 (59%) were treated with insulin. The $HbA_{1c}$ level was 59 (IQR 49-68) mmol/mol. Additional baseline characteristics are described in Table 1.

**Table .** Baseline characteristics of the included participants.

| Baseline characteristics | All participants (N=17) |
|---|---|
| Age (years), median (IQR) | 68 (56-72) |
| Gender (male), n (%) | 12 (71) |
| Race (White), n (%) | 17 (100) |
| BMI ($kg/m^2$), median (IQR) | 29 (26-32) |
| Diabetes duration (years), median (IQR) | 18 (11-21) |
| $HbA_{1c}$[a] baseline (mmol/mol), median (IQR) | 59 (49-68) |
| Diabetes treatment, n (%) | |
| Metformin | 11 (64) |
| GLP-1[b] receptor agonist | 12 (71) |
| SGLT2[c] inhibitor | 12 (71) |
| Basal insulin | 6 (35) |
| Basal-bolus insulin | 4 (24) |
| How often do you measure BG[d]?, n (%) | |
| Never | 2 (12) |
| 1 - 4/month | 5 (29) |
| 2 - 3/week | 2 (12) |
| 4 - 6/week | 1 (6) |
| 1 - 2/day | 4 (24) |
| 3 or more/day | 3 (18) |
| How often do you send text messages?, n (%) | |
| 1 - 3 d/mo | 1 (6) |
| 1 - 2 d/wk | 1 (6) |
| 3 - 5 d/wk | 1 (6) |
| 6 - 7 d/wk | 14 (82) |
| How often do you use other apps on your phone?, n (%) | |
| 1 - 3 d/mo | 0 (0) |
| 1 - 2 d/wk | 1 (6) |
| 3 - 5 d/wk | 0 (0) |
| 6 - 7 d/wk | 16 (94) |

[a]$HbA_{1c}$: hemoglobin $A_{1c}$.

[b]GLP-1 receptor agonist: glucagon-like peptide-1 receptor agonist.

[c]SGLT2 inhibitor: sodium-glucose transport protein-2 inhibitors.

[d]BG: blood glucose.



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## Clinical Feasibility

### *Focus Areas*

Participants reported that the feature of setting focus areas was of great value to them, and all wanted to share their choice of focus areas.

They were most likely to choose blood glucose measurement (17 times, for 10 participants), exercise (14 times, for 9 participants), food (8 times, for 5 participants), medication-taking (7 times, 4 participants), or sleep (4 times, for 3 participants) as a focus area during the study. Weight management (1), mood (1), and heart rate (2 times for 1 participant) were also chosen as focus areas.

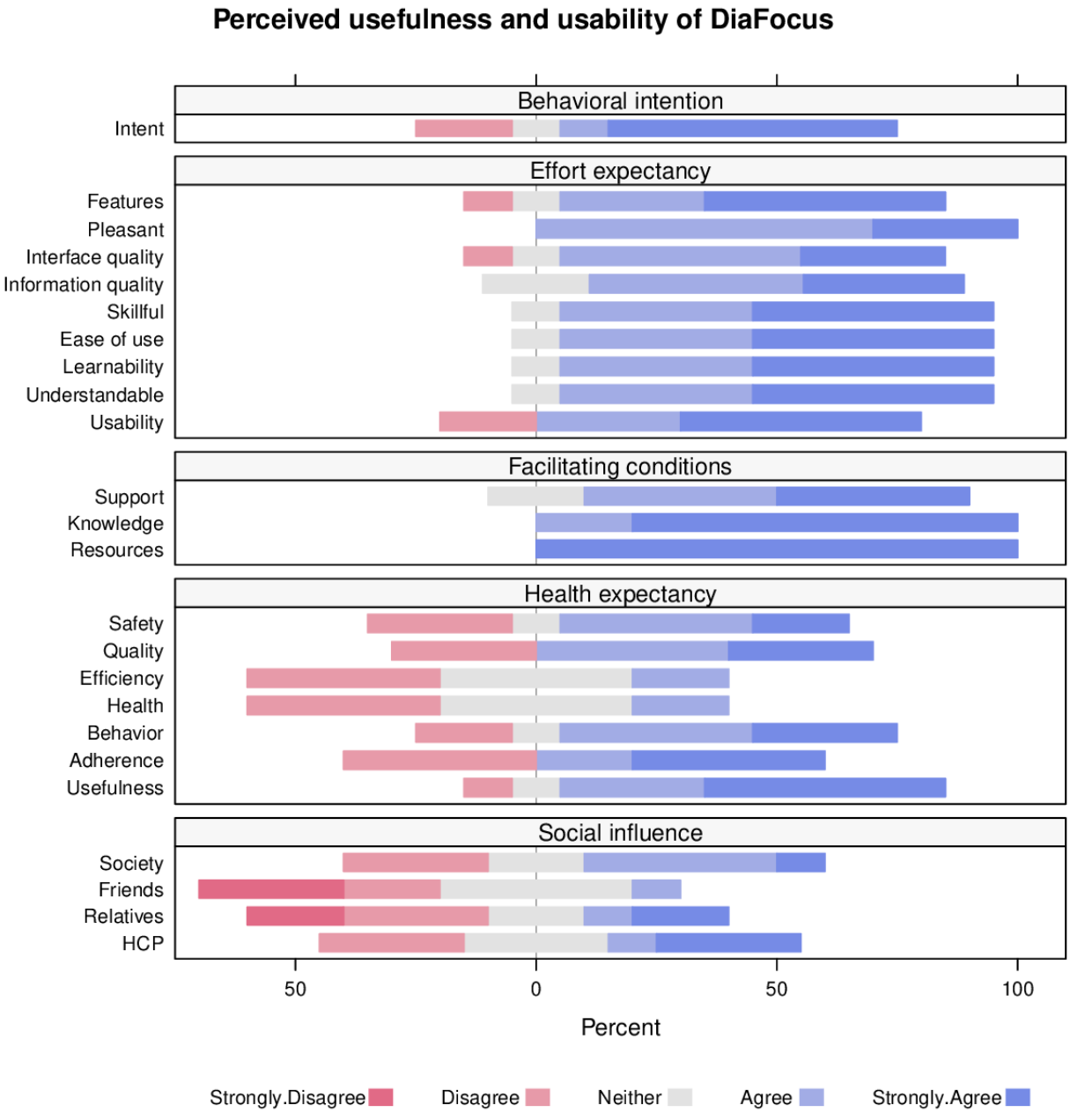
### *Questionnaires in the App*

The questionnaires were planned to be triggered 14 days before the clinical visits. Due to initial technical issues, not all participants received the questionnaires before visits 2 and 3. At baseline, all participants' median WHO-5 well-being score was 68 (out of 100). Two participants had WHO-5 score ≤50, indicating low emotional well-being. A sleep questionnaire was triggered for 10 out of the 17 participants (59%) during the study. A depression and anxiety questionnaire was triggered for 6 of the participants during the study.

### *CUMACF Questionnaire*

Of the 15 participants who completed the study, 3 had indicated no interest in being contacted later. A total of 10 of the remaining 12 participants were reachable and willing to reply to the CUMACF questionnaire. A summary of their responses is shown in Figure 4.

**Figure 4.** The results of the CUMACF (CACHET Unified Method for Assessment of Clinical Feasibility) questionnaire.






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For each statement, the proportion of respondents strongly disagreeing or disagreeing is shown in red, neither disagreeing nor agreeing in gray, and agreeing or strongly agreeing in blue. Agreeing or Strongly Agreeing to a statement generally indicates a positive response or perception.

Regarding Behavioral Intention, 70% (7/10) of the participants "agree" or "strongly agree" that they would use the system for 3 months if it were available as a service.

Regarding Effort Expectancy, 90% (9 out of 10) participants, for example, have very favorable views of how easy the system is to understand, learn, and use. Furthermore, 80% (8/10) also expect the usability to be high.

Regarding the Facilitating Conditions, participants almost uniformly agree that the necessary conditions would be available for them to use the system; all (10/10) agree they have the technical equipment and knowledge to use the system but 80% (8/10) indicate that they nevertheless expect a technical hotline would be available.

Regarding Health Expectancy, participants are generally positive regarding the overall usefulness, their expected adherence, and behavior; 80% (8/10) agree or strongly agree that the system is useful. Regarding the expected health outcome and efficiency, they are less positive. However, 70% (7/10) agree or strongly agree that the system would improve the quality of the treatment and 60% (6/10) agree or strongly agree that it would reduce the risk of complications.

Participants' views on Social Influence are mixed.

#### *Participant Feedback and Comments*

Comments from participants were subsequently reviewed and grouped according to the overall themes addressed using the CUMACF questionnaire. These are summarized below according to (1) perceived usefulness and structure, (2) expectations toward technical integration, (3) overall impact on health outcomes, and (4) finally Social Influence and privacy.

One participant commented that using focus areas and structured follow-up was "helpful to reduce and address concerns" and "help to emphasize the most important elements to handle." Seven out of the 10 participants (70%) indicated they were willing to use such a system in the future. Others, however, commented that they expected such a system to be "more polished" and "well-integrated with, for example, automatic transfer of blood glucose measurements" to the system.

When asked if the system could potentially reduce complications of their diabetes, 1 participant commented, "…but I already have complications." Thus, even if the participants were generally positive about the usefulness of the approach, they did not expect that using the system would improve their overall health, as also seen in the lower rating of the efficiency and health scores of the Health Expectancy.

Some participants, when asked about Social Influence from friends and colleagues, commented that they "certainly didn't involve others" in their diabetes. Another, however, explained that "once his family understood what DiaFocus was about, they strongly encouraged him to use the system." Hence, diabetes seemed, for many, to be perceived as a private matter, and thus, the Social Influence to use a system like DiaFocus is low.

#### *Technical Issues*

Ten of the 17 (59%) participants reported technical issues with the app, requiring technical support. During the study, technical problems were identified and fixed on an ongoing basis, and new versions of the software were deployed continuously. Major issues uncovered and reported by participants were impaired step count function, drained phone battery, and unavailable functions after app updates (eg, triggering of questionnaires). In addition, the HCPs reported missing questionnaire data, which complicated the assessment of psychosocial issues. Hence, the participant's active app use is difficult to report accurately.

### Clinical Efficacy

#### *Participant-Reported Outcomes*

At baseline, the median DDS score was 1.8 (IQR 1.2-2.2), indicating a low level of diabetes distress, and 1.7 (IQR 1.1-2.4) after 6 months, yielding a median change of 0.18 (IQR 0-0.52; *P*=.18). The total PCDS score was 32 (range 26-32) at baseline and the median change at study end was 1.0 (IQR −3 to 3; *P*=.85). The total DTSQs score was 32 (range 27.5-34) at baseline and remained unchanged after 6 months with a median difference of 0 (IQR 0-1; *P*=.70).

#### *$HbA_{1c}$ and Body Weight*

The median $HbA_{1c}$ level was 59 (IQR 49-68) mmol/mol at baseline with a median change of 0 (IQR −10 to 3) mmol/mol (*P*=.1) at study end. The median body weight remained unchanged during the study (*P*=.33).

## Discussion

### Principal Findings

This clinical pilot study assessed the use of the DiaFocus system in an outpatient setting for 6 months for adults with T2D. The participants were generally positive about the iPDM treatment approach and found the DiaFocus system feasible to incorporate into their diabetes management. However, no significant clinical changes were seen in participant-reported outcomes, $HbA_{1c}$ level, or body weight. The findings of this study expand upon our previous technical feasibility study [13] by demonstrating how the app can be used in a diabetes clinic to support communication between users and HCPs. Accordingly, participants reported that the feature of setting focus areas and discussing these in the clinic was of great value to them. Sleep was often chosen as a focus area, and a sleep questionnaire was triggered for more than half of the participants. Moreover, a depression and anxiety questionnaire was triggered for one-third of them, indicating a need to address additional health-related areas in diabetes management, including psychosocial issues, during outpatient clinic visits. This need was also emphasized by participants during the interviews, who expressed a desire for a broader focus on diabetes-related health issues beyond just diet, exercise, medication, and smoking.



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During the study period, there was a small but insignificant decrease in $HbA_{1c}$ levels. Several previous mHealth intervention studies have demonstrated improved glycemic control; however, most of these interventions also included coaching features, that is, automated messages providing feedback and motivation [9,21], which were not included in the DiaFocus app.

In addition, we did not demonstrate significant changes in participant-reported outcomes (questionnaires DDS, PCDS, and DTSQs). These findings could simply be due to the low number of participants in this pilot study, but the outcomes might also have been influenced by the technical issues with the app. However, despite technical issues with the app, the results from the CUMACF questionnaire indicated that the participants who responded were positive toward the perceived usefulness and usability of a system such as DiaFocus. The concepts were easy to understand and use and were seen as providing value, and many participants would use such a system if it were available to them. These findings are also reflected in the qualitative comments by the participants.

Overall, even if the present implementation experienced technical issues that were only partially resolved during the study, the usability and usefulness of the overall concepts were perceived positively by the participants.

### Limitations

First, a limitation of this study is the feasibility outline, meaning that the study was conducted as a single-arm study with a small sample size without a power calculation. The findings should therefore be interpreted with caution. Second, we included a well-controlled and highly motivated population of individuals with T2D who already had a smartphone. In addition, we did not collect data on socioeconomic status or comorbidities, which may have influenced the outcome of the study. Accordingly, the findings may not be generalizable to other populations. Third, although the CUMACF questionnaire overall shows positive expectations for a system like the one implemented, it could partly result from a sampling bias, as one-third of the participants who were not reachable or willing to reply to a follow-up interview and the CUMACF questionnaire could have been more negative toward the system. Fourth, the absence of a control group limits our ability to definitively attribute any observed improvements to the intervention. Finally, technical difficulties that may have caused some active app usage data to be missing mean that this perspective cannot be properly addressed in the analysis.

### Future Directions

To ensure more accurate and comprehensive results, this feasibility study suggests that future studies should be powered to detect possible significant differences in clinical outcomes. Such studies should also involve larger and more diverse populations to enhance generalizability. This could include individuals with newly diagnosed diabetes, individuals managed in primary care settings, or with higher $HbA_{1c}$ levels. In addition, investigating experiences with the DiaFocus system from a health care provider's perspective would provide valuable insights and complement the present findings, helping to understand its impact on clinical workflows, communication, and diabetes management. Finally, ensuring a robust technical platform already at the beginning of the study is important to be able to better report and analyze app usage and patients' engagement with the system throughout the study.

### Conclusions

This pilot study demonstrated that the DiaFocus system was clinically feasible and well accepted among users with T2D, even though no changes were observed in participant-reported outcomes. However, some aspects of the system, including app functionality and technical stability, need optimization before larger and long-term studies are conducted.

## Acknowledgments

The authors would like to thank Dr Dagmar Kownatka and Dr Allan Jones (with Roche at the time of the study design) for their inspiration and contribution to the overall iPDM-Go project. We would also like to thank Alban Maxhuni and Mads VS Christensen for technical support, and Matteo E Hoffmann for helping with the data analysis and all the participants in the DiaFocus pilot study. iPDM-GO has received funding from the European Institute of Innovation and Technology (EIT). EIT receives support from the European Union's Horizon 2020 research and innovation program. The clinical study investigators (Nanna Lind, Merete B. Christensen, and Kirsten Nørgaard) took the initiative to conduct this clinical pilot study. The funding was used for the salary of the study nurse and physician at Steno Diabetes Center Copenhagen and operational expenses at the Technical University of Denmark. None of the project group members has any financial interests in the funding organization. The study participants did not receive any economic compensation for participating in this study. Generative artificial intelligence was not used in the manuscript writing.

## Data Availability

Deidentified datasets generated or analyzed during the study are not publicly available due to the feasibility aspect that may lead to future internal research but are available from the corresponding author upon reasonable request.

## Authors' Contributions

NL, PB, JEB, CCP, KN, and MBC were involved in designing the study and the system; NL and MBC ran the study and analyzed the clinical data and questionnaires. PB and JEB designed and deployed the DiaFocus system, were responsible for the evaluation



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interviews, and analyzed the data from the app. NL, PB, and MBC wrote the first draft of the manuscript. All authors discussed and interpreted the results and reviewed and revised the manuscript before submission.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional material.
[DOCX File, 21 KB - diabetes_v10i1e63894_app1.docx ]

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## Abbreviations

**CUMACF:** CACHET Unified Method for Assessment of Clinical Feasibility
**DDS:** Diabetes Distress Scale
**DTSQ:** Diabetes Treatment Satisfaction Questionnaire
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**HCP:** health care professional
**iPDM:** integrated personalized diabetes management
**PCDS:** Perceived Competence for Diabetes Scale
**REDCap:** Research Electronic Data Capture
**SDCC:** Steno Diabetes Center Copenhagen
**T2D:** type 2 diabetes
**WHO-5:** World Health Organization Well-being Index

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# A Novel Mobile Health App to Educate and Empower Young Adults With Type 1 Diabetes to Exercise Safely: Prospective Single-Arm Pre-Post Noninferiority Clinical Trial

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## Abstract

**Background:** A novel mobile health (mHealth) app "acT1ve," developed using a co-design model, provides real-time support during exercise for young people with type 1 diabetes (T1D).

**Objective:** This study aimed to demonstrate the noninferiority of acT1ve compared with "treatment as usual" with regard to hypoglycemic events.

**Methods:** Thirty-nine participants living with T1D (age: 17.2, SD 3.3 years; $HbA_{1c}$: 64, SD 6.0 mmol/mol) completed a 12-week single-arm, pre-post noninferiority study with a follow-up qualitative component. During the intervention, continuous glucose monitoring (CGM) and physical activity were monitored while participants used acT1ve to manage exercise. CGM data were used to assess the number of hypoglycemic events (<3.9 mmol/L for ≥15 minutes) in each phase. Using a mixed effects negative binomial regression, the difference in the rates of hypoglycemia between the preapp and app-use phases was analyzed. Participants completed both a semistructured interview and the user Mobile Application Rating Scale (uMARS) questionnaire postintervention. All interviews were audio-recorded for transcription, and a deductive content analysis approach was used to analyze the participant interviews. The uMARS Likert scores for each subscale (engagement, functionality, esthetics, and information) were calculated and reported as medians with IQRs.

**Results:** The rates of hypoglycemia were similar for both the preapp and app-use phases (0.79 and 0.83 hypoglycemia events per day, respectively). The upper bound of the CI of the hypoglycemia rate ratio met the prespecified criteria for noninferiority (rate ratio=1.06; 95% CI 0.91-1.22). The uMARS analysis showed a high rating (≥4 out of 5) of acT1ve by 80% of participants for both functionality and information, 72% for esthetics, and 63% for overall uMARS rating. Content analysis of the interview transcripts identified 3 main themes: "Provision of information," "Exercising with the App," and "Targeted Population."

**Conclusions:** The mHealth app "acT1ve," which was developed in collaboration with young people with T1D, is functional, acceptable, and safe for diabetes management around exercise. The study supports the noninferiority of acT1ve compared with "treatment as usual" with regards to hypoglycemic events.

**Trial Registration:** Australian New Zealand Clinical Trials Registry ACTRN12620001066976; https://www.anzctr.org.au/ACTRN12620001066976.aspx

***(JMIR Diabetes 2025;10:e68694)*** doi:10.2196/68694

**KEYWORDS**

mobile health app; exercise; acT1ve; type 1 diabetes; young people; blood glucose level



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## Introduction

Children with type 1 diabetes (T1D) diagnosed before the age of 10 years have a 30-fold higher risk of coronary heart disease in early adulthood [1], and despite advances in care, life expectancy is reduced by 12 to 16 years [1]. Cardiovascular disease is the most common cause of shortened life expectancy in T1D and is clearly linked to key modifiable factors, including exercise [2-6]. In this respect, there is evidence that regular exercise has the potential to improve clinical outcomes and reduce cardiovascular morbidity and mortality in people with T1D [2]. Indeed, the amount of exercise an adult with T1D undertakes is inversely related to glycated hemoglobin $A_{1c}$ ($HbA_{1c}$) levels, BMI, the prevalence of diabetic ketoacidosis, retinopathy, microalbuminuria, hypertension, and dyslipidemia [3]. Furthermore, physically active children and adolescents with T1D display better glycemic levels, endothelial function, body composition, neurocognitive, and psycho-behavioral function [4-6].

Despite the many benefits of regular exercise, many people with T1D do not meet the current physical activity recommendations [7], especially adolescents with T1D who are less active than their peers without T1D [8]. Apart from the risk of exercise-mediated hypoglycemia, inadequate patient and health care provider knowledge about exercise management are barriers to an active lifestyle in young people living with T1D [9,10], and programs designed to increase physical activity have so far been ineffective [11].

Although detailed exercise recommendations have been provided by key professional societies and organizations for the prevention of exercise-mediated hypoglycemia [12-14], these recommendations can be challenging to follow and are often found in medical journals that are not readily accessible to the general T1D community and clinicians alike. A recent survey conducted by our team led us to propose that providing exercise guidelines in a mobile health (mHealth) app would be useful as a decision-support aid around exercise management for adolescents and young adults with T1D [10]. Indeed, mHealth apps that track diabetes-related health information, provide education, and connect patients to support systems could potentially facilitate patients' self-management and improve diabetes-related outcomes. Increasingly, patients with diabetes have thus been using mHealth apps to assist with their diabetes self-management [15-19]. Currently, there are no commercially available apps that specifically support diabetes self-management and provide individualized information around exercise in young people living with T1D. The Diactive-1 app has been recently developed by a team of researchers from the University of Turin, Italy. This app is being tested to explore the potential benefits for various aspects of T1D management, including personalized physical exercise [20].

We recently developed in collaboration with young adults with T1D and the digital health company Curve Tomorrow, the novel mHealth app, "acT1ve" [21]. The app was based on recent exercise guidelines consensus [12-14] and developed following a user-centered design process that engaged end-users to ensure app effectiveness [22]. In a recent pilot trial, acT1ve was found to be informative, functional, and acceptable with high user satisfaction, making it a promising intervention for exercise management [23]. Thereafter, improvements to the app were made based on the feedback gathered from the pilot trial. However, a component that has yet to be investigated relates to the safety surrounding app usage. This is an important element to be addressed, given that the process of gaining Australian regulatory body approvals to allow for the app to reach the market requires the app to comply with the essential principles relating to safety. For this reason, the primary objective of the current study was to conduct a clinical trial to test the safety of acT1ve at providing real-time support for young people with T1D during exercise in a free-living setting by showing the noninferiority of acT1ve compared with "treatment as usual" with regards to hypoglycemic events. The secondary objectives of the study were to explore the overall usability, acceptability, and experience of acT1ve over a 4-week period, and to gather qualitative feedback on the user experience of acT1ve and changes in exercise behavior and trends.

## Methods

### Design

The project adopted a single-arm pre-post noninferiority study design and was performed under free-living conditions in adolescents and young adults with T1D from September 2020 to December 2021. The CONSORT (Consolidated Standards of Reporting Trials) checklist is provided in Checklist 1.

### Study Participants

Forty-two individuals (males and females) were recruited to participate in the study (Table 1). Inclusion criteria included age (12 - 25 years), T1D diagnosis (>6 months), insulin therapy (multiple dose insulin [MDI] regimen or continuous subcutaneous insulin infusion [CSII]), being able or willing to perform regular exercise (≥2 sessions per week), smartphone ownership either Android or iPhone, and English competency. Exclusion criteria were reduced cognitive capacity that impaired the ability to consent/assent and non-English speaking individuals. Participant recruitment was performed through the Western Australian Children's Diabetes Database and approached via email or phone, or by a researcher face-to-face when they attended Perth Children's Hospital diabetes clinics. Flyers were provided to the PCH Diabetes Clinical Service, and the study was advertised on Diabetes community organizations' websites, social media, and their newsletters.



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**Table .** Participant demographics.

| Demographics | Participants (n=39) |
|---|---|
| Sex, n (%) | |
| Male | 19 (49) |
| Female | 20 (51) |
| Age (years), mean (SD) | 17.2 (3.3) |
| $HbA_{1c}$[a] (%), mean (SD) | 7.9 (1.5) |
| $HbA_{1c}$ (mmol/mol), mean (SD) | 64.0 (6.0) |
| Insulin regime, n (%) | |
| CSII[b] | 21 (54) |
| MDI[c] | 18 (46) |
| T1D duration (years), mean (SD) | 6.9 (1.2) |
| BMI (kg/m2), mean (SD) | 22.6 (3.9) |
| Physical activity levels, median (IQR) | |
| Exercise intensity (METs)[d] | 5.4 (4.8, 6.4) |
| Weekly exercise duration (min) | 80.9 (35.4, 163.9) |
| History of mobile app use, n (%) | |
| General exercise-based | 8 (21) |
| Diabetes-specific exercise-based | 0 (0) |
| Type of mobile device used for acT1ve app, n (%) | |
| Apple iOS | 31 (79) |
| Android | 8 (21) |

[a]$HbA_{1c}$: glycated hemoglobin A1c.

[b]CSII: continuous subcutaneous insulin infusion.

[c]MDI: multiple daily injections.

[d]MET: metabolic equivalent of task.

Previously analyzed data collected as part of a longitudinal randomized controlled trial [24], in a sample of 12 to 25-year-old participants, along with data collected in a pilot study [23], were used to inform parameters of the sample size power calculation. Given the (1) estimated rate of hypoglycemic events<3.9 mmol/L was approximately 0.3 events per 24 hours (2) a dispersion parameter (theta) ranging between 2 to 2.5 and (3) correlation between rates of hypoglycemic events measured longitudinally ranging between 0.5 - 0.7, a noninferiority limit was identified based on discussions with clinicians and was set at a 50% increase in event rate. Based on an intervention duration of 4 weeks, with expected equivalent rates, and specifying the more conservative of the above parameters (theta=2 and correlation=0.5), 1000 simulations were conducted, indicating that a sample of 40 participants would provide over 85% power for the upper boundary of a 95% CI to fall below the noninferiority limit.

## Study Flow

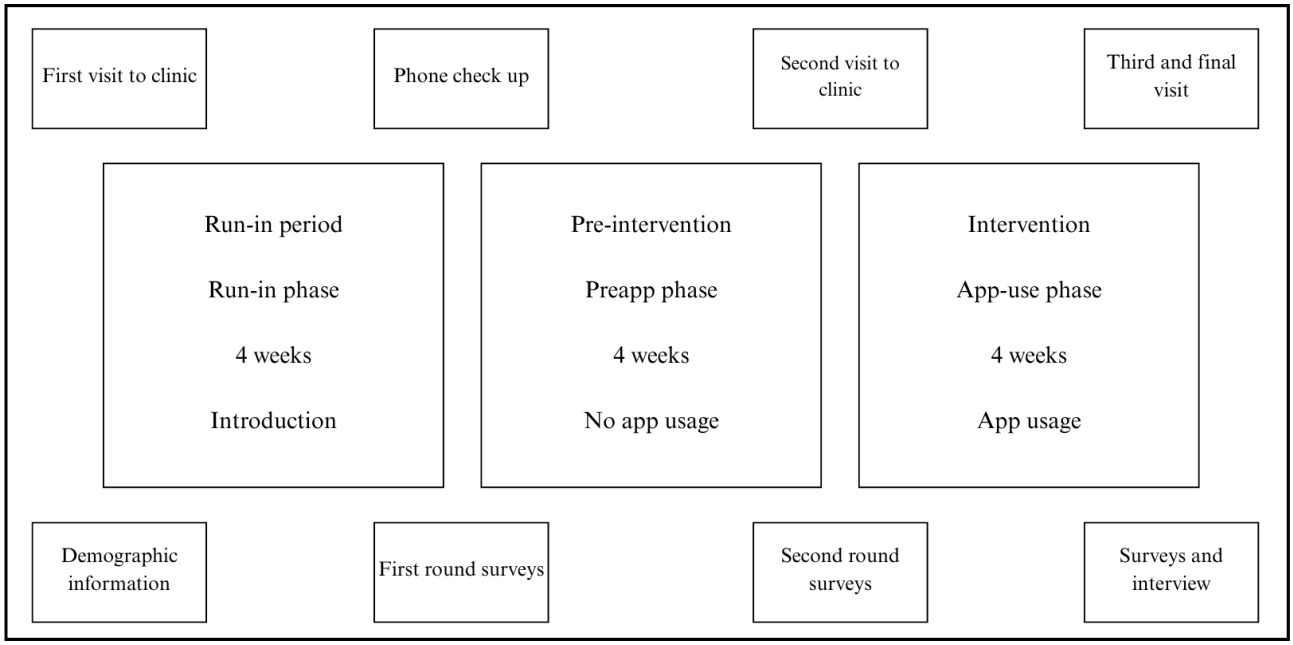
### *Overview*

All participants were required to complete the study intervention over a 12-week period during school terms to ensure minimal variation for both children and adolescent participants. Each 12-week period was split into 3 phases, with each phase lasting 4 weeks (Figure 1). The participants attended our research facility on 3 occasions throughout the study: at the start of the run-in phase (Week 1), at the start of the preapp phase (Week 5), and at the end of the app-use phase (Week 12). Participants' glucose levels during the study period were monitored using a Dexcom G6 continuous glucose monitoring system (CGM), and physical activity events were recorded with a Garmin Forerunner Activity-monitoring watch or, if the activity watch was not worn during exercise, a self-reporting logbook. Participants were also required to complete a series of questionnaires in Weeks 5, 8, and 12. During each phase, participants wore the CGM throughout the study period and activity monitoring watch, only while exercising.



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**Figure 1.** Schematic representation of the study design.




### *Run-in Phase*

The 4-week run-in phase was used to familiarize the participants with the CGM and activity watch. During the first visit, demographic and descriptive characteristics of participants were collected, which included: age, sex, duration of diabetes, $HbA_{1c}$ level, insulin therapy, and exercise patterns. Thereafter, participants were sent home and instructed to familiarize themselves with the CGM and activity watch. Physical activity events and data from each participant's watch were linked and tracked through their individual Garmin Connect online account. The CGM data were monitored through the Dexcom Clarity (Dexcom, Inc) online software. The participants were also reminded to record their activity in their paper logbook if it was not recorded on the activity watch and to log the reasons for any gaps in physical activity participation. This routine was set up to ensure smoother data collection during the subsequent preapp phase. Activity watch and CGM were monitored weekly to ensure that these pieces of equipment were functional and to ensure the consistent collection and storage of the data through the software used.

### *Preapp Use Phase*

During the preapp phase, participants continued to wear the CGM and activity watch as per the run-in phase and were encouraged to exercise and follow their usual blood glucose management routine. A requirement for the study was that participants were currently or willing to exercise a minimum of 2 times a week. For already active participants, they were asked to go about their usual exercise routines. Participants who were not currently exercising 2 times a week were encouraged to do so as part of the study. We defined exercise duration of 5 minutes or more as a session of exercise. This phase was primarily aimed at collecting the data to be compared with that of the intervention phase (app-use phase). Participants were contacted in the event that gaps in the data collection were identified. Participants were also asked to complete their first set of questionnaires online in week 5, with the links to the questionnaires being sent to their respective emails.

### *App-Use Intervention Phase*

At the commencement of the app-use phase, participants returned to the research facility to have the acT1ve app downloaded on their smartphones and to complete their end of preapp series of questionnaires. Then, the participants' profiles were set up within the app, and they were instructed to follow the in-built onboarding process, which guided them through the different sections and functions of acT1ve app before leaving the research facility. Participants were instructed to use the app for 4 weeks to assist them with their exercise-related diabetes management. Participants continued to use the CGM and the activity watch as per the preapp phase. Throughout the App-use phase, participant data were monitored on a regular basis, and participants were contacted should there be any missing data. Data regarding participants' use of the app was recorded on REDCap (Research Electronic Data Capture) [25]. During their final visit, at the end of the app-use phase, participants were assisted in deleting the acT1ve app from their device before completing their final set of questionnaires. In addition, participants completed the user Mobile Application Rating Scale (uMARS) questionnaire [26] and participated in a semi-structured face-to-face interview to provide feedback on their experiences of using the app.

## acT1ve Mobile App

The acT1ve app uses an exercise advisor algorithm developed in-house that is based on recently published evidence-based guidelines [23] and provides 240 possible pathways, which are dependent on user inputs [23]. Participants are prompted to answer questions about the type, intensity, and duration of the physical activity they are about to complete, time elapsed since the last insulin bolus, and their current blood glucose levels. This information is then used to provide personalized insulin dosing and carbohydrate advice for exercise lasting up to 60 minutes. In addition, acT1ve provides more information on



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hypoglycemia treatment, pre- and postexercise insulin and carbohydrate advice, and an educational food guide that highlights the importance of low and high glycemic index (GI) foods in the context of exercise management.

### Continuous Glucose Monitoring (CGM)

Continuous glucose monitoring data were collected using the Dexcom G6 sensor. Each participant had their own personal Dexcom Clarity account where their data were collected and stored in 5-minute intervals. At the end of the participant's study period, a member of the research team downloaded the CGM data in a CSV Excel (Microsoft) file, and all data were deidentified for analysis.

### Monitoring of Physical Activity

Participants were assigned their individual Garmin account, with instructions provided on how to pair their Garmin Forerunner 735XT activity monitoring watch to the Garmin Express mobile app. Physical activity events were monitored using the Garmin Connect desktop application. In the event where an activity could not be registered on the activity watch, participants were instructed to log such an activity in a paper diary. Physical activity events recorded on the activity watch were downloaded at the end of each study phase. To determine if any exercise bout is a 'true' event, the duration of the exercise bout recorded by the activity watch had to be ≥5 minutes in duration. All physical activity events that were <5 minutes were considered accidental/error and were excluded from the final analysis. Metabolic equivalent of tasks (METs) was used as a measure of exercise intensity. One MET is defined as the amount of oxygen consumed while sitting at rest and equates to an oxygen consumption rate of 3.5 ml/kg/min [27]. Classification of exercise intensity was based on the following MET levels as recommended by the American College of Sports Medicine guidelines: [28] light intensity activity (1.1 - 2.9 METs); moderate intensity activity (3.0 - 5.9 METs); and vigorous intensity activity (≥6.0 METs). The calculation of energy expenditure based on MET data depended on the method used to assess physical activity (activity watch or paper diary entries). When the energy expended during exercise was available from the activity watch, the following formula was used to calculate energy expenditure and thus exercise intensity (Energy expenditure calories = (MET level of activity x 3.5x Weight (kg) x minutes of activity)/200) [29]. In the absence of MET data, exercise intensity was calculated based on a compendium of predicted MET values for specific activities as outlined in the 2011 Compendium of Physical Activities [29].

### uMARS Questionnaire

The uMARS questionnaire [26] was used to evaluate acT1ve app. This tool is used to assess the overall quality of mHealth apps and provides a 20-item measure that includes four objective quality subscales, namely engagement, functionality, esthetics, and information quality, and 1 subjective quality subscale. A total quality score is obtained from the weighted average of the 44 subscales. Another subscale, consisting of 6 items, is added to measure users' perceived impact of the evaluated app [26], where the details of the subscales have been described previously [23]. At the end of the app-use phase, the uMARS questionnaire was administered to the participants. Scores for the four objective subscales were determined by the mean score of each of its individual questions. The perceived impact and subjective quality of acT1ve for each participant were calculated by averaging the scores of their related questions but were not considered in the total quality score.

### Participant Interview

At the participants' final study visit, they were asked to participate in a semistructured interview. The interview questions (Multimedia Appendix 1) were designed to gain an understanding of the participants' experiences of using the app for exercise, their usability and acceptability of the app, overall experience, and any recommendations. The interviews were conducted by 3 researchers trained in qualitative interviewing techniques. Two of the interviewers were unknown to the participants. The third interviewer was a member of the project team known to the participants but was not in a senior position or involved with the participant in an ongoing capacity, either in research or their clinical care. After each interviewer conducted their first interview, the other interviewers listened to the recording to review interviewing methods for consistency. All interviews were audio-recorded for transcription and analysis.

### Outcomes

The primary outcome of the study was the rate of level 1 hypoglycemia (<3.9 mmol/L for ≥15 min) as collected by the CGM device during each study phase. The secondary outcomes were: incidence of level 2 hypoglycemia (<3.0 mmol/L for ≥15 min), time spent with sensor glucose levels between 3.9 and 10 mmol/L, time spent above target glucose range (>10 mmol/L), incidence of level 1 and 2 hypoglycemia or treated hypoglycemia during the subsequent 24 hours after exercise [1], overall perceived quality of acT1ve as measured by the uMARS questionnaire [26], changes in exercise patterns (ie, exercise frequency, duration, and intensity), and qualitative feedback relating to user experience of acT1ve.

### Statistical Analyses

#### *Quantitative Analysis*

To evaluate the noninferiority of acT1ve use over a 4-week period, we tested the null hypothesis that acT1ve treatment was not associated with a higher rate of level 1 hypoglycemic events, as defined above, than "treatment as usual" (preintervention phase). To accept the null hypothesis and conclude noninferiority of the intervention, the upper bound of the 95% CI of the ratio of the rate of hypoglycemic events in the intervention phase to the preintervention phase had to fall below the noninferiority limit of 1.5. Our primary analysis thus assessed the difference in the rate of level 1 hypoglycemia between the preapp and app-use phases. This was analyzed using a mixed effects negative binomial regression including a random effect for participant and a fixed effect for study phase (preapp and app-use phases). The dispersion parameter was estimated using maximum likelihood estimation approximating the integrals over the random effects with an adaptive Gaussian quadrature rule. The incidence rate ratio, along with its 95% CI, was calculated.



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Percent time in ranges and continuous secondary outcomes were analyzed using a linear mixed model including a random effect for individual and a fixed effect for study phase (preapp and app-use phases). Percentages and medians IQRs (IQR: 25%-75%) were calculated for the monitoring of "true" and acT1ve app physical activity events recorded during both phases, each uMARS subscale, and total score. Means (pooled SDs) for exercise frequency, intensity, and duration across the respective study phases were analyzed, and the magnitude of change between phases for each of the exercise components was reported using Hedges *g* and interpreted as small (g=0.2), moderate (g=0.5), or large (g=0.8) [30]. Statistical significance for all quantitative analyses was set at $P<.05$.

### *Qualitative Analyses*

A deductive content analysis approach [31] was used to analyze the participant interviews, as some questions were based on previously identified concepts from the pilot app trial study. Three researchers (ST, RL, and AR) worked independently to read and reread all transcripts to develop categories from the data. Researchers met to discuss categories and determine themes that encompassed the participant experience in relation to the research question.

### Ethical Considerations

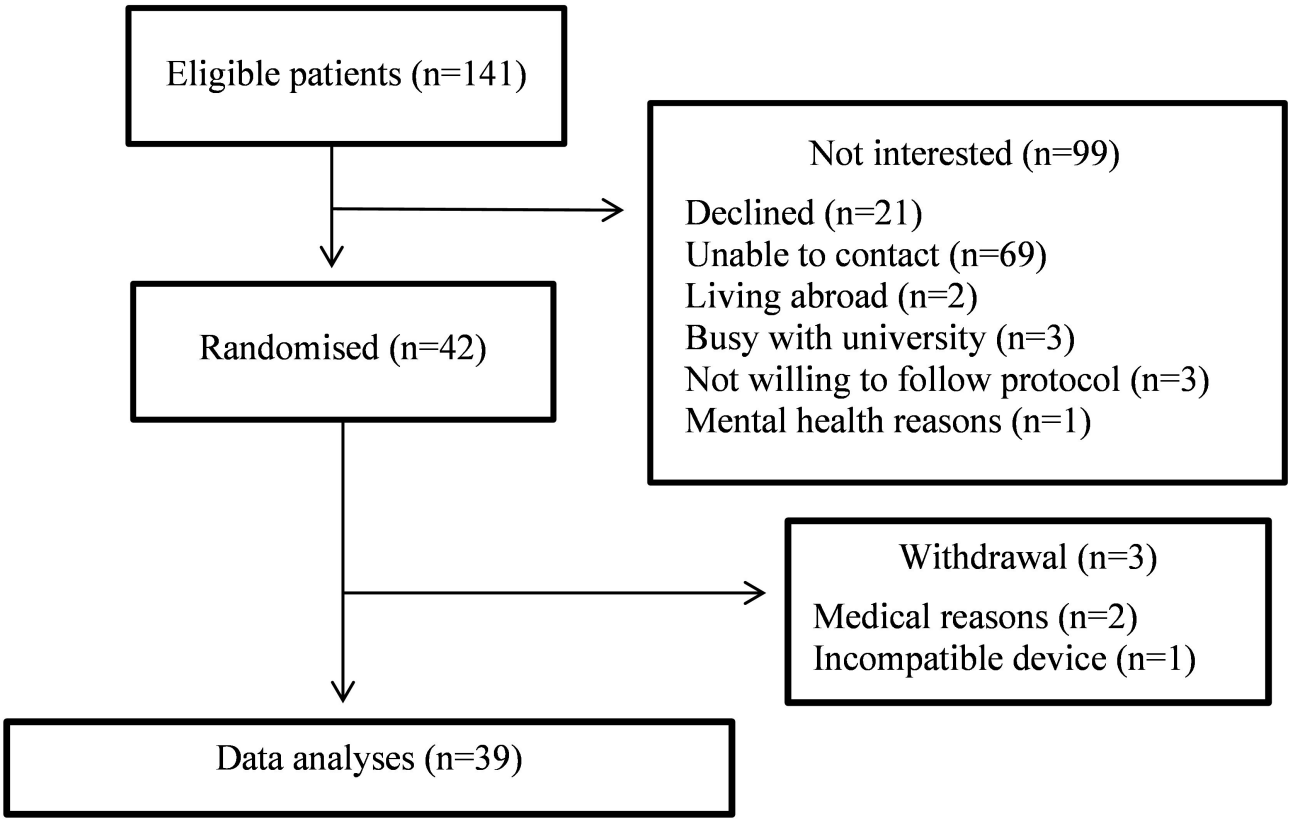
The study was approved by the Child and Adolescent Health Human Research Ethics Committee (RGS0000003886), and all participants provided consent in accordance with the Child and Adolescent Health Human Research Ethics Committee, registered with the National Health and Medical Research Council's Australian Health Ethics Committee. In addition, parental consent was also obtained for participants under the age of 18 years. All study data were deidentified. Participants were provided US $65 in cash at the end of their participation. The project is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12620001066976).

## Results

### Demographics

As illustrated in Figure 2, 42 individuals (20 males and 22 females) consented and were enrolled in this study, with 39 included in the final analysis (demographics presented in Table 1). Three participants withdrew in the run-in period. Two participants were excluded because of acute health issues (1 had a viral infection followed by chronic fatigue, and the other had issues relating to mental health), and the data from 1 participant was excluded due to incompatibility between the mobile device and the Dexcom CGM app.

**Figure 2.** The CONSORT (Consolidated Standards of Reporting Trials) flow chart for participants in the trial.




### Quantitative Results

#### *Glycemic Outcomes*

Similar rates of level 1 (0.79, SD 0.82, and 0.83, SD 0.84 events per day, respectively) and level 2 hypoglycemia (0.25. SD 0.48 and 0.24, SD 0.50 events per day, respectively) were observed for the preapp and app-use phases during the subsequent 24 hours after exercise. The upper bound of the confidence interval of the level 1 hypoglycemia rate ratio met the prespecified criteria for noninferiority (rate ratio=1.06, 95% CI 0.91-1.22; Figure 3A-B). The percentage of time spent within the target



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glucose range and the time spent above target glucose range during the subsequent 24 hours after exercise did not differ between preapp and app-use phases (Table 2).

Similar rates of level 1 and level 2 hypoglycemia, the percentage of time spent within the target glucose range, and the time spent above the target glucose range were observed during and 1 hour after exercise for the preapp and app-use phases (Table 3).

**Figure 3.** Change in hypoglycemia rate from preapp to app-use phase. (A) Box and whisker plot of Level 1 hypoglycemic events in preapp and app-use phases. (B) Change in rate from preapp to app-use phase presented as a rate ratio with 95% CIs. The red line represents the clinically meaningful increase in level 1 hypoglycemia events.

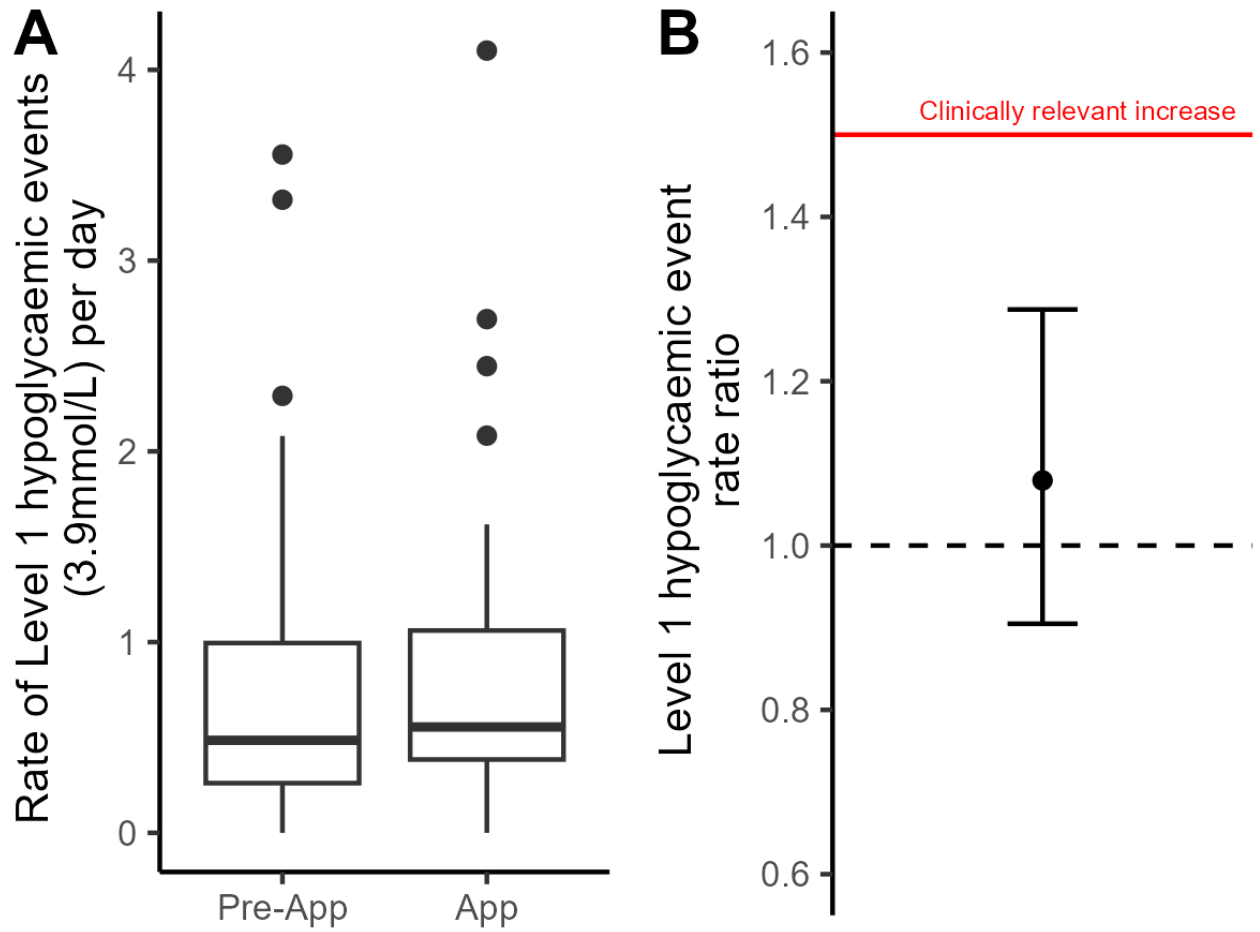



**Table .** Key glycemic metrics during 24 hours after exercise.

| CGM[a] metric | Preapp phase, mean (SD) | App-use phase, mean (SD) | *P* value |
|---|---|---|---|
| Time in range (%) | 53.3 (17.4) | 54.5 (16.7) | .27 |
| Time high (%) | 43.3 (18.9) | 42.3 (18.1) | .35 |
| Mean IGL[b] | 10.1 (2.2) | 10.0 (2.1) | .44 |
| SD IGL[c] | 3.78 (0.95) | 3.80 (0.85) | .49 |

[a]CGM: continuous glucose monitor.

[b]IGL: interstitial glucose levels.

[c]SD IGL is the mean of all the SDs of all participants and reflects glycemic variability.



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**Table .** Key glycemic metrics during/immediately after exercise.

| CGM[a] metric | Preapp phase, median (IQR) | App-use phase, median (IQR) | *P* value |
|---|---|---|---|
| Time spent <3.0 mmol/L (%)[b] | 0 (0,0) | 0 (0,1.67) | .12 |
| Time spent <3.9 mmol/L (%)[b] | 0.71 (0, 3.77) | 1.65 (0, 8.35) | .25 |
| Time spent 3.9 - 10.0 mmol/L (%)[c] | 53.7 (25.6, 69.3) | 50.5 (32.6, 70.8) | .96 |
| Time spent >10.0 mmol/L (%)[c] | 45.0 (27.4, 72.8) | 42.2 (22.9, 67.4) | .77 |
| Mean SGL[d] (mmol/L)[c] | 10.3 (8.2, 11.9) | 9.7 (7.9, 12.2) | .52 |
| SD SGL[e] (mmol/L)[b] | 3.1 (2.6, 4.0) | 3.0 (2.7, 3.9) | .91 |

[a]CGM: Continuous glucose monitor.

[b]*P* value calculated using the Wilcoxon signed rank.

[c]*P* value calculated using paired *t* test.

[d]SGL: sensor glucose levels.

[e]SD SGL is the mean of all the SDs of all participants and reflects glycemic variability.

### *Types of Exercise Events Recorded*

For both the preapp and app-use phases, approximately 42% of the exercise activities participants engaged in were aerobic-based activities (ie, walking, jogging, running, and cycling). The other activities that participants engaged in were: (1) sport-specific (eg, team-based sports and archery); (2) water-based (eg, swimming, surfing, and rafting); (3) strength-based (eg, gym, weightlifting, and Pilates) and (4) nonstructured exercise (eg, gardening, housework, and school-based activities). These made up approximately 24%, 14%, 14%, and 7% of the activities participants engaged in across both the preapp and app-use phases, respectively.

### *Monitoring of Physical Activity Events and acT1ve App Use*

The median frequency of "true" exercise events per week recorded via both the activity watch and paper diary was similar between Preapp (1.75; IQR 1.00 - 3.00 events) and App-use phases (1.75; IQR: 1.25 - 3.00 events). In the app-use phase, the median frequency of events per week was 1.5 (IQR: 0.75 - 2), with no significant difference observed between 'true' exercise events and app-recorded events ($P>.05$).

### *Changes in Frequency, Intensity, and Duration of Exercise*

There were no significant differences in total monthly exercise frequencies (10.74, SD 9.35 vs 10.33, SD 9.57; $g=0.09$), average exercise intensity (5.4, SD 2.4 vs 5.4, SD 2.6 METs; $g=0.02$), average exercise duration (46.6±31.3 vs 48.9±33.5 min; $g=0.07$) and total monthly exercise workload (3403.0, SD 4768.3 vs 2697.8, SD 2770 MET-min; $g=0.18$; all $P\geq.43$) between preapp and app-use phases.

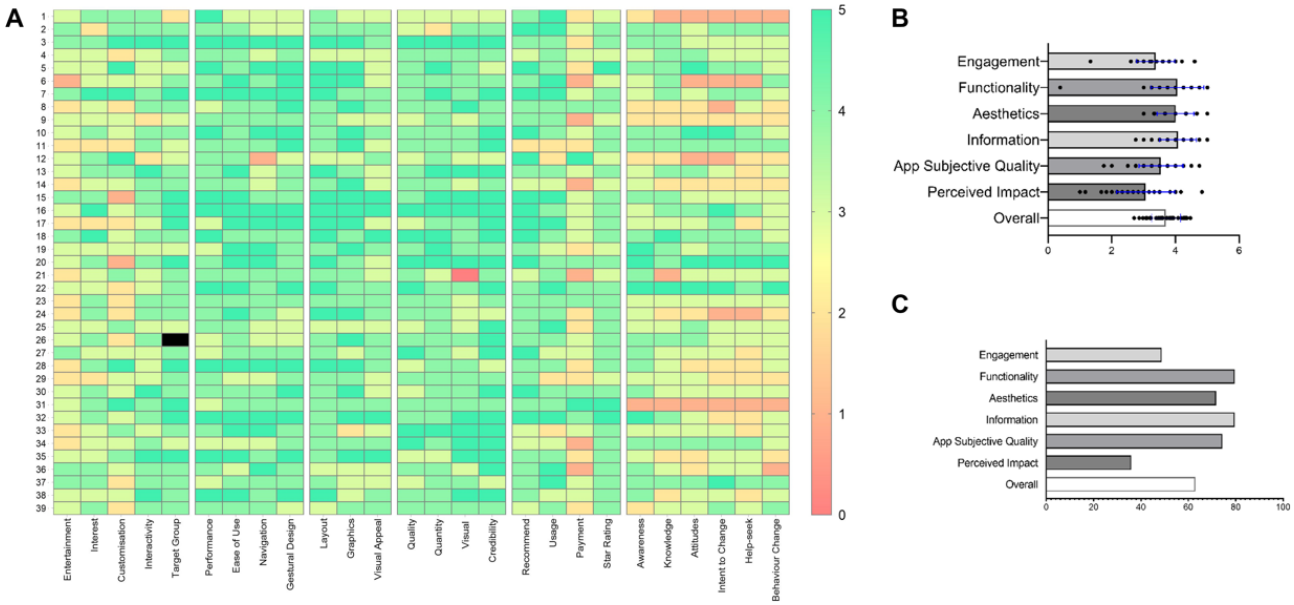
### *uMARS*

The use of acT1ve app was associated with a uMARS total quality median score of 4 (IQR 3.1 - 4.3; Figure 4), which corresponds to a "good" score for overall acceptability. The uMARS objective quality subscale scores (Figure 4) for engagement, functionality, esthetics, information, application quality, and perceived impact were 3.4 (IQR 3.0 - 3.8), 4.1 (IQR 3.8 - 4.7), 4.0 (IQR 3.7 - 4.3), 4.0 (IQR 3.8 - 4.5), 3.6 (IQR 3.3 - 4.0), and 3.2 (2.5 - 3.8), respectively.



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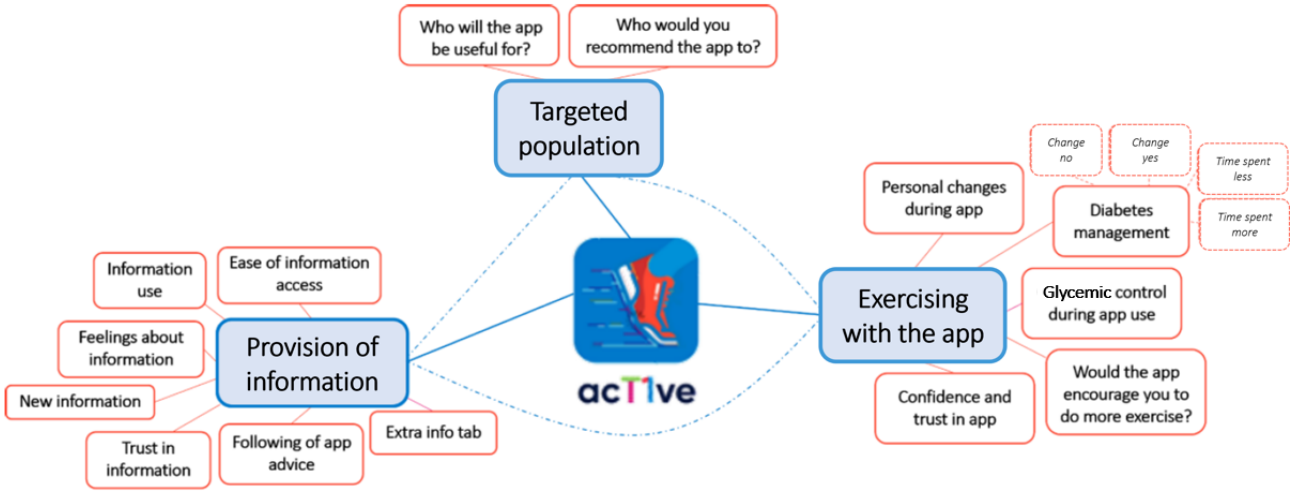
**Figure 4.** User Mobile Application Rating Scale (uMARS) questionnaire scores. 5A: Individual participant questionnaire response scores; 5B: Average quality scores for each uMARS category; and 5C: Percentage of participants rating a score of ≥4 (“good” or “excellent”) for each category.




## Qualitative Results

The interview analysis identified 3 main themes: “Provision of information”; “Exercising with the App”; and “Targeted Population” (Figure 5).

**Figure 5.** Identification of themes and subthemes from thematic interview analysis.




### *Provision of Information*

The “more info” tab in the app contained information about hypo treatment, food guide, and pre- and postexercise advice. This information reflected the international guidelines and served as an educational toolbox for participants. The information tab was viewed by all participants, with comments including that the information was extensive and interesting, with some participants recommending that it needed important aspects to be highlighted by color or bold font. Many participants commented that once they had read the information, they felt that they did not need to refer back to the information on subsequent occasions. Some participants who had longstanding diabetes found the information interesting but not new, while others liked that it acted as a good refresher for information that they had forgotten.

> *Most of the time there wasn’t quite so much planning involved because I didn’t have to like figure things out as much, I could just put in like my sugar levels, insulin levels as they were, and then get the information and just go.* [Participant #23]

Participants felt they could trust the information as it had been provided by a reliable source and were happy that they could access it readily if needed.

> *Yeah, but like it helped a lot. I have more confidence. It’s like actual information that has been put across that you can trust and use.* [Participant #17]



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### *Exercising With the App*

Participants found the app easy to navigate, straightforward, and user-friendly, and liked the simplicity of the interface and how easy it is to navigate the app. One participant noted that,

> *It was easy, like it's just... the way they made it is like so simple, it like reminds you of like apps that have nothing to do with diabetes at all...* [Participant #40]

All participants accessed the app for exercise at least once; however, more than half of the cohort did not use the app for their regular exercise. A plausible explanation for this may be that most participants who were recruited for the present study were already very active and had already determined a management plan for their routine exercise regimen that seemed to work. Some participants who followed the recommended advice from the app reported that the app suggested consuming more carbohydrates or reducing their insulin dose more than what they normally would. Despite this, many participants felt reassured by the information, as it indicated that they were performing the desired diabetes management strategies required during exercise performance.

Participants who used the app for new or spontaneous exercise felt comfortable following the recommendations and reported that following the recommendations resulted in reduced postexercise hypoglycemia and/or improved glycemia throughout the exercise or activity period.

> *Yes, it was definitely easier and definitely gives me more self-confidence to know that what I'm doing, ... I'm like, ... more likely to be safer when riding and having, ...not having the risk of going low and having hypo...* [Participant #19]

The use of the app did not result in an overall increase in exercise or activity; however, 5 participants commented that using the app may encourage them to do a new exercise.

### *Targeted Population*

The app was not used to its full potential by most study participants, as those who exercise frequently were already confident in their management and either forgot to use it or felt it was an extra step to their preparation. Many participants used the app out of curiosity and because they had agreed to the study. All participants commented that this app would be better suited to those individuals with T1D, who were new to exercise, newly diagnosed, or who had fears around engaging in regular exercise [2].

> *I think it would be good for people who have just gotten diagnosed because they wouldn't really know, and they won't have that much information, but I think the app would help them a lot and how to get them started with their sugar levels with activities* [Participant #1]

Participants mentioned this app would also be beneficial for parents to increase their confidence when encouraging their child to become more independent with their diabetes management, or when their child was away from them.

## Discussion

### Principal Findings

Given that it is a requirement by several regulatory bodies to subject any new therapeutic tool to noninferiority testing to indicate that the tool in question is not worse when compared to "treatment as usual," the aim of the current study was to test the safety of the novel mHealth app "acT1ve." The study supports the noninferiority of acT1ve compared with "treatment as usual" with regards to hypoglycemic events, with no difference in the rates of level 1 and level 2 hypoglycemia between both the preapp and app-use phases of the study. Hence, "acT1ve" is a safe app that can be used to guide diabetes management during and after exercise. Even though the use of mHealth technologies has become common practice for diabetes self-management [32,33], there are currently no commercially available apps that provide real-time evidence-based advice for managing glucose levels around exercise. The "acT1ve" app has the potential to fill this gap.

The noninferiority and thus safety of the acT1ve app is supported by the finding that hypoglycemia rate and the percentage of time spent both in the target glucose range (3.9 to 10 mmol/L) as well as above the target glucose range (>10 mmol/L) were similar for both the preapp and app-use phases. These are important findings in the context of the noninferiority testing that is required by the Australian regulatory body to make this app reach the market.

Many mobile app–based interventions have been reported to improve glycemic management in diabetes [34]. Here, in contrast, there was no trend for the use of acT1ve to improve blood glucose management before or during exercise. Such a finding is not surprising, particularly in view of the comments made by some of our participants who noted that the acT1ve app was more likely to be beneficial for newly diagnosed individuals or individuals who are new to exercise. This was not the case for any of our participants, as they had been diagnosed with T1D for at least one year and had been exercising regularly at the time they joined the study. Future studies are thus required to examine the benefit of our app in improving glycemic management in people who engage in unpredictable heterogeneous patterns of physical activities or those who experience a sudden transition from an inactive lifestyle to one that is more physically active.

Exposure to the acT1ve app during the App-use phase did not result in any significant changes in exercise frequency, intensity, duration, and workload (Figure 4) compared with the Preapp phase. A plausible explanation for this lack of significant differences between the preapp and app-use phases may be related to the tendency of many individuals to stick to their routine and perform activities that they are more well-versed in or comfortable with. In this respect, it is noteworthy that the average pattern of activity of our participants was similar to that of people without T1D and of equivalent age in Australia [35], with the exception of strength-based activities. Also, our results should be interpreted with caution since the way the exercise data were collected may have masked some small but significant changes between treatment phases. Indeed, data were



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collected from the combination of available data from the 3 different monitoring platforms (ie, acT1ve, Garmin watch, and paper diary). Also, the calculations to estimate exercise intensity were based on either the use of a MET formula [36] or on predetermined MET values for specific activities outlined16 which are prone to error.

The participant interviews highlighted that participants did not use the app to its full potential. The average duration of diabetes of our cohort was 6.9 years, and most were already very active before starting the study. This suggests that participants were happy with the management plan they already had in place for exercise and used the app only to supplement their current exercise management regime. However, all participants stated that they enjoyed using the app and found the information to be trustworthy and reassuring. All participants felt the app was better suited to individuals who were newly diagnosed or new to exercise. In addition, participants felt the accuracy of the information would encourage those individuals who were reluctant or fearful to engage in exercise, as well as benefit parents and their young children who were growing and navigating diabetes and exercise. In addition, all participants indicated that they would either use the app again or would recommend it to others.

The acT1ve app received good scores for each of the uMARS subscales and its overall quality. The acT1ve app was found to be engaging, usable, informative, and functional with appropriate esthetics. The participants also liked the design of the app. The acT1ve app also compares favorably with the uMARS scores of 89 popular diabetes apps [32]. Indeed, this subset of mobile health apps ranked “acceptable-good” in engagement, functionality, and esthetics, and they ranked “poor-acceptable” in information, app quality score, and app subjective score [32]. Our qualitative analyses also revealed that many participants liked the simple interface of the app, which was easy to navigate, straightforward, and user-friendly. Some of the participants found the information provided by the app to be relevant, appropriate, and clear, with a simple and easy flow of presentation. However, a few found the navigation a little confusing.

Participants’ feedback for future improvements of the app included advice for exercise that lasts longer than one hour, more flexibility in recording the duration of their activity, integration of CGM levels into the app, and facilitation of communication with health care providers. In addition, they suggested the addition of video options for visual learners. Most of these app features desired by the participants were recommended in the initial exercise workshops that we had conducted before developing “acT1ve.” However, these recommendations could not be incorporated into the app design due to the lack of funds.

### Strengths and Limitations

Some of the strengths of the study are both the testing in a free-living setting of an app that is co-designed with young people with T1D and the use of both quantitative and qualitative methodologies to gain an objective and subjective perspective regarding the usability and acceptability of the app. We recognize the various limitations of this study. First, as alluded to earlier, was the lack of a control group, a study design that was adopted to increase the power of our study, but at the expense of its validity. Indeed, the use of a one-arm study design prevents disentangling treatment effects from other effects such as the Hawthorne effect, order effect, regression to the mean, and factors affecting the frequency of physical activity over time. To minimize the impact that these factors might have on our findings, the study was completed during school term to ensure a stable physical activity pattern, and contact with research staff was kept to a minimum. Despite adopting those measures, there were other challenges faced during this study, mainly the COVID restrictions on sports and activities in place in Western Australia, as well as school exams during the intervention phase.

The second limitation was the short duration of the study and small sample size. The study duration of 12 weeks is inadequate to capture seasonal variations in exercise or “novelty waning” effects. Although the sample size and study duration were statistically sufficient for demonstrating noninferiority, a longer trial with a larger cohort could uncover more nuanced effects on glycemic outcomes, exercise habits, and sustained user engagement. To formally test efficacy and benefits of acT1ve and overcome the potential Hawthorne and selection biases of a single-arm study, future randomized controlled trials with a larger sample size and a 6- to 12-month extension will incorporate validated behavior-change measures and comparator arms to assess whether observed improvements reflect true intervention effects or observation biases.

The third limitation was the limited generalizability to less experienced or less active individuals. Most of our participants were physically active and confident in their exercise-related glucose management, and it remains unclear how acT1ve might perform among newly diagnosed individuals. We recognize that adolescents newly diagnosed with T1D or those with sedentary lifestyles may face unique behavior-change challenges (lower baseline self-efficacy and minimal exercise habits). In our future studies, we plan to recruit a more heterogeneous sample across age, activity levels, and years since diagnosis. Since more than half of the cohort did not use the app for their regular exercise, we will include subgroup analysis in future work, stratifying by prior baseline exercise experience and diabetes management proficiency, to determine which subgroups might derive the greatest benefit from the app.

## Conclusions

In summary, despite the limitations inherent to our study design, we conclude that “acT1ve,” a mHealth app which was developed in collaboration with young people with T1D, is safe for diabetes management around exercise. Our findings suggest that our app may play a more important role in helping individuals manage their blood glucose in the face of sudden changes in their pattern of physical activity. Whether this is the case and whether the other possible benefits uncovered by our qualitative data hold true await the performance of a larger-scale randomized control trial to examine the extent to which the use of acT1ve app promotes greater self-efficacy in managing diabetes around exercise.



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## Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

## Authors' Contributions

VBS, PAF, GJS, EAD, and TWJ contributed to the conceptualization and methodology of the study. VBS, EAD, and TWJ contributed to funding acquisition. VBS, RL, WHKS, and HCR contributed to the project administration, resources, software, and supervision. VBS, RL, AR, ST, and GJS contributed to the investigation, data curation, formal analysis, and validation. VBS, RL, and ST contributed to visualization. VBS, RL, and ST contributed to writing the original draft. All authors contributed to writing, review, and editing. EAD is responsible for the integrity of this work.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview questions.
[PDF File, 172 KB - diabetes_v10i1e68694_app1.pdf ]

Checklist
CONSORT checklist.
[PDF File, 143 KB - diabetes_v10i1e68694_app2.pdf ]

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## Abbreviations

**CGM:** continuous glucose monitoring
**CONSORT:** Consolidated Standards of Reporting Trials
**CSII:** continuous subcutaneous insulin infusion
**GI:** glycemic index
**$HbA_{1c}$:** glycated hemoglobin $A_{1c}$
**MDI:** multiple daily injections
**MET:** metabolic equivalent of tasks
**mHealth:** mobile health
**REDCap:** Research Electronic Data Capture
**T1D:** type 1 diabetes
**uMARS:** user Mobile Applications Rating Scale

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# A Tailor-Made Mobile App With a Local Cuisine Database for Self-Management of Type 2 Diabetes Mellitus: Randomized Controlled Trial

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## Abstract

**Background:** There are many mobile apps for diabetes self-management; however, most target Western populations and lack dietary content relevant to Asian contexts. Our mobile app addresses this gap by providing self-care tools and a database of regionally relevant foods.

**Objective:** This study aimed to evaluate the effectiveness of the app in improving glycemic control and self-care behaviors among outpatients with uncontrolled type 2 diabetes at our hospital.

**Methods:** We conducted a randomized controlled trial with adults with type 2 diabetes, hemoglobin $A_{1c}$ ($HbA_{1c}$) of >7%, and access to a smartphone. Participants were randomized to an intervention group (daily use of the Rama Diabetes Care app) or a control group (standard care), with all receiving diabetes self-management education and support. The app includes 6 features, notably a nutritional logging system with a verified database of Thai and commonly consumed foods, including Asian and Western dishes, as well as blood glucose monitoring, exercise and medication tracking, symptom screening, and weight logging. The primary outcome was $HbA_{1c}$ level, and secondary outcomes included fasting plasma glucose (FPG), low-density lipoprotein cholesterol, estimated glomerular filtration rate, BMI, self-care behaviors, and user satisfaction with the app. The study was conducted between November 29, 2023, and October 30, 2024.

**Results:** A total of 129 participants were randomized (intervention: n=64, 49.6%; control: n=65, 50.4%). Participants in the intervention group were younger (mean age 54.6, SD 14.3 years vs 61.9, SD 12.0 years; *P*=.002), whereas baseline $HbA_{1c}$ (mean 9.3%, SD 1.96%) and FPG (mean 179.5, SD 5.9 mg/dL) levels were similar between the groups. Over 6 months, the intervention group showed a greater $HbA_{1c}$ reduction than the control group (mean difference −0.24%), but the difference was not statistically significant (*P*=.13). Among participants aged <65 years, FPG at 6 months was significantly lower in the intervention group (mean difference −29.3 mg/dL; *P*=.03). App satisfaction was rated as moderate.

**Conclusions:** The mobile app achieved glycemic control comparable to that achieved through standard care, with significant improvement in FPG among participants younger than 65 years. Tailor-made apps integrating regionally relevant dietary content may support effective self-management in type 2 diabetes and warrant further evaluation in larger, long-term studies.

**Trial Registration:** ClinicalTrials.gov NCT06176703; https://clinicaltrials.gov/study/NCT06176703

***(JMIR Diabetes 2025;10:e83685)*** doi:10.2196/83685

**KEYWORDS**

Asian; culture; lifestyle; healthy diet; mobile health; mHealth; self-management

## Introduction

Type 2 diabetes mellitus (T2DM) is a major global health challenge that requires lifestyle modification and often pharmacological therapy. Beyond glycemic control, contemporary management emphasizes patient empowerment through education, behavioral support, and individualized care. The American Diabetes Association highlights the central role of diabetes self-management education and support (DSMES), recommending developmentally and culturally tailored education to enhance knowledge, confidence, and sustainable self-care behaviors [1]. In Thailand, a systematic review by Jerawatana et al [2] found that DSMES participation significantly reduced hemoglobin $A_{1c}$ ($HbA_{1c}$) level by 0.66% within 6 months, underscoring the clinical value of structured education.



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Despite its proven benefits, DSMES in Thailand remains predominantly hospital based and resource intensive, limiting accessibility amid the rising prevalence of diabetes. Digital health innovations, particularly mobile health (mHealth) apps, offer scalable solutions to extend DSMES into daily life. The World Health Organization defines mHealth as the use of mobile and wireless technologies to support health objectives [3]. With smartphones now embedded in everyday life, a 2022 systematic review identified 458 mobile apps supporting diabetes medication adherence, with numbers continuing to rise [4]. From the user perspective, one-third of individuals currently use mHealth apps for diabetes self-management, and more than half express interest in future adoption [5]. Moreover, a recent systematic review reported that 11 of 12 studies showed significant $HbA_{1c}$ reductions with mobile app use [6]. However, apps vary widely in design and features, and few incorporate content relevant to Thai users, such as local dietary databases or Thai-language interfaces.

In Thailand, existing tools such as DM Thai Diary for type 1 diabetes and EASYDM for medication adherence [7] address only selected aspects of care, and no comprehensive application for T2DM is available [8]. To address this gap, our institute developed the Rama Diabetes Care app, which provides a comprehensive nutritional database featuring both Thai and international foods and integrates 6 essential self-care domains (nutrition, medication adherence, blood glucose monitoring, physical activity, psychosocial well-being [symptom screening], and weight management) into a single, all-in-one platform. This study evaluated its effectiveness in improving glycemic control and self-care behaviors among patients with uncontrolled T2DM.

## Methods

### Ethical Considerations

All patients provided written informed consent. Patient data were fully anonymized prior to analysis, with access strictly limited to the study team and the software developer. No financial compensation or reimbursement was provided to participants. The study protocol was approved by the Human Research Ethics Committee of the Faculty of Medicine Ramathibodi Hospital, Mahidol University (MURA2023/872). This trial has been registered on ClinicalTrials.gov (NCT06176703).

### App Design and Development

The Rama Diabetes Care app (Figure 1) was developed based on DSMES principles to provide comprehensive self-management support for patients with T2DM, including self-monitoring and interpretation of blood glucose, physical activity tracking, nutritional therapy, and other self-care tasks. The app was developed by Vernity in collaboration with the Faculty of Medicine of Ramathibodi Hospital. To ensure reliability and content validity, the app's content was rigorously reviewed by a multidisciplinary team; specifically, the nutritional database was verified by certified nutritionists, whereas other app components and clinical algorithms were validated by endocrinologists to ensure medical accuracy. The app provides alerts to help patients maintain appropriate blood glucose levels and support digital recording of self-monitoring data, reducing reliance on paper logs. It also delivers educational content to promote effective diabetes self-management. While the app does not offer real-time physician-patient interaction, users can contact the emergency number within the app or reach the diabetes care team through the available channels if questions or urgent issues arise. To strictly comply with the hospital's cybersecurity protocols, the app operates as a stand-alone platform without direct electronic medical record integration. Instead, it functions as a digital logbook, allowing patients to present visualized data directly from their smartphones to physicians during consultations for immediate treatment adjustments.



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**Figure 1.** The 6 core features of the Rama Diabetes Care app: symptom screening, blood glucose monitoring, medication logging, dietary intake logging, physical activity tracking, and body weight monitoring. As an example of app use, the app operates through the following steps: (1) tapping the app icon, (2) selecting the desired category (shown in this figure as the "food" category), (3) choosing the meal to be logged, and (4) entering the name of the consumed food item. The app then displays the energy content of the selected food, which can be saved for future reference or modification. API: application programming interface.




The app comprises 6 key features. Nutritional logging is a key feature of the app, incorporating a verified database of Thai and commonly consumed international foods. Nutritional values for international dishes were obtained from the US Department of Agriculture FoodData Central database, whereas nutritional values for Thai dishes were calculated using INMUCAL (version 3.0) and the Nutrition 100 g program, both developed by the Institute of Nutrition, Mahidol University, and subsequently verified by certified nutritionists. The app provides energy (kcal), carbohydrate (g), sodium (mg), fat (g), and sugar (g) information, offering immediate feedback on dietary appropriateness and statistical overviews. Other features include blood glucose monitoring, with alerts indicating whether levels are within the target range (70 - 180 mg/dL); medication logging, with reminders and intake recording; exercise tracking with manual or device-synchronized entries; daily weight



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logging; and symptom screening evaluating quality of life and diabetic foot issues. To support long-term monitoring, the app features comprehensive visualization tools, enabling users to view nutritional and physical activity trends over various timelines (daily to yearly), blood glucose summaries highlighting abnormal readings, and longitudinal weight graphs. Collectively, these features serve as reminders for behavioral modification and provide essential data for optimizing future medical treatment.

The app is compatible with both iOS and Android systems. Technical issues were addressed by the research team in coordination with the developers.

### Recruitment and Data Collection

Patients attending DSMES sessions at the diabetes counseling group in the outpatient department on Tuesday and Thursday mornings were invited to participate in the study. The study was conducted between November 29, 2023, and October 30, 2024. Eligible participants were adults (≥18 years) with T2DM, access to a smartphone and the internet, and no prior use of this app. For patients aged ≥65 years who were not proficient with smartphone use, daily caregivers could operate the app on their behalf, with informed consent obtained from the caregivers. Exclusion criteria included use of continuous glucose monitoring or insulin pumps, pregnancy, or visual or hearing impairments.

Eligible patients were randomly assigned to the intervention or control group using a block of 2 generated by an independent statistician. The investigator performed allocation via a digital concealed system. To prevent data contamination, access to the app, which is not publicly available, was restricted through unique log-in credentials (username and password) generated exclusively by the research team, and participants were strictly instructed not to share these credentials. Participants in the intervention group received training on app use and were encouraged to engage with the app at home. One week after randomization, a follow-up phone call was made to assess adherence and address any app-related issues.

Baseline laboratory data, including $HbA_{1c}$ level, fasting plasma glucose (FPG), estimated glomerular filtration rate, and low-density lipoprotein cholesterol (LDL-c), were retrieved directly from the hospital's electronic medical record. Data obtained within 3 months before enrollment were permitted. However, in most cases, these values were obtained on the screening day during the participants' scheduled visits. BMI was calculated from body weight and height measured at screening. Outcomes were assessed at 3 and 6 months after randomization. The primary outcome was $HbA_{1c}$ level. Secondary outcomes included objective measurements (FPG, estimated glomerular filtration rate, LDL-c, and BMI) and subjective outcomes assessed via questionnaires. For these objective measurements, we coordinated with the participants' attending physicians to ensure that the required tests were ordered during follow-up visits. Assessment bias was minimized by relying on these objective values, which were processed by hospital laboratory staff blinded to group allocation. Subjective outcomes were assessed using validated questionnaires, including the DSMES questionnaire, metabolic equivalent of task score, Global Physical Activity Questionnaire, Generalized Anxiety Disorder–7, Patient Health Questionnaire–9, EQ-5D-5L, and satisfaction with diabetes management. Intervention participants additionally rated their satisfaction with the app at 3 and 6 months using a Likert scale developed by the research team. Finally, to ensure impartiality during the evaluation phase, data analysis was conducted on deidentified data after completion of the 6-month follow-up. Six-month outcomes were analyzed using available data only, and participants with missing outcome data at the 6-month follow-up were excluded from the analysis. The study protocol remained unchanged after trial commencement, with no modifications to eligibility criteria, interventions, or outcome assessments.

### Statistical Analyses

The sample size was calculated using 2 independent means based on the study by Goodarzi et al [9], resulting in a total of 128 participants (64 in each group). Baseline characteristics of the study population were summarized as percentages for categorical variables and as means and SDs or medians and IQRs for continuous variables as appropriate. Baseline $HbA_{1c}$ level was defined as the value measured within 3 months before the DSMES session, whereas follow-up $HbA_{1c}$ values were obtained at physician appointments, allowing for a deviation of up to 1 month from the 3- and 6-month time points.

Comparisons of outcomes between the intervention and control groups at each time point were performed using independent-sample 2-tailed *t* tests for normally distributed data and Mann-Whitney rank sum tests for nonnormally distributed data. Statistical significance was set at $P<.05$. Subgroup analyses were conducted using the same methods, and baseline imbalances were adjusted in outcome analyses as appropriate. All statistical analyses were performed using Stata (version 18.0; StataCorp LLC).

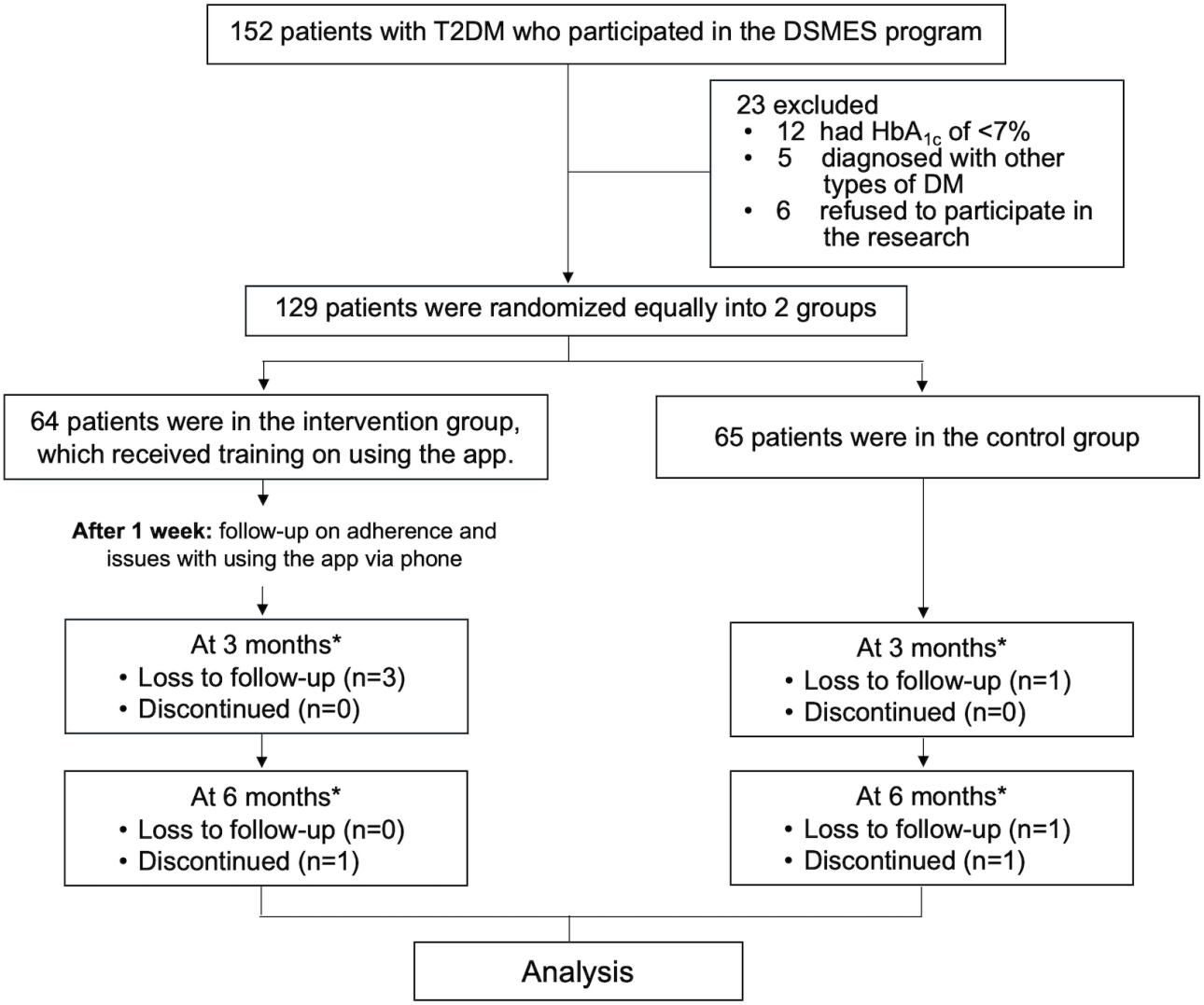
## Results

A total of 152 participants from the diabetes counseling group were initially assessed for eligibility (Figure 2), of whom 23 (15.1%) were excluded for not meeting the inclusion criteria, leaving 129 (84.9%) participants (mean age 58, SD 1.2 years; n=74, 57.4% female; mean BMI 27.3, SD 5.2 $kg/m^2$; mean duration of diabetes 9.7, SD 0.3 years) who were randomized into the intervention (n=64, 49.6%) and control (n=65, 50.4%) groups. Mean baseline $HbA_{1c}$ levels were 9.3% (SD 2%) in the intervention group and 9.1% (SD 1.6%) in the control group, with no statistically significant difference ($P=.61$). Participants in the intervention group were significantly younger than those in the control group (mean 54.6, SD 14.3 years vs mean 61.9, SD 12.0 years, respectively; $P=.002$; mean age difference of 7 years). Other baseline characteristics, including duration of diabetes and proportion of patients receiving insulin therapy and other medications, were comparable between groups (Table 1).



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**Figure 2.** Study flowchart. DM: diabetes mellitus; DSMES: diabetes self-management education and support; $HbA_{1c}$: hemoglobin $A_{1c}$; T2DM: type 2 diabetes mellitus *Assessment included objective assessment ($HbA_{1c}$, low-density lipoprotein cholesterol, estimated glomerular filtration rate, and BMI) and subjective assessment (self-care behaviors via questionnaire and satisfaction of the app; only for the intervention group).






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**Table .** Baseline characteristics.

| Characteristic | Intervention group (n=64) | Control group (n=65) | *P* value |
|---|---|---|---|
| Age (y), mean (SD) | 54.6 (14.3) | 61.9 (11.9) | .002 |
| Female participants, n (%) | 35 (54.7) | 39 (60.0) | .29 |
| Duration of diabetes mellitus (y), median (IQR) | 9.2 (1-20) | 10.2 (1-22) | .31 |
| Number of diabetic complications[a], n (%) | | | .14 |
| 0 - 1 | 47 (73.4) | 42 (64.6) | |
| 2 - 3 | 16 (25.0) | 22 (33.8) | |
| 4 - 6 | 1 (1.6) | 1 (1.5) | |
| Patients treated with insulin, n (%) | 44 (68.8) | 43 (66.2) | .59 |
| Previously attended a DSMES[b] program, n (%) | 44 (68.8) | 49 (75.4) | .15 |
| Education beyond a bachelor's degree, n (%) | 47 (73.4) | 32 (49.2) | <.001 |
| Body weight (kg), mean (SD) | 73.0 (16.1) | 69.8 (18.9) | .30 |
| BMI (kg/m$^2$), mean (SD) | 27.6 (4.9) | 26.9 (5.6) | .52 |
| Fasting plasma glucose (mg/dL), mean (SD) | 177.6 (66.0) | 181.3 (68.7) | .76 |
| $HbA_{1c}$[c] (%), mean (SD) | 9.3 (2.0) | 9.1 (1.6) | .61 |
| LDL-c[d] (mg/dL), mean (SD) | 118.7 (43.4) | 99.1 (38.5) | .02 |
| eGFR[e] (mL per min per 1.73 m$^2$), mean (SD) | 80.3 (28.8) | 73.9 (34.5) | .25 |
| Questionnaires about diabetic self-care | | | |
| DSMES score, mean (SD) | 59.5 (11.2) | 51.3 (12.3) | <.001 |
| MET[f] score, median (IQR) | 202.14 (0-3080) | 228.76 (0-2700) | .17 |
| GPAQ[g] score, median (IQR) | 53.6 (0-960) | 174.5 (0-3150) | .67 |
| GAD-7[h] score, median (IQR) | 2.4 (0-9) | 1.7 (0-8) | .06 |
| QOL[i] score, mean (SD) | 5.9 (1.6) | 6.1 (1.3) | .33 |

[a]Diabetic complications: diabetic retinopathy, diabetic kidney disease, diabetic neuropathy, and clinical atherosclerotic cardiovascular disease.

[b]DSMES: diabetes self-management education and support.

[c]$HbA_{1c}$: hemoglobin A1c.

[d]LDL-c: low-density lipoprotein cholesterol.

[e]eGFR: estimated glomerular filtration rate.

[f]MET: metabolic equivalent of task.

[g]GPAQ: Global Physical Activity Questionnaire.

[h]GAD-7: Generalized Anxiety Disorder–7.

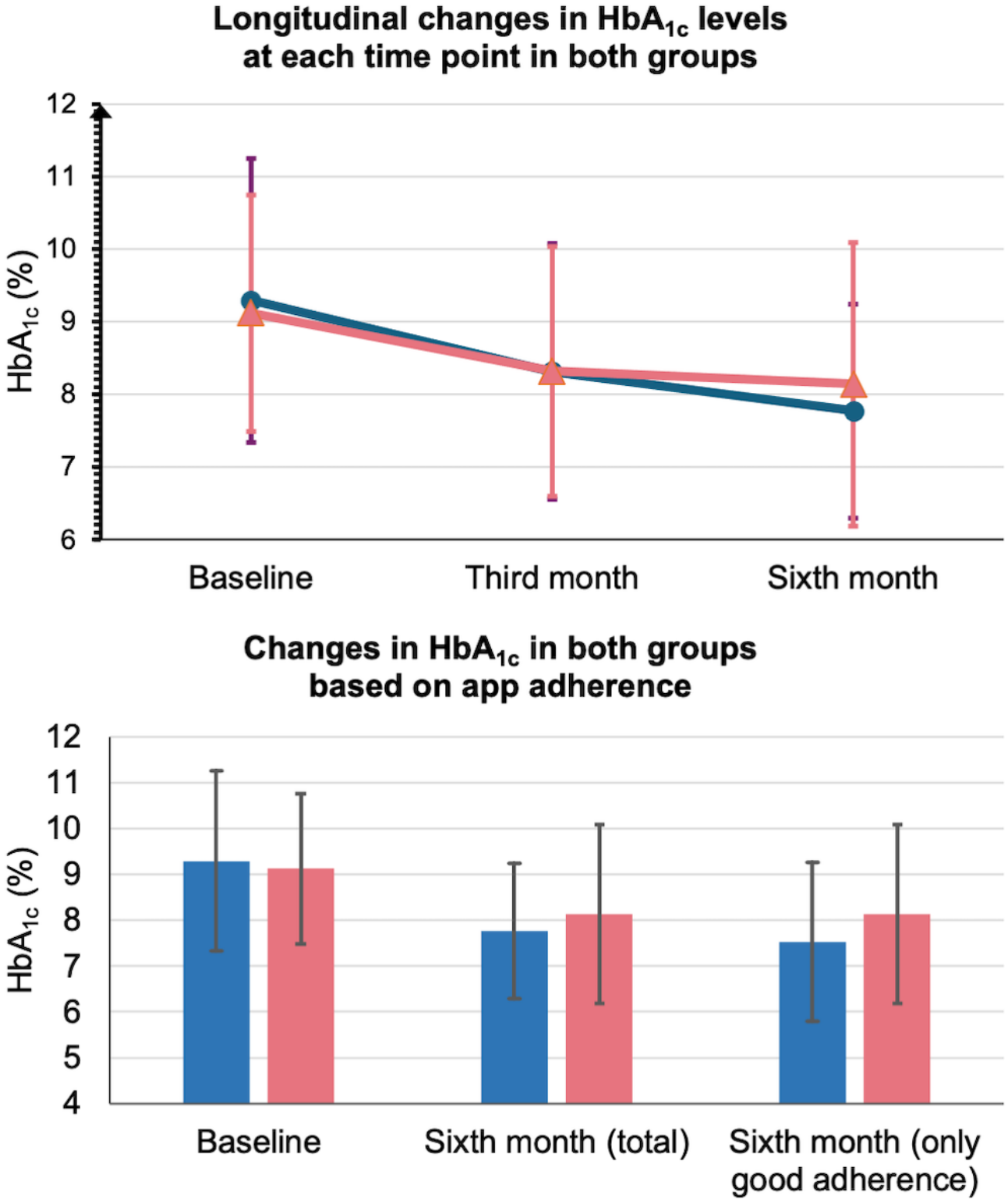
[i]QOL: quality of life.

At 3 months (Figure 3), both the intervention and control groups showed a trend toward reduced $HbA_{1c}$ levels (mean 8.3%, SD 1.8% vs mean 8.3%, SD 1.7%, respectively), consistent with reductions in FPG (mean 142.2, SD 51.7 mg/dL vs mean 159.8, SD 62.6 mg/dL, respectively). Other parameters—including body weight, serum LDL-c, and diabetes-related questionnaire scores—showed only minor changes from baseline, as detailed in Multimedia Appendix 1.



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**Figure 3.** Comparative changes in hemoglobin $A_{1c}$ ($HbA_{1c}$) levels between the intervention and control groups. The blue lines and boxes indicate the intervention group, and the pink lines and boxes indicate the control group.




At 6 months, the end of data collection, 4.7% (6/129) of the total participants were lost to follow-up, including 4 in the intervention group and 2 in the control group. In the intervention group, 4.7% (3/64) of the participants discontinued due to difficulties using the app, and 1.6% (1/64) transferred care to another hospital. In the control group, 1.5% (1/65) of the participants were lost to follow-up, and 1.5% (1/65) transferred treatment to another facility. Mean $HbA_{1c}$ levels were 7.8% (SD 1.5%) in the intervention group and 8.1% (SD 1.9%) in the control group, with a nonsignificant difference of 0.24%. FPG was approximately 10 mg/dL lower in the intervention group at 6 months (mean 133.4, SD 43.1 mg/dL vs mean 144.9, SD 67.9 mg/dL), also without statistical significance. Participants in the intervention group exhibited significantly higher DSMES scores from baseline to 6 months. Additional outcomes are detailed in Multimedia Appendices 1 and 2.



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Subgroup analyses were conducted among participants potentially more likely to benefit from the app (Multimedia Appendix 3), including those aged <65 years, with diabetes duration of >10 years, educational level above a bachelor's degree, and BMI of >25 kg/m$^2$. Notably, a statistically significant difference in FPG was observed specifically in participants aged <65 years. In the subgroup of participants aged <65 years, mean FPG at 6 months was 178.8 (SD 66.2) mg/dL in the intervention group and 193.1 (SD 75.5) mg/dL in the control group, with a statistically significant mean difference of 29.3 mg/dL. Average adherence to the app, defined as the proportion of days with recorded blood glucose measurements, was 55.8%. Among participants with good adherence (>50%), the mean 6-month $HbA_{1c}$ level was 7.5% (SD 1.7%) in the intervention group and 8.1% (SD 1.9%) in the control group ($P$=.51). Mean satisfaction scores for the app were 23 and 24 out of 35 at 3 and 6 months, respectively, indicating moderate satisfaction. Item analysis revealed that participants rated the app's benefits for diabetes self-management highest among all domains. Regarding safety, no app-related adverse events were observed during the study period. There were no reports of severe hypoglycemia or hospitalizations due to hyperglycemic crises resulting from the use of the app.

## Discussion

### Principal Findings

The culturally tailored, Thai-language Rama Diabetes Care app, incorporating regional foods and Thai fonts, is feasible and can support diabetes self-management by providing behavioral alerts and accessible educational content. The inclusion of a verified database covering Thai dishes and specific ingredients (eg, chili paste or *nam phrik*) ensures that the app is highly practical for Thai users. This feature serves as a tool for dietary reflection, allowing patients to assess nutritional value before consumption and develop mindful eating habits that support glycemic control. Furthermore, unlike paper-based methods, the digital interface offers convenience and real-time accessibility, encouraging consistent self-monitoring. In this randomized controlled trial, both groups exhibited reductions in $HbA_{1c}$ level at 6 months, with a greater, though not statistically significant, decrease observed in the app group. FPG was lower in younger intervention participants, and DSMES scores were consistently higher in the app group throughout follow-up.

The modest, nonsignificant reduction in $HbA_{1c}$ level observed in this study is consistent with findings from previous research on DSMES. The approximately 1% $HbA_{1c}$ level reduction in the control group receiving DSMES alone aligns with results of prior studies that have reported reductions of 0.66% [2] and 1.5% [10] at 6 months. Variations across studies may be attributable to factors such as physician-directed medication adjustments and baseline patient motivation. Intervention groups using apps in past systematic reviews showed variability in glycemic responses, often influenced by differences in app design, user engagement, and participant characteristics [6,11-15]. For example, the BlueStar diabetes app—the first Food and Drug Administration–approved mobile prescription therapy in the United States—showed no significant $HbA_{1c}$ level reduction in a multicenter pragmatic trial in Canada, likely due to the main barrier of low app use [16]. In our study, although the app demonstrated a downward trend in $HbA_{1c}$ level beyond 6 months, the relatively short follow-up period may have limited the ability to detect statistically significant differences. Overall, participants expressed moderate satisfaction with the app. Users specifically appreciated the immediate feedback and safety alerts provided by the app, particularly regarding the appropriateness of their dietary choices and capillary blood glucose levels. Notably, the highest satisfaction ratings were driven by the perceived benefits of the app in supporting effective diabetes self-management. User feedback also indicated interest in longer app use, suggesting that extended engagement could yield more pronounced improvements. These findings highlight app adherence as a critical determinant of efficacy and may partially explain the modest outcomes observed in this trial. In this study, adherence greater than 50% was not associated with a statistically significant reduction in $HbA_{1c}$ level, suggesting that higher levels of adherence may be necessary to achieve clinical benefits. Further investigation is warranted.

Subgroup analysis revealed that participants younger than 65 years using the app had lower FPG, potentially reflecting greater motivation and proficiency with technology. In contrast, no differences in glycemic control were observed in subgroups defined by BMI of ≥25 kg/m$^2$, diabetes duration of ≥10 years, or education above a bachelor's level. Evidence from a systematic review of 28 studies indicates that younger, more technology-savvy individuals are more likely to engage effectively with mHealth apps [17]. Similarly, a prospective cohort study in China found that patients younger than 40 years with newly diagnosed T2DM experienced greater $HbA_{1c}$ level reductions and improved self-monitoring and physician-patient communication when using a diabetes app [18]. These findings suggest that mobile apps may confer greater benefits in certain populations, highlighting the challenge of designing apps that are usable and effective across diverse user groups.

In addition to glycemic outcomes, this study evaluated patient-reported outcome measures (PROMs), which, according to the US Food and Drug Administration guidance for medical product development, involve questionnaires that allow patients to report on their physical and psychosocial health as well as their quality of life [19]. There is prior evidence suggesting that mHealth interventions can improve both $HbA_{1c}$ and quality of life while reducing diabetes-related distress [20]. App users exhibited higher PROM scores than controls, although the differences were not statistically significant. This may reflect limited emphasis of the app on quality of life domains such as mental health support. Short-term follow-up may also limit detection of meaningful changes, and baseline psychological status could influence responses. Future iterations of the app should integrate features targeting PROMs to more comprehensively support patient-centered outcomes.

This study has several strengths. Its randomized controlled trial design allowed for rigorous evaluation, with comprehensive collection of both objective and subjective outcomes—the latter



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being particularly valuable for assessing digital health interventions. Follow-up was robust, with less than 10% (6/129, 4.7%) participant attrition. Importantly, this study demonstrates the feasibility and potential efficacy of the Rama Diabetes Care app, a comprehensive, Thai-language platform featuring extensive nutritional data on local foods, thereby reducing usability barriers for Thai patients with T2DM. Distinguishing itself from existing tools such as Carbs App and DM Thai Diary that focus primarily on carbohydrate counting, our app offers a verified database of over 500 items with complete nutritional profiles (energy, sodium, fat, and sugar). These comprehensive data are clinically vital for holistic management, allowing patients to control not just blood glucose but also body weight, blood pressure, and lipid profiles. Consistent with prior research, culturally adapted digital interventions, such as Spanish-language programs in the United States, have been shown to improve glycemic control in users compared to nonusers [21]. Moreover, unlike specialized tools such as mySugr (focused on glucose monitoring) or EASYDM (focused on medication), our app consolidates 6 essential self-care features into a single "all-in-one" platform. This design streamlines the user experience, enabling holistic self-management without the burden of switching between multiple apps.

Limitations should also be noted. The app did not include features such as patient coaching or real-time patient-health care provider communication, which could further enhance glycemic outcomes. Incorporating these features could enhance the app's effectiveness in glycemic control, as demonstrated in many previous studies [21,22]. Suboptimal adherence likely contributed to the modest effects observed in this study. Future app iterations may benefit from incorporating engagement strategies such as automated notifications, reward systems, and culturally relevant prompts. Sustaining an mHealth platform also requires continuous updates, user-centered design, simplified data entry (eg, photo-based inputs), and robust data security [6]. A study conducted in China found that, among all app domains, patient ratings were lowest for engagement [23]. Additionally, adequate funding is essential for maintenance, and scaling the app for nationwide use may necessitate government support to benefit users broadly. Finally, to maximize clinical impact, future development should focus on educational content that promotes meaningful behavior change, as well as integration of patient-reported outcomes.

## Conclusions

A culturally tailored, Thai-language mobile app with a local cuisine database reduced $HbA_{1c}$ levels more than DSMES alone at 6 months, although the difference was not statistically significant. The intervention also significantly lowered FPG in participants younger than 65 years, potentially reflecting greater motivation and proficiency in using digital self-management tools in this group.

## Acknowledgments

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## Data Availability

The datasets analyzed during this study were derived from participants' electronic health records and app use logs. Due to privacy and confidentiality restrictions, these data are not publicly available but may be obtained from the corresponding author on reasonable request and with appropriate institutional approvals.

## Authors' Contributions

Conceptualization: SW and CS
Data curation: SW, WP, and CS
Formal analysis: SW, WP, and CS
Investigation: SW, WP, and CS
Methodology: SW and CS
Supervision: SW and CS
Writing—original draft: SW



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Writing—review and editing: CS
All authors discussed and interpreted the results and reviewed and revised the manuscript before submission.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Primary outcome of the study.
[DOCX File, 20 KB - diabetes_v10i1e83685_app1.docx ]

Multimedia Appendix 2
Secondary outcomes of the study.
[DOCX File, 28 KB - diabetes_v10i1e83685_app2.docx ]

Multimedia Appendix 3
Subgroup analysis.
[DOCX File, 24 KB - diabetes_v10i1e83685_app3.docx ]

Checklist 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File, 462 KB - diabetes_v10i1e83685_app4.pdf ]

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## Abbreviations

**DSMES:** diabetes self-management education and support
**FPG:** fasting plasma glucose
**HbA1c:** hemoglobin A1c
**LDL-c:** low-density lipoprotein cholesterol
**mHealth:** mobile health
**PROM:** patient-reported outcome measure
**T2DM:** type 2 diabetes mellitus


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# Exploring Desired Features of Mobile Health Apps for Patients With Diabetes to Enhance Engagement and Self-Management: Qualitative Study

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## Abstract

**Background:** Diabetes mellitus (DM) is a chronic condition requiring effective self-management to maintain glycemic control and prevent complications. Mobile health (mHealth) apps offer potential solutions by providing real-time monitoring, personalized feedback, and educational resources. However, their long-term adoption is hindered by a lack of user involvement in the development process and insufficient cultural adaptation. This study aims to explore the perspectives of patients with DM in Hong Kong on the functionalities and features of mHealth apps, highlighting the importance of tailoring these apps to meet local cultural needs.

**Objective:** The objective of this study is to understand the views of patients with DM on the development of mHealth apps and the demand for app functions in order to provide a basis for the development of DM prevention apps.

**Methods:** This descriptive qualitative study conducted semi-structured interviews with 10 patients with DM attending a District Health Centre in Hong Kong in May 2024, using a purposive sampling strategy. The transcribed data were analyzed by the inductive content analytical method, and themes were extracted with the aid of NVivo (version 15.0; QSR International) software.

**Results:** In total, 7 key themes were identified: accurate information resources, automatic tracking and monitoring of health metrics, reminders, personalized customization options, intuitive usability, efficient data-sharing capabilities, and interactive design. Additionally, the study emphasizes the importance of cultural adaptation and the potential of artificial intelligence–enabled mHealth apps to enhance personalized information delivery. Ensuring the credibility and professionalism of information sources is also essential.

**Conclusions:** The results provide valuable insights for enhancing the self-management capabilities of patients with DM and inform the future development of mHealth apps focused on DM prevention.

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**KEYWORDS**

diabetes mellitus; mHealth; mobile app; self-management; smartphone

## Introduction

Diabetes mellitus (DM) is a chronic disease characterized by high incidence, disability rates, and mortality, posing significant threats to human health and representing a major public health concern [1]. Effective self-management practices—such as tracking blood glucose levels, adhering to medication or insulin therapies, monitoring nutrition, and engaging in regular physical activity—are crucial for maintaining glycemic control and preventing diabetes-related complications [2]. The advent of mobile health (mHealth) smartphone apps has introduced an innovative approach for patients with DM to enhance their self-care capabilities [3-5]. However, despite their proven effectiveness in DM management, the long-term use of these mHealth apps has been hindered by high attrition rates [6]. This attrition has been attributed to insufficient consideration of end-users' preferences and self-management needs, which are vital for fostering long-term engagement and informing the development of effective mHealth solutions [7,8].

To date, limited studies have explored patients' usage patterns, feature preferences, and recommendations for essential DM mHealth apps. Existing evidence suggests diverse views among patients regarding the key functionalities required to support their self-care needs. While some studies highlight preferences for data recording, social coaching, reminders, and remote collaboration with health care professionals [9,10], others emphasize the importance of carbohydrate counting, glucose tracking, and activity monitoring [11,12]. Additionally, some



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studies on patient needs did not include participants who had actual app usage, limiting the applicability of their findings [13].

Prior research has emphasized the importance of cultural adaptation in the success of mHealth apps [14]. Insufficient tailoring of app functionalities to align with cultural norms, values, and preferences has posed significant challenges for DM self-management, reducing patients' overall acceptability, adherence, and the effectiveness of such interventions [15]. Therefore, it is crucial to adjust self-management mHealth apps for patients with DM based on distinct cultural, lifestyle, and dietary habits across different regions and ethnicities. Most existing research has been conducted in Western countries, such as the United Kingdom [11,16,17] and the United States [13,14], as well as in Mainland China [10,18]. Very few studies have focused on the health care system and cultural landscape of Hong Kong.

Hong Kong, as a densely populated and highly urbanized city with a blend of Eastern and Western influences, exhibits distinctive dietary habits, lifestyle patterns, and linguistic frameworks. For example, the popularity of Cantonese cuisine alongside Western fast food has increased the demand for dietary caloric conversion features within mHealth apps. Furthermore, the necessity for multilingual support—including Cantonese, English, and Mandarin—highlights the importance of incorporating multilingual design and voice recognition capabilities to enhance user accessibility and engagement.

In light of these contextual factors, this qualitative study aims to explore the requirements and preferences of patients with DM in Hong Kong for the functions and design of mHealth apps. The insights gained are expected to enhance their self-management capabilities and provide valuable references to inform the design and development of such apps.

# Methods

## Study Design

This study used a descriptive qualitative research design, grounded in the philosophical tenets of naturalistic inquiry [19]. This qualitative approach uses everyday language and low-inference interpretative processes to represent reality by describing experiences or events [20]. It is suitable for informing diverse practical applications, such as clinical interventions, scoring systems, needs assessments, questionnaire development, and surveys [19]. Therefore, this method was well-suited to our aim of gaining rich, contextualized insights into the requirements and preferences of patients with DM for mHealth app features.

We collected data using semi-structured, in-depth interviews. The interview guide was developed based on prior experience and a review of relevant literature, aligned with the study's objectives. Before the formal interviews, 2 patients with DM were pre-interviewed, and the interview outline was adjusted according to the pre-interview analysis results. The formal interview outline is presented in Textbox 1. The study outcomes were reported according to the Consolidated Criteria for Reporting Qualitative Research [21].

**Textbox 1.** Semi-structured interview guide.

1. Could you share some of your experiences with your diabetes mellitus (DM) condition and the challenges you've faced in self-management?
2. Do you currently use an mHealth app to manage your DM, or have you used one in the past?
   a. Which mHealth management apps have you used? How long and how often have you used them?
   b. What features do you find particularly useful in these apps? Are there any features that are not very useful and could be improved further?
3. We are aiming to develop an mHealth app to help manage your daily health. What features would you like to see in it?
4. Is there anything else you would like to add on the topics we have discussed today?

## Participants and Recruitment

A purposive sampling approach was used to select participants diagnosed with DM for the qualitative interviews. Eligible patients were recruited from the Hong Kong District Health Centre in May 2024. Recruitment posters were displayed at the center to solicit participant involvement. A research assistant established initial phone contact with eligible patients, introducing the study, explaining the consent procedures, and informing them about the duration of the in-depth interviews. Patients willing to participate were scheduled for in-person interviews conducted on-site at the center. All eligible participants who initially consented completed the scheduled interview sessions without dropouts or refusals.

The inclusion criteria were as follows: (1) diagnosed with DM according to the 2019 WHO diagnostic criteria; (2) aged 18 - 80 years; (3) no cognitive impairment and able to communicate effectively with health care professionals; (4) signed informed consent and agreed to participate in the study. The exclusion criteria were as follows: (1) patients with severe complications or significant dysfunction of other major organs; (2) patients with incomplete data or who withdrew from the study.

The sample size was determined based on the principle of information saturation. After the 8th interview, no new themes emerged, and 2 additional interviews were conducted to confirm saturation, ultimately resulting in a total of 10 participants. To protect patient privacy, these individuals have been labeled as P1 through P10. Demographic information was collected for each participant before initiating an interview session and is reported in Table 1.



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**Table .** Demographic and health characteristics of total participants.

| Characteristic | Participants, n (%) |
|---|---|
| Age (years) | |
| 60 - 75 | 10 (100) |
| 76 or older | 0 (0) |
| Gender | |
| Male | 9 (90) |
| Female | 1 (10) |
| Education | |
| Primary school | 1 (10) |
| High school | 6 (60) |
| Tertiary education | 3 (30) |
| Employment status | |
| Employed | 2 (20) |
| Unemployed | 0 (0) |
| Retired | 8 (80) |

## Data Collection

Face-to-face interviews, each lasting 60 minutes, were conducted in an independent activity room at the Center, free from external distractions. The research team, led by a principal investigator and supported by 2 research assistants, conducted all interview sessions and collected field notes throughout the process. The team had undergone comprehensive training in qualitative research methods, equipping them with the necessary skills and expertise for this study.

Each interview commenced with a brief introduction. Interviews were recorded with participant consent and guided by a pre-tested, semi-structured protocol. No other individuals were present during the interviews. Participants were not involved in the design, conduct, or reporting of the dissemination of this research. All interviews were conducted in a single session, with no repeat interviews.

Prior to the interviews, participants were informed of the study's purpose and assured of privacy protections. The main topics included factors influencing effective DM management and perceived useful features of mHealth apps for improving self-care. During the interviews, researchers actively listened, used appropriate questioning techniques, and promptly recorded key information. They also observed and documented participants' nonverbal cues, such as pauses, smiles, body language, and mood changes. After each session, a reflective diary was written to identify and correct any issues for the next interview.

## Data Analysis

All interviews were audio-recorded and transcribed verbatim. Inductive content analysis was applied to examine the data at both the manifest and latent levels, following the methodology outlined by Elo and Kyngäs [22], which involved open coding, category development, and abstraction. This analytical process was completed using NVivo (version 15.0; QSR International) software. Initially, 2 researchers (NY and WAKC) iteratively reviewed the transcribed text. The analysis began with open coding, where the researchers generated descriptive notes directly in the margins, which were then transferred to a coding sheet to generate subcategories. Following the open coding, the lists of resulting subcategories were grouped into main categories based on both differences and similarities. This analytical process involved ongoing, iterative discussions with the research team to refine the codes and categories, aiming to enhance the overall trustworthiness of the study's findings. To further ensure credibility, 2 researchers independently coded the data, followed by peer debriefing meetings with the research team to refine the coding framework. An audit trail documenting analytical decisions was maintained to promote dependability. Transferability was supported by detailed reporting of participant demographics and rich contextual descriptions. Quality assurance was incorporated through methodological rigor, including researcher training, data triangulation, and audit trail maintenance.

Data from 7 principal codes and 12 subcodes were assembled into the interest domain (categorization). Data from the remaining codes were considered not relevant to the research aim and were therefore treated as dross (Table 2). The informants were not invited to comment on the transcriptions or provide feedback on the findings. Although participants discussed the functions they valued in an mHealth app, formal prioritization techniques, such as structured ranking exercises, were not used. Instead, relative priorities were inferred based on the frequency and emphasis with which different functions were mentioned during the interviews.



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**Table .** Desired features and functionality for diabetes mellitus (DM) self-management mHealth app.

| Theme or domain | Subtheme |
|---|---|
| Information resource | Provide clinically validated and comprehensive information covering key self-care aspects such as disease, comorbidities, exercise, and medication. |
| | Offer guidance to support informed choices regarding diet, fitness, and lifestyle factors. |
| Automated tracking and monitoring | Track and store historical data, including diet, physical activity, blood glucose levels, and medication usage. |
| | Automatically convert image data (eg, food photos) into electronic records. |
| Reminder | Deliver appropriate reminders and alerts for tasks such as monitoring blood sugar regularly, managing medication, and attending health care appointments. |
| Personalized customization | Provide personalized health recommendations, delivering just-in-time information. |
| | Automatically generate customized goals, feedback, and action plans based on user input data in a flexible manner. |
| Intuitive usability | Use simple visual design, and provide interpretation and translation of medical knowledge and test results. |
| | Incorporate multilingual support and voice recognition capabilities. |
| Efficient data sharing | Enable seamless integration with the health care system for effective care coordination. |
| Interactive design | Incorporate in-app peer support communities and forums. |
| | Enable real-time web-based communication with healthcare coaches. |

### Ethical Considerations

This study was approved by the Institutional Review Board of a university in Hong Kong (HSEARS20230705003). All participants provided written informed consent after receiving detailed information about the study's purpose, procedures, and their right to withdraw at any time without penalty. The present study was conducted according to the principles indicated in the Declaration of Helsinki. These procedures were designed in accordance with institutional data protection policies and ethical standards for qualitative health research. During the interviews, participants were informed that they could refuse to answer any questions they did not wish to answer. To protect their privacy and confidentiality, audio recordings were stored securely, and any identifying information was removed from transcripts. The interview data were anonymized through the coding process to further ensure participant privacy.

## Results

### Participant Characteristics

Among the 10 interviewees, ages ranged from 60 to 75. The majority were retired males with at least a high school education background, and there was only one female participant in the semi-structured interviews.

### Desired Features and Functionality for mHealth App

#### *Theme 1: Information Resource*

Some participants expressed a desire for mHealth apps to provide clinically validated and comprehensive information covering key areas such as disease knowledge, prevention of comorbidities, dietary information, guidelines for safe and effective exercise, and guidance on medication usage and side effects.

> *I'm trying to cope with my DM and accept it, but I absolutely want to prevent any complications, particularly with my feet and vision. But the thing is, I'm not totally sure about the specific disease knowledge I need to actually prevent those issues. At the same time, the Internet is full of knowledge, but you don't know which is right and which is wrong.* [Participant #5]

> *It can be hard to know the amount of sugar in fruits. It's difficult to figure out how much we've actually consumed. Sometimes, we may think that eating fruit is healthy, but we might have actually eaten a lot without realizing it.* [Participant #8]

> *I'd like to know details about the food, like how many calories are in a packet of fries, and other related information. Especially some classic local foods, you know? Like those egg waffles and curry fish balls. It would be really helpful to have all that in the app. For instance, I looked up the sugar content of an orange, and it was surprisingly high, so I decided not to eat it and gave it to someone else.* [Participant #5]

> *If I take 10,000 steps, the app can tell me how many calories I have burned. It's really helpful to have this tool to assist me in making healthier choices.* [Participant #1]

In addition, some participants expressed a need for decision-making support to help them navigate various choices



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and self-care options for managing their DM effectively. Particularly in events such as social gatherings and celebrations like weddings, the diversity and complexity of food options can be overwhelming. They felt this type of guidance would empower them to make more informed decisions about their treatment, lifestyle modifications, and overall disease management.

> *I want to go to McDonald's and eat something, but I don't know how much I should eat. It would be great if this app had that information. For example, it tells me that I can eat half a burger.* [Participant #5]

> *When faced with a variety of foods at certain festivals or events, it can be challenging not knowing which options are safe and which require caution regarding portion sizes. It would be helpful if the app could provide guidance on what I should eat.* [Participant #4]

### *Theme 2: Automated Tracking and Monitoring*

Participants expressed the need to track and record their food intake, medication, and blood sugar levels, as they often forget these details, which helps them understand their overall health status.

> *Tracking our diet would be helpful. It would allow us to take control of our food intake and avoid overeating.* [Participant #8]

> *I often forget to record my blood sugar levels, which should be measured three to four times a day.* [Participant #2]

> *I hope it can remember my previous blood sugar levels and dietary information, so I can have a better understanding of how my blood sugar changes. It would be great if the app offers options for different time periods like before and after meals, including breakfast. Additionally, I would like to be able to record my dietary habits.* [Participant #6]

> *For instance, some basic features, like tracking your daily steps, distance, and calories burned, are available on many smartphones. These functions can be helpful to some extent, and you don't even need to wear a watch.* [Participant #7]

Additionally, participants emphasized the importance of the app automatically converting image data, such as food photos, into electronic records. This automated data tracking functionality would streamline the process of logging dietary intake and other health metrics, making it easier for them to monitor and manage their condition.

> *Simply take a photo of your meals and food items here to keep a record. It's a convenient way to keep a record and make a rough estimate.* [Participant #6]

### *Theme 3: Reminder*

Participants appreciated the app's ability to provide timely reminders and alerts to support their self-care, such as prompts to check blood sugar, manage medications, and attend appointments. However, while a "nudge" feature was generally seen as a helpful memory aid, especially for recalling multiple tasks, too many nudges were considered annoying.

> *If this feature exists, it would be much more convenient. It provides health warnings, reminding you that high levels could be dangerous. The app can also prompt you at 9pm, 'you should now walk 1000 steps.'Then you go and walk 1000 steps. This is good because it not only helps build bones, but also has benefits for DM.* [Participant #4]

> *Having a reminder or alert feature is helpful, but if I ignore it today and the same alert appears again tomorrow, I might not pay attention to it. However, if I continue to see the same alert every day, I will eventually take action and follow the advice.* [Participant #3]

> *It can be annoying when pop-ups appear frequently, so it's good to have it there when you need it. Like, when you walk past a McDonald's, it could give a reminder to everyone to try and avoid eating too much fried and greasy stuff. I do not want to have too many cues. Beep, you're not allowed to eat at McDonald's. Beep, you can't eat desserts there.* [Participant #3]

> *Just one reminder per week, and if you haven't checked it within that time, it will give you another prompt.* [Participant #2]

### *Theme 4: Personalized Customization*

Participants noted that the app should deliver personalized and customizable health recommendations tailored to their individual needs and circumstances. They wanted this guidance to be provided proactively, with the right information at the right time, to empower their decision-making and improve their DM management.

> *It would be more useful if the app provides personalized recommendations, as general information may not be as helpful since most people are already familiar with it. Everyone has their own unique characteristics, and their treatment plans may differ. The app could use something to provide tailored reminders based on individual circumstances and specific timings.* [Participant #7]

Moreover, the system should generate customized feedback and goals according to their health management standards. If users' diets or other habits change, the targets and action plan will be promptly updated so they can make self-adjustments to achieve their daily management goals, including food intake, medication, and exercise.

> *The recommended information can be categorized based on age. For example, let's say between the ages of 40 and 50, or 50 and 60, the recommended exercise intensity or calorie consumption may differ. In the app, there is a data point that shows how many pounds or how many units of exercise are required to meet the goal based on your age, height, and weight. This way, it can assist people of different ages and body types. You can input your own data, such*



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> *as weight and height, and the app will calculate accordingly.* [Participant #7]
>
> *If your blood glucose levels have been consistently high for a period of time, the app will remind you to pay attention and check if there are any differences in your diet or other aspects. For instance, if your blood glucose levels have risen, the app will provide an analysis to help you reflect on whether you may have consumed excessive food or high-sugar items. It prompts you to consider any changes in your diet or other factors that could have contributed to the increase. It offers monitoring features to help you understand your situation.* [Participant #1]

### *Theme 5: Intuitive Usability*

Participants stated that test results and reports can be difficult to comprehend. They hoped that mHealth apps could use simple visual design elements, like charts and graphs, to make information easy to understand.

> *In the hospital, typically the test results are presented in a report, which helps the doctor to view and understand our health condition. However, these reports can be too complicated for us to comprehend easily. Is it possible to have a visual representation of the trends in values like blood sugar? It would be helpful if we could understand our health status through simple charts or graphs, rather than having to read complex data.* [Participant #7]
>
> *After recording these values in the app, there is a feature that shows the trends over time? Usually, these records are for follow-up visits with the doctor, but I often don't understand them. Can the app provide a visual representation of the trends for easier interpretation?* [Participant #3]

In addition, some participants expressed a need for the app to provide interpretations, translations, and explanations for the data, as they may not fully understand the meaning behind the letters.

> *In the app, it can provide interpretations and comparisons of medical test results. For example, it uses codes like HbA1C to represent specific meaning, but we might not understand them. Can it provide translations for these codes? The app can also explain common medical terms and abbreviations, such as total cholesterol and triglycerides, to help us better understand the test report. Additionally, it can provide interpretations of common test results, such as the presence of protein in urine, and tell us if they are normal or abnormal. This feature helps us better understand and compare the test results.* [Participant #7]

Beyond these key functions, participants also hoped the app would accommodate diverse user needs through the incorporation of multilingual capabilities. The ability to interact with the app in one's preferred language was viewed as essential for ensuring accessibility and usability. Moreover, participants highlighted the value of voice recognition features, which would allow them to easily input data and access information using voice commands.

> *With my vision problems, I was worried the app might be hard for me to use. But the voice commands make it so much more accessible. Saves me a lot of trouble, that's for sure.* [Participant #2]
>
> *As a native Cantonese speaker, being able to use the app in Cantonese is just fantastic. I don't have to stress about mispronouncing things or using the wrong vocabulary - it's just so convenient.* [Participant #3]

### *Theme 6: Efficient Data Sharing*

Some participants requested an automated data-sharing feature across health care institutions to improve accessibility and coordination of care.

> *"Is there a way for an app to automatically share the data with hospitals and clinics? It would be really helpful for people who go to public clinics or get their medications from pharmacies. This way, hospitals and doctors would know what's going on with the person. It would make things easier and faster for everyone."* [Participant #6]

### *Theme 7: Interactive Design*

It was suggested that mHealth apps should include a web-based consultation feature with experts for convenient advice on non-urgent issues. Additionally, some patients with DM proposed having a forum-like function to connect with others, share experiences, and discuss common challenges in managing their condition.

> *"Getting to the hospital isn't always convenient for us. Having the option for online consultations with doctors through the app would be beneficial."* [Participant #2]
>
> *"I think it would be really helpful if there was a forum feature in our app. It could allow us to connect with each other. When you chat with a fellow diabetic patient, you can learn and support each other. When we encounter unclear situations, suggestions from other patients can help us relax."* [Participant #7]

## Discussion

### Principal Findings

Descriptive qualitative research was conducted with patients with DM in Hong Kong to understand the value and usefulness of various mHealth app features that may improve their self-management. Participants identified key features such as accurate information resources, automatic tracking and monitoring of health metrics, reminders, and personalized customization options. They also emphasized the importance of intuitive usability, efficient data-sharing capabilities, and an interactive design.

Participants highlighted the significance of providing clinically validated, comprehensive DM-related content within mHealth apps. They envisioned the app as a centralized, authoritative



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resource covering key self-care aspects, such as disease knowledge, prevention of comorbidities, exercise recommendations, and medication management. Beyond informational resources, participants emphasized the need for decision support to guide users in making informed choices about diet, fitness, and other lifestyle factors. This aligns with the broader challenge faced by many patients with DM who often lack access to professional, disease-specific knowledge, as existing web-based resources tend to be fragmented and unreliable [23]. This research emphasizes drawing upon evidence-based guidelines, current literature, focus groups, and interviews to develop a robust, validated knowledge base [24]. The involvement of users, developers, and clinical experts is considered essential during the app development stage, as this multilateral, user-centric approach is crucial for empowering patients to optimize their self-care regimens [25].

Participants also expressed a desire for the app to automatically track and monitor health metrics, with the ability to recognize and convert images into corresponding data for storage. Regular tracking of health is often regarded as a burden by patients with chronic diseases [26]. Knowing one's history of physical activity and other health-related data through a tracking function was seen as beneficial and motivating [12]. This aligns with prior research showing that over 70% of health apps are designed to support healthy eating, with features like carbohydrate counting and diet tracking [27]. Automatically recognizing images and converting them into data that can be uploaded eliminates the need for manual tracking, which is a significant deterrent to the uptake of DM apps [16].

Participants claimed that reminder functions helped them be more aware of and accountable for their DM self-management activities, consistent with findings from prior studies [28-30]. Reminders and alerts can improve safety by warning of hypoglycemia or hyperglycemia and enhance self-management outcomes by improving medication adherence, physical activity, and clinical appointments [9]. However, current reminders are often ignored due to poor design and frequent pop-ups [13]. Regular self-care behaviors are crucial for effective DM management, and a recent study found that nearly a quarter of individuals with DM report frequently forgetting to take their DM medication [31]. Including a customizable and attention-grabbing reminder function in a self-management app is therefore vital.

Consistent with prior research [10], this study found that formulating corresponding personalized management strategies based on the user's health assessment data is significant for a self-management app. The app's ability to dynamically update its content and functionality based on the user's evolving needs is a critical differentiator. For example, Duan et al [10] interviewed pregnant women with at least one risk factor for gestational DM who hoped that solutions tailored to their specific characteristics could encourage them to maintain healthy living habits during app use. Similarly, a qualitative study on Saudi women found that obese individuals were restricted from performing enough physical exercise outdoors [32]. The app should recommend personalized exercise routines aligned with the user's conditions and preferences. Personalized features in health apps can improve user compliance with lifestyle interventions, one of the most common strategies in mHealth apps [33]. The app should leverage artificial intelligence (AI) algorithms to provide personalized information and recommendations, tailoring content, reminders, and feedback based on user preferences, blood glucose control, and self-management knowledge. Participants expect personalized feedback based on their tracked data and the ability to customize reminder frequency and timing based on their needs. Excessive reminders were deemed annoying [12].

Most participants emphasized that good usability design is crucial for the adoption and continued usage of mHealth apps, especially for older adults with DM and patients with lower overall literacy, whose reduced physical or cognitive capabilities can be obstacles when effectively using apps [13,34]. This includes using plain, simple language with explanations, providing multi-language options, and presenting information in visual forms such as illustrations and videos. These design elements are key for attaining health literacy, as suggested by the German guideline for evidence-based health information [35]. Previous studies have pointed out that multimedia content can better adapt to the learning styles of different individuals, enable patients to take a more active role in learning, and encourage them to study more actively [36]. Research has found that information retained from watching videos is stronger than that acquired from browsing text or static images alone [37]. Therefore, when designing apps, developers should use visual methods to present a variety of health information and educational resources for patients with DM to meet their needs for information support.

This study also underscores the need for cultural adaptation when developing DM mHealth apps for local patient populations. Tailoring the app's content and features to align with users' regional or ethnic cultural, lifestyle, and dietary habits can enhance satisfaction and engagement [38,39]. For instance, the app could incorporate region-specific calorie calculation functions, dialect support in voice recognition, and integration of traditional Chinese medicine principles such as syndrome differentiation and seasonal wellness [40]. Future application development should consider co-design approaches involving target users, inclusion of multilingual interfaces, and alignment of content with culturally accepted dietary and lifestyle practices to improve engagement and usability.

This literature demonstrates that in-app peer support and professional health coaching are appealing features for patients, aligning with previous findings that interactive functions are the most popular in mobile health apps [41,42]. Some studies have used telephone or messaging groups to support patients with DM [43,44]. However, these approaches often face challenges in providing timely feedback between providers and patients, and the information shared can be easily forgotten. Therefore, designing an interactive DM management mHealth app is crucial.

Such interactive apps can formulate targeted behavior change plans for users, continuously monitor their behavioral patterns, and provide personalized feedback, effectively motivating users to complete desired self-management behaviors [45,42,46]. The literature indicates that 2-way mHealth communication between



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health care providers and patients may enhance glucose monitoring, patient adherence, and clinical outcomes, such as reduced $HbA_{1c}$ levels [47]. Additionally, peer support is crucial for developing and sustaining patients' self-management skills, as it allows for sharing experiences, attitudes, and coping strategies, increasing their ability to manage the stress of self-care [48,49]. Collectively, participants with DM recommended including both provider-patient communication and peer support in apps, which is worth considering by app developers [46].

To maintain innovation and competitiveness in the evolving mHealth landscape, apps informed by this study should incorporate adaptive features that reflect both user needs and technological advancements. Integrating AI-driven personalization, culturally tailored content, and co-designed interfaces with patients can differentiate such tools from generic solutions [50]. Moreover, building in mechanisms for real-time user feedback, continuous performance analytics, and agile updates will enable ongoing refinement in response to emerging trends. Collaborations with interdisciplinary teams—including health care professionals, technologists, and patient advocates—will be essential to ensure sustained relevance and market adaptability.

While AI-powered mHealth apps hold promise for delivering personalized diabetes care, their implementation presents several challenges that warrant consideration. Key concerns of the participants include algorithmic transparency, clinical validity, and data privacy [42]. To ensure safety and reliability, AI tools must undergo rigorous testing against established clinical benchmarks, with transparent reporting of algorithm design and performance metrics. Regular auditing and bias detection mechanisms should also be incorporated to maintain fairness and accuracy across diverse patient populations. In addition, privacy-preserving techniques—such as federated learning and differential privacy—may be adopted to protect patient data while enabling the development of adaptive, intelligent systems. These considerations are critical for future implementation and warrant further investigation through interdisciplinary research that integrates technical feasibility, ethical safeguards, and patient trust.

### Strengths and Limitations

Previous research has primarily concentrated on users' experiences and evaluations of developed apps after they have been used, with limited user involvement in the design process. This gap can lead to suboptimal user retention. In this study, we conducted in-depth interviews to investigate the preferences and functional needs of mHealth apps among individuals with DM. The insights gained are crucial for informing the development of future interventions and apps.

Additionally, we conducted thorough interviews with patients with DM in Hong Kong, where there is currently a lack of relevant research. Recognizing the importance of cultural adaptation for the success of mHealth apps, our findings can contribute to enhancing engagement among Hong Kong patients, thereby improving self-management levels and reducing health care costs. Furthermore, we emphasized the importance of using AI to provide personalized, timely, and culturally relevant information and feedback, which can also alleviate the workload of health care professionals. Ensuring the credibility and professionalism of AI information sources is essential to avoid misunderstandings that could delay treatment.

This study has several limitations. First, this study is limited by its relatively small sample size and recruitment from a single community health center, which may affect the generalizability and diversity of findings. Patients with different ages, disease durations, severity levels, and lifestyles may have distinct needs for mHealth apps, which were not fully captured. In addition, perspectives from health care professionals, such as diabetologists and diabetes educators, were not included, representing an important avenue for future research. Future studies should aim to recruit larger and more diverse samples from both community and hospital settings. Second, we were unable to capture data on how self-management experiences and perceptions of mHealth might differ across various identities (such as gender, age, and ethnicity), which could have provided richer insights into these subgroups. Third, while patients' preferences for mHealth app features were explored qualitatively, the study did not adopt formal prioritization methods. Future studies should consider using structured prioritization techniques to systematically capture and rank patient preferences across diverse populations.

This study did not evaluate the actual behavioral changes or clinical health outcomes following mHealth app use, which limits our ability to assess the real-world impact of the proposed features. As the design phase preceded implementation, outcomes such as glycemic control, treatment adherence, and lifestyle modifications were not measured. This limits the ability to draw conclusions about the long-term effectiveness of such apps in supporting self-management.

## Conclusions

Our findings highlight the importance of tailoring these apps to local cultures, particularly through the integration of local food options, recommendations, and language preferences. Key features desired to enhance self-care behaviors include credible resources, automatic tracking and monitoring of health metrics, reminders, personalized customization, user-friendliness, efficient data-sharing capabilities, and in-app support via virtual interactions with peers and health care professionals. The results of this study provide valuable insights for enhancing the self-management capabilities of patients with DM and for the future development of mHealth apps aimed at DM prevention.



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## Data Availability

All data generated or analyzed during this study are included in this manuscript.

## Authors' Contributions

AW conceptualised the study; AW and NY researched literature and conceived the study. AW, NY, BY, and YL were involved in protocol development, gaining ethical approval, patient recruitment, data collection, and data analysis. AW and NY wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

## Conflicts of Interest

None declared.

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## Abbreviations

**DM:** diabetes mellitus
**mHealth:** mobile health


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# Development of a Smartphone App for Women Living With Gestational Diabetes Mellitus: Qualitative Study

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## Abstract

**Background:** Gestational diabetes mellitus (GDM), a type of blood glucose intolerance or hyperglycemia that occurs during pregnancy, is a common condition increasing in prevalence both globally and in Australia. Mobile health apps have been shown to be a useful resource for women with type 1 diabetes and could successfully contribute to GDM management by facilitating healthy behaviors.

**Objective:** This study aimed to seek the perspectives of health care consumers (HCCs) and health professionals (HPs) regarding the development of a smartphone app for women living with GDM.

**Methods:** A co-design process with 4 distinct phases underpinned the development of SugarMumma. Phase 1 involved a nonsystematic literature search followed by the creation of an app functions wish list. In phase 2, semistructured interviews with HCCs and HPs were undertaken and then thematically analyzed. In phase 3, a prototype was designed based on social cognitive theory and stakeholder recommendations. Agile project management methodology was used, followed by "user acceptance testing." During phase 4, a second round of individual interviews was undertaken with HCCs and HPs. The same qualitative methods outlined in phase 2 were used.

**Results:** In phase 2, individual and didactic interviews were undertaken with HCCs (n=2) and HPs (n=6). Two overarching themes encompassing recommendations for app development emerged: (1) functionality and (2) individualized care. SugarMumma was created in phase 3. Phase 4 involved a second round of individual interviews with HCCs (n=1) and HPs (n=5), resulting in the final theme (3) future directions.

**Conclusions:** With increasing numbers of people using smartphones, mobile health apps can help manage chronic conditions such as GDM. SugarMumma was designed following extensive stakeholder input. Good functionality, regular notifications, appealing visual aids, positive feedback, relevant dietary advice, and exporting information to HPs are important features to include.

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**KEYWORDS**

smartphone apps; mobile apps; mHealth; gestational diabetes mellitus; blood glucose level; self-management; smartphone app; mhealth; women's health; diabetes; mellitus; glucose intolerance; hyperglycemia; pregnancy; type 1 diabetes; mobile health application; evidence-based; application; interview; chronic condition; dietary; self-management

## Introduction

Gestational diabetes mellitus (GDM) is a type of glucose intolerance or hyperglycemia indicated by the onset of elevated blood glucose levels (BGLs) during pregnancy [1]. It is one of the most common pregnancy-related complications, with an increasing prevalence both worldwide and in Australia [2,3]. According to the Australian Institute of Health and Welfare, GDM was diagnosed in 1 out of 6 women who gave birth during 2020 - 2021 [4]. Causation is multifactorial, including rising maternal age, high rates of maternal overweight and obesity, and an increasing proportion of women from high-risk ethnic groups giving birth in Australia [1-3,5]. The recent change in diagnostic benchmarks from the previous Australasian Diabetes in Pregnancy Society criteria to those recommended by the International Association of the Diabetes in Pregnancy Study Groups has all contributed to a dramatic increase in the prevalence of GDM in Australia [4,5].



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Most Australian public hospitals support a traditional model of care that includes an initial group education class for women diagnosed with GDM facilitated by a credentialed diabetes educator and dietitian, in addition to offering one subsequent individual consultation with either of these health professionals (HPs) and an endocrinologist [4,6,7]. Contemporary best practice management includes (1) lifestyle recommendations such as the consumption of low glycemic index foods, carbohydrate monitoring, appropriate gestational weight gain, BGL, surveillance, and regular physical activity [6,7] and (2) pharmacotherapy encompassing insulin injections or oral hypoglycemic agents such as metformin [7,8]. Through Australia's National Diabetes Service Scheme, most women diagnosed with GDM have access to a free glucose monitor and subsidized products such as blood glucose strips for the duration of their pregnancy [9].

Nevertheless, due to Australia's immense land mass, women who reside in remote and rural areas have limited access to health care facilities that offer routine GDM testing in addition to specialist education and support services. The PANDORA (Pregnancy and Neonatal Diabetes Outcomes in Remote Australia) observational study [10] revealed higher rates of maternal diabetes in First Nations women when compared with their non–First Nations counterparts. In this study's cohort, the GDM and diabetes in pregnancy subgroup experienced poorer birth outcomes with an increased proportion of large for gestational age babies (19% vs 11%) [10]. In 2018, across Australia and New Zealand, Sina et al undertook a thematic analysis of 15 diabetes in pregnancy services. Their findings highlighted not only the difficulty of dealing with increased patient numbers using the traditional model of care but also the complexity of delivering appropriate care for women from culturally and linguistically diverse (CALD) backgrounds [11]. Two recent systematic reviews provide additional support, having revealed that high levels of unmet needs exist in both women from CALD and non-CALD backgrounds [12,13].

Despite BGLs usually returning to normal after parturition, women who experience GDM have a higher risk of developing Type II diabetes, metabolic syndrome, and cardiovascular diseases in the future [14-16]. Furthermore, there is an increased risk of childhood obesity and type II diabetes for their offspring. These outcomes indicate that strategies to optimize GDM management and mitigate potential sequelae are warranted.

There is recognition that mobile health (mHealth) apps could be an important adjunct in GDM management, particularly given the growing evidence for their efficacy in routine type I diabetes care [8]. Several advantages of mHealth apps have been proposed [8]. They enable users to monitor their own health and support them in managing chronic disease independently. In addition, they have been shown to promote healthy behaviors, provide important resources for managing the disease in question (such as type II diabetes), and collect useful health data [17]. Yet, there is a paucity of holistic (encompassing lifestyle recommendations in addition to medication, weight, and BGL monitoring) mHealth apps available for women with GDM. Nevertheless, those that are available mostly include journaling capabilities for glycemic readings and diet [18-21]. Previous research has argued that the most desirable features of mobile apps for GDM self-management involve interactive feedback, credible information, and the capability for integration into existing health care services. Other suggested features include greater personalization or woman-centeredness [22,23].

A recent systematic review looked at the effectiveness of specific mHealth apps for the management of GDM [24]. Very few interventions reported on the clinical effectiveness of GDM-specific mHealth apps [25,26]. The authors reasoned this was predominantly due to both health care consumers (HCCs) and HPs' reluctance in using new technology, difficulty with navigation, and complications with integration into existing health systems [20,21,26-28,29]. In addition, pharmacotherapy, nutritional, and physical activity outcome data collection and analysis were reported to be lacking [24].

Stakeholder involvement in health research is highly desirable, with national guidelines developed explicitly for this purpose [30]. Stakeholders may include individuals with lived experience of the phenomenon in question, HPs, and academics [31]. This collaborative approach can help identify different perspectives and ideas that would not necessarily be considered by the research team alone. In addition, collaboration between software engineers and the research team is considered vital for ensuring that knowledge from multiple disciplines is used to inform app design and avoid type 1 (where designers do not accommodate user characteristics, preferences, context, or needs) and type 2 (where designers do not accommodate the clinical reality) errors [32].

Therefore, our study aimed to seek the perspectives of HCCs with lived experience of GDM and HPs involved in the care of HCCs with GDM regarding the appropriate information and functions to include in the development of an app for women living with GDM.

## Methods

The SugarMumma app was developed using a co-design process, including 4 distinct phases and supported by an evidence-based approach [33,34].

### Phase 1

The research team included 9 academic clinicians from the University of Canberra's health disciplines of nutrition and dietetics, midwifery, nursing, pharmacy, and exercise physiology in addition to 3 academics from the faculty of business, government, and law. In late 2022, the research team carried out a nonsystematic literature search of GDM apps available on the market. A paucity of smartphone apps, covering all essential components for the holistic management of GDM, was identified (refer to Multimedia Appendix 1) [29]. Following a round table discussion, the research team put together a "wish list" of functions they would like included in an app of this kind (refer to Multimedia Appendix 2). The team brainstormed potential names for the app and came up with SugarMumma as it conjured happy "sweet" thoughts. In previous years, dietary advice has been heavily focused on eliminating sources of simple carbohydrate, like sucrose, from the diet—an approach that was highly restrictive. Currently, a whole diet approach is



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recommended where women are encouraged, as part of this approach, to consume carbohydrate foods (including simple sugars) in amounts tailored to the individual [11,12].

## Phase 2

To complement the research team's "wish list," a series of HCC and HP consultations were planned. A study information flyer was circulated through the university's intranet and via the research team's broader professional networks. Key stakeholders of interest included HCCs with lived experience of GDM and HPs with a current role in GDM management. Following this recruitment drive, didactic interviews (n=3) and individual interviews (n=2) were undertaken online via Teams (Microsoft Corp) in March 2023 at a time that suited participants. CKA, DD, and MEH facilitated these due to their extensive experience as qualitative researchers.

The interview schedule was developed by the research team following a review of the relevant literature [1-4,8,10,12]. Questions revolved around essential features to include in the app and were kept deliberately open, enabling participants to talk with minimum interruption and without judgment. At the end of each interview, participants were given the opportunity to clarify their views and to add any information relating to the topic that may have been missed. All interviews were audio recorded in addition to the lead facilitators (CKA, DD, and MEH) taking handwritten notes. These recordings were then transcribed verbatim by four research assistants (EM, TA, CPJC, and NRI), cross-checked for consistency and entered into a word processing document.

Data were analyzed using a 6-step thematic process as described by Braun and Clarke [35]: (1) familiarization with the data, (2) generating initial codes, (3) interpreting and sorting codes into themes, (4) reviewing themes for coherent patterns, (5) defining and naming the themes, and (6) producing the report. CKA, DD, NRI, EM, CPJC, and TA analyzed all interviews, generating initial codes and discussing the preliminary findings with the broader team. Following this, CKA and NI inserted these codes under relevant themes using an inductive process.

Credibility was addressed by researcher triangulation throughout the analytical process, with CKA, MB, and DD having considerable professional experience working with HCCs with GDM, and MEH having extensive expertise in qualitative research. Feedback from the researchers was discussed at meetings until consensus was reached. The resulting themes, incorporating key recommendations, were then passed on to the app development company.

## Phase 3

The research team engaged an app development company to design the prototype based on information and recommendations from phases 1 and 2. A series of online meetings was undertaken in April and June 2023 between the research team and the app developer to figure out essential and desired features that also heeded budgetary constraints. In addition, it is important to note that social cognitive theory (a behavioral change model) [36] was used as a foundational anchor for the development of SugarMumma. From the end of June 2023 to mid-October 2023, the app developer worked on an initial prototype, suitable for both iOS and Android devices. The React Native framework was determined to be the best "fit" for SugarMumma's evolution. It is designed to provide a seamless development experience with five key benefits (Table 1).

The Agile project management methodology was then used [37]. App features were developed in short sprints, which enabled individual features to evolve in a modular framework. This process allowed for scalable additions and removals to be completed efficiently [38]. Prior to initiating the second round of key stakeholder feedback, lead research facilitators (DD, MEH, and CKA) undertook their own user acceptance testing (UAT). Testing included checking functionality and ensuring clinical information was accurate. No problems were identified. The final version of SugarMumma and hosting website were ready by early October 2023 for key stakeholder UAT.

**Table .** Key benefits of using React Native framework.

| Benefits | Description |
|---|---|
| Cross-platform development | Allows developers to write code once and reuse it across multiple platforms. This means that developers can use the same codebase to create apps for both iOS and Android, saving significant development time and effort. |
| Faster development | Uses a "hot reloading" feature that enables developers to see the changes they make to the code in real time. This feature speeds up the development process, as developers can quickly identify and fix issues as they arise. |
| Cost-effective | Allows developers to write code once and use it across multiple platforms, it significantly reduces the cost of development. This is because it eliminates the need for developers to write separate codebases for each platform. |
| Large developer community | It has a large developer community, which means there are plenty of resources, tools, and libraries available to help developers build mobile apps. This community also provides ongoing support and updates, making it easier for developers to stay up to date with the latest technologies and best practices. |
| Native performance | Uses native components, which means that the resulting mobile app has the same performance and user experience as a natively developed app. |



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### Phase 4

HCCs and HPs from phase 2 were notified by email in mid-October 2023 about the completion of SugarMumma's initial prototype and, if they agreed to continue with their involvement, were given 7 days to access the app. They were encouraged to operate the app as if it were for their own use. Following the UAT, individual interviews with an HCC (n=1) and HPs (n=5) were undertaken with the same methods as described in phase 2. The only difference was during data analysis where a more deductive approach was taken compared to phase 3, as the aim was to review the actual app (not simply a wish list) and to ascertain if it met HCCs' needs. Finally, recommendations were passed on to the app company for consideration in future development of SugarMumma.

### Ethical Considerations

This study was supported by funding from the Australian Digital Translation Fund. Before each phase of this study, participants (both HCCs and HPs) gave informed written consent. Ethical approval was granted by the University of Canberra's Human Research Ethics Committee (reference 202311994). All participant details were kept confidential with pseudonyms used to ensure anonymity. HCCs each received a compensation of Aus $100 (US $64.87). HPs provided their time free of charge.

## Results

### Overview

See Table 2 for participant characteristics.

Data analysis revealed two themes resulting from phase 2: functionality and individualized care. Interviews had an average duration of 45 minutes each (both didactic and individual).

**Table .** Demographics of HCCs and HPs.

| Characteristics | Participants, n |
|---|---|
| **Health professionals, sex** | |
| **Sex** | |
| Male | 1 |
| Female | 5 |
| **Age (years)** | |
| 25 - 44 | 1 |
| 45 - 65 | 5 |
| **Experience of working in GDM[a] (years)** | |
| 0 - 5 | 2 |
| 5 - 10 | 2 |
| >10 | 2 |
| **Occupation** | |
| Endocrinologist | 1 |
| Diabetes nurse educator | 2 |
| Midwife | 1 |
| Obstetrician | 1 |
| Dietitian | 1 |
| **Healthcare consumers, previous experience** | |
| Recent experience living with GDM | 2 |

[a]GDM: gestational diabetes mellitus.

### Phase 2: Qualitative Interviews

#### *Functionality*

Participants emphasized the need for SugarMumma to be a patient-centered, informative app that could:

> *… remind women about appointments [HP1] in addition to including information resources that are reliable and educational… (these) would be very useful [HP1]. The app also needed to be GDM-specific: I never even heard of any GDM specific apps (when I was pregnant) … I didn't use one [HCC2] and No HP suggested any to me either.* [HCC1]

Similarly, other HCCs claimed that SugarMumma should aim to make life less challenging:

> *I was told to record all my diet and BGLs on an A4 piece of paper…. I was terrible at that. I would have loved a smartphone app [HCC2]. The desired*



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> *capacity for an app to easily record ones BGLs [W1] led another HCC to add that graphing BGLs …..… would be interesting and useful.* [HCC2]

The value of providing HCCs with evidence-based guidance was acknowledged by HPs:

> *… most of the ones I use for my people are really around carb counting and insulin dosing… so they (the women) put in what they are eating, and it tracks everything… [HP2] in addition to getting them to do a (food and BGL) diary, we try to do whatever we can to get some information on them…* [HP2]

It was emphasized that the app should ideally be compatible with various devices so that all potential users can download it:

> *…a lot of them (patients) have OPPO phones, you know most of the apps are only compatible with Samsung or iPhone…* [HP2]

Ultimately, it was felt that SugarMumma should be straightforward to use to cater for the diverse needs of Australia's multicultural society as one HP pointed out:

> *... we have a large proportion (of women) with very low health literacy. So, it (needs to) be simple for them.* [HP2]

Both the HCCs and HPs felt SugarMumma would make coordination of maternity care easier:

> *I think it would be very useful to pass information on to my doctor and being added to the record…. I remember the nurse coming in and looking at the book (for BGL's) and then typing (the levels) into the computer and saying do you remember exactly what number that was when you scribbled it in….* [HCC1]

Communicating GDM-related health data between an HCC and her HP team via SugarMumma was seen as an important feature:

> *Maybe none of your figures (BGL's) may be concerning, like a single one, however there could be a pattern, and so you don't know that and you may not have an appointment but something that triggers you to contact the doctor or them to get in touch.…… especially if you are not close (in proximity) to doctors.* [HCC1]

In addition, it was suggested that SugarMumma should enable the consensual sharing of data:

> *for research or whatever but also knowing it can be anonymised.…… because if women are collecting all this data, it is useful to have in terms of what else can be done.* [HCC1]

In some situations, it was recognized that communication between a HCC and their HP via SugarMumma may be less stressful than a face-to-face meeting:

> *A lot of them (women) struggle with what their glucose levels are doing... they don't want to show us what is really happening despite usually being motivated (to follow recommendations).* [HP2]

### *Individualized Care*

It was recognized that a user-friendly app, tailored to the individual, could empower self-management especially when there was no immediate need for HP intervention:

> *...(for example, to) take the load off….. knowing when you might be high in insulin (and then should eat something)…. or when there is the need for a bit of prepreparation if you are going out for dinner and require more insulin.* [HCC1]

Up-to-date information that is constantly available and easily accessible was very appealing, with one of the HCCs claiming: "Meal plans would be very helpful to include" (in SugarMumma; HCC2). In addition, a range of foods and recipes that were not just*:* "Anglo focused" (HCC1). The need for more culturally appropriate inclusions, particularly for populations with challenging engagement patterns, was highlighted:

> *We have the large islander population, we have (an) aboriginal population, and not to generalize too much but our islander population is probably the most challenging because they really don't engage with healthcare and don't see the value in it.* [HP2]

HCCs acknowledged that SugarMumma could motivate individual users to monitor other important variables relevant to pregnancy in addition to BGLs, for example:

> *It is really good to help track weight…. I found the information (available from HPs) quite confusing…. I was in that overweight category when I got pregnant.…… I didn't put on much during my pregnancy and there wasn't much information about if you are in that middle bit.……and how normal is that as I knew the baby was growing but particularly when you are having your first pregnancy you're worried about everything….. like should I be putting on weight…. Knowing what is normal…. And knowing what information is relevant is very important to include.* [HCC1]

The importance of physical activity for the management of BGLs was emphasized by HPs who proposed integrating features that: "Encourage all our women to go for a 10 min walk after they eat" (HP2). A University branded app was believed to be credible, thus a motivator for its use: "Yeah, I think it's really good that it's coming from like a tertiary institution" (HCC2).

### *Phase 3: App Development*

SugarMumma was developed with BGL, insulin, diet, physical activity, and weight tracking functions in addition to providing glycemic and weight gain targets. A facility to record food intake concentrating on carbohydrates is a key feature. Links to government-approved websites on topics such as pregnancy-related nutrition and exercise were also included. SugarMumma provides medication reminders and the ability to generate reports if desired by HCCs (refer to Multimedia Appendices 3 and 4).



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### *Phase 4: Qualitative Interviews*

Greater use of photos and icons instead of extensive text was suggested as one way to enhance user friendliness of the initial prototype: "…maybe something like pictures…… to click on for what they (HCCs) want to use rather than lot of words" (HP2) as well as "a lot of dropdowns rather than lots of free text… like just the ease of use I guess" (HP4). Whereas other HPs expressed a preference for manual input of numerical data: "I didn't particularly like scrolling through the numbers... I'd rather type in what my number is" (HP3).

Likewise, HPs highlighted the need for SugarMumma to send more supportive, individualized messages especially when there are extended periods of time between antenatal appointments:

> *I just sort of wish there was something (in the app)….. just a little prompt to say it has been noticed you've got this many highs and this range, therefore maybe consider contacting your diabetes healthcare provider or something like that.* [HP2]

HCCs generally found SugarMumma to be useful compared to a paper book for communicating lifestyle and BGL data. However, frustration was voiced around how food was encouraged to be recorded: "I wouldn't necessarily know the grams of something I've eaten" (HCC2).

HPs discussed the challenge of setting specific fasting targets which may differ from state to state and from HCC to HCC and not simply include generic glycemic recommendations: "I worry sometimes when you tell some of the women a specific number, they get quite hung up on that number" (HP3). It was also suggested that not using continuous BGL measurements but the provision of guidance on "what to do if it is too high (BGL)…., and where to go for help (if this happens)" (HP5). A further suggestion was to make SugarMumma multilingual to accommodate the diverse range of ethnicities as: "not everybody has English as the first language either…" (HP3).

It recognized that an app for GDM management could include information relevant to the postpartum period and beyond:

> *They also talk about your kids getting it (diabetes) and what to look out for later and even in terms of the data if you can download it and then email it to your doctors…..*. [HCC2]

Ultimately, it was recognized that for SugarMumma to be effective, it "must be allowed to integrate into the existing health systems" (HP6).

## Discussion

### Principal Findings

An extensive search of the peer-review literature in addition to qualitative interviews with HCCs and HPs informed development of SugarMumma, a smartphone app for the management of GDM. Key considerations were the importance of functionality and individualized care. Our findings are consistent with similar work of this kind [29].

### Comparison With Previous Work

Good functionality, reliable information in addition to key utilities such as BGL monitoring, appointment reminders, and ability to generate health reports if desired are key features of SugarMumma. Similarly, Garnweidner-Holme et al [25] stressed the importance of a simple and easy-to-navigate menu design for pregnancy-related apps. Nevertheless, in phase 4, HPs suggested the inclusion of more dropdown menus and less text, believing this would enhance user-friendliness.

Safiee et al [29] previously identified that app first impressions are provoked by the simplicity of language and attractive visuals. Likewise, participants in our study highlighted a preference for images and icons over words to facilitate easy interpretation of BGLs, medications, exercise, and weight data (with relevant feedback) [29,39-41].

Previous studies have reported some women's difficulty in remembering the copious amounts of information provided during antenatal care appointments [19,29,42]. A "one-stop shop" of credible resources to assist women in managing GDM is one of the proposed benefits of SugarMumma [41,42]. A qualitative study of mHealth apps identified that users rely on recommendations from a wide range of sources including strangers, friends, authoritative figures including HPs, and recognizable branding to inform app selection [42-44]

Frontline intervention for GDM management requires dietary monitoring [45,46]. Electronic food diary systems provide an opportunity for improved self-management, beneficial to both HCCs with GDM and HPs [46]. Our study indicated some participants considered carbohydrate monitoring to be a more important feature than BGL surveillance. Nevertheless, the measurement of food in grams was reported to be confusing. This correlates with similar work by Safiee et al [29], where they found that participants preferred measurements in bowls or teaspoons over dimensions in grams [29].

Participants in our study believed the generation of multifactorial reports (eg BGL or Food or Activity) to be an important function along with notetaking with the ability to contextualize data [44,46]. Similar literature has highlighted a desire for direct in-app communications with HPs, which is currently lacking in many diabetes apps [44,47]. Falsification in reporting BGLs due to HCCs embarrassment or for the purpose of receiving positive feedback has been acknowledged previously [19,29]. Automatic but consensual transfer of data from HCCs' mobile phones to their HP may negate this risk.

Visual cues are a powerful tool in engaging user experience, with consideration to culture and varying degrees of health literacy. Images may assist culturally and linguistically diverse users to navigate the app where their preferred language is not available and has the potential to diminish feelings of social exclusion. Inclusivity may also be fostered by adjusting illustrations to be appropriate for different ethnic groups [42]. Feedback from the initial prototype of SugarMumma described the overall design and language largely appropriate for the target audience. Nevertheless, it is currently only available in English.

Access to service provision for GDM management can be challenging based on factors including rurality or competing



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demands. These challenges are compounded by the overwhelming and drastic increase in the frequency of antenatal consultations associated with a GDM diagnosis [45,48]. HCCs and HPs alike identify the challenges in accessing health services for GDM management, including absence from work, reduced income, travel, and inconvenience (particularly if parenting other children) [29,48]. The use of smartphone apps such as SugarMumma as an adjunct for GDM management may help decrease travel time, minimize unnecessary appointments, reduce absence from work, and potentially lower stress [49,50].

### Future Directions

Our research has not only informed the initial stages of app development but also provided a pathway for further refinements. mHealth has an increasingly complementary role to current GDM management interventions, in the context of a limited number of HPs and an increasing number of GDM diagnoses [29]. The SugarMumma app has been designed with the long-term goal of seamless integration with existing documentation systems, to be used as an adjunctive tool to standard GDM interventions. When introduced immediately following diagnosis, HPs perceive similar GDM management apps as appropriate tools for management [40,41].

Women receive a significant amount of support and monitoring during their pregnancy; however, both HCCs and HPs suggest that this level of support and follow-up is often abandoned postbirth [45]. Considering the impact of the baby's health on motivation for GDM management, loss of motivation is unsurprising after birth [19]. We hope to expand the functionality of the SugarMumma app to include provision for women during the postnatal period by highlighting the risk of type 2 diabetes mellitus and importance of ongoing screening.

There are some limitations that must be acknowledged. This study contained only a small sample size of HCCs and HPs, thus limiting the rigor of our results. We acknowledge that our participants' views may not reflect those living with GDM or caring for HCCs with GDM elsewhere. Most of our participants were female HPs without lived experience of GDM. This may have influenced the support needs and app functions emphasized in our findings. The small number of interviews was due to participant scheduling constraints. It is also important to point out that the SugarMumma app has been designed as an adjunct to usual maternity care and in no way should replace the individual advice provided by a HP.

### Conclusion

With the increased number of people using smartphones in their daily lives, mHealth apps are being considered as a novel way to manage chronic conditions such as GDM. This study has revealed that key stakeholders appreciate features including simplicity, regular notifications, appealing visual aids, and positive feedback. Future work is planned to enhance the current prototype.

## Acknowledgments

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## Data Availability

Some datasets are available from the corresponding author on reasonable request, although authors will require the explicit permission of the relevant external organizations.

## Authors' Contributions

CKA and DD secured funding for development of SugarMumma. CKA, DD, MB, AS, AD, MJ, MM, MEH, AS, and IK designed the research study and supervised the research conduct. CC, EM, NRI, and TA with the assistance of CKA transcribed and then analysed the interview data. All authors contributed substantively to the interpretation of the data, helped to prepare the manuscript, and read and approved the final manuscript.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Summary of the currently available gestational diabetes mellitus apps in the market.
[DOCX File, 17 KB - diabetes_v10i1e65328_app1.docx ]

Multimedia Appendix 2
The "wish list"—what academic health clinicians would you like to see in a holistic app for women living with gestational diabetes mellitus?
[DOCX File, 16 KB - diabetes_v10i1e65328_app2.docx ]

Multimedia Appendix 3



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SugarMumma screenshot (I).
[DOCX File, 259 KB - diabetes_v10i1e65328_app3.docx ]

Multimedia Appendix 4
SugarMumma screenshot (II).
[DOCX File, 192 KB - diabetes_v10i1e65328_app4.docx ]

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## Abbreviations

**BGL:** blood glucose level
**CALD:** culturally and linguistically diverse
**GDM:** gestational diabetes mellitus
**HCC:** health care consumer
**HP:** health professional
**mHealth:** mobile health
**PANDORA:** Pregnancy and Neonatal Diabetes Outcomes in Remote Australia
**UAT:** user acceptance testing


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# Understanding Device Integrations Within Diabetes Apps: Mixed Methods Analysis of App Features and User Reviews

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## Abstract

**Background:** Diabetes management involves a large degree of data collection and self-care in order to accurately administer insulin. Several mobile apps are available that allow people to track and record various factors that influence their blood sugar levels. Existing diabetes apps offer features that enable integrations with various devices that streamline diabetes management, such as continuous glucose monitors, insulin pumps, or regular activity trackers. While this reduces the tracking burden on the users, the research highlighted several issues with diabetes apps, including issues with reliability and trustworthiness. As pumps and continuous glucose monitors are safety-critical systems—where issues can result in serious harm or fatalities—it is important to understand what issues and vulnerabilities could be introduced by relying on popular diabetes apps as an interface for interacting with such devices.

**Objective:** As there is a lack of research examining in detail the integrations and potential suitability of apps as part of a wider self-management ecosystem, our goal was 2-fold. First, we aimed to understand the current landscape of device integrations within diabetes apps and how well they meet users' needs. Second, we identified the key issues users of the most popular apps face currently and what features are the source of these issues.

**Methods:** Through searches in Android and iPhone app stores, we systematically identified 21 diabetes apps that offer integrations. We conducted a detailed analysis of 602 user reviews. For each review, we recorded its sentiment, features and issues, and additional contextual information provided by the review writers. We used descriptive statistics to analyze the features and issues. We also analyzed the reviews thematically to identify additional trends related to the context of use and the consequences of issues reported by the users.

**Results:** The reviews focused on key features that users found the most important, including device integrations (n=259, 43%), tracking (n=194, 32.2%), data logging (n=86, 14.3%), and notifications (n=70, 11.6%). We found that 327 (54.3%) of the reviews were negative versus 187 (31.1%) positive and 88 (14.6%) neutral or mixed, and the majority of reviews (n=378, 62.8%) mentioned issues. The biggest issues related to device integrations included inability to connect with external devices (n=95, 25.1%), inability to store, manage, or access data (n=49, 22%), unreliable notifications and alerts (n=35, 9.2%), issues caused by or related to software updates (n=31, 8.5%), hardware issues (n=24, 6.4%), and issues with accessing the app, related services, or associated hardware (n=12, 3.2%).

**Conclusions:** Apps for diabetes management are a useful part of self-care only if they are reliable and trustworthy, reduce burden, and increase health benefits. Our results provide a useful overview of desired features for diabetes apps alongside key issues for existing integrations and highlight the future challenges for artificial pancreas system development.

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**KEYWORDS**

diabetes mellitus; health apps; mHealth; mobile health; mobile apps; self-management; user experience

## Introduction

### Background

Diabetes is defined as a group of disorders that share both hyperglycemic (hyper) and hypoglycemic (hypo) events caused by insulin insufficiency [1]. Hyperevents occur when blood sugar is too high, while hypoevents occur when blood sugar is too low. The 3 most common types of diabetes include type 1 diabetes (T1D), in which the pancreas does not produce insulin; type 2 diabetes (T2D), in which body cells become resistant to insulin over time; and finally, gestational diabetes, which occurs during pregnancy [2]. Due to the nature of the disease, diabetes involves a large degree of data collection and self-care in order



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to accurately administer insulin and avoid these hyper- and hypoevents. As a result, there is a large burden placed on individuals to track blood sugar levels, carbohydrate intake, activity levels, medications, insulin levels, and so on.

To assist with diabetes management, several technologies have been developed in order to help lower the burden for diabetics as well as to increase health benefits [3]. Since the 1990s, with the discovery of short- and long-acting insulin, insulin pen devices have been used to allow diabetics to better control their blood sugar levels [4]. Newer technologies have been developed, as access to technology has increased, such as continuous glucose monitors (CGMs), which allow for easier data collection on blood sugar levels, or insulin pumps for automatic scheduled delivery of insulin. Access to these relatively low-cost devices has also led to do-it-yourself (DIY) artificial pancreas (AP) systems, which use a combination of these medical devices with software systems such as web or mobile apps in order to create a closed loop between automatically taking blood sugar levels and administering insulin as needed [5].

Examples of AP systems include open-source projects like Nightscout [6] or OpenAPS [7]. Both systems have 3 key components: a CGM sensor to collect information on blood sugar levels, an insulin pump to administer insulin, and a place to log information, such as a website or mobile app [6,7]. The exact devices and ways in which this information is used are up to the end user who is modifying the out-of-warranty devices. Interviews and trials with patients, care providers, and families demonstrate reduced levels of anxiety or fear and better health outcomes [8-10]. In addition, patients and parents are asking for devices that reduce their burden so that diabetes has little impact as possible on their everyday life [11,12].

While DIY AP systems are an ad hoc but useful solution to a serious issue, the necessity for them has been created due to the slow and lengthy processes required for developing safety-critical medical technologies [13,14]. While authors highlight the benefits of the devices, there is also discussion around the need for adequate regulation of commercially available AP systems in addition to collaboration between industry, care providers, and patients to ensure that the developed systems are fit for purpose [15,16]. For example, Drew [17] highlighted that from the DIY movement, at least 1 open-source algorithm has been approved by the US Food and Drug Administration; however, it can be difficult to make devices from different manufacturers work together, causing interoperability issues.

To software engineers, these issues are not surprising, as in their essence, AP systems are internet of things (IoT) systems, combining multiple actuators and sensors in order to deliver a product. As such, the key challenges that occur in IoT systems—such as connectivity issues or device and data privacy [18]—may also apply in the context of integrating different diabetes devices and apps. For AP systems, in particular, we can see these issues occurring in the above DIY solutions. This is further compounded by the fact that the management of each type of diabetes is different, and while some elements are common, management for specific individuals is also unique, requiring a complex set of system requirements [19].

To help address this issue, several diabetes apps have been developed to serve as a way for end users to interpret their data and make informed decisions about insulin dosage. These apps can work with a combination of devices as part of an AP system or alternative care approach. Wu et al [20] reviewed how diabetes apps contributed to lifestyle changes and demonstrated that they are effective for T2D. Conversely, Zhang et al [21] found in their survey that the use of apps was higher among patients with T1D than T2D [22]. Key features for diabetes apps include but are not limited to medication management, blood glucose management, physical activity, diet and nutrition, and weight management [23]. Performance expectancy of these functions and social influence are key factors in patients regularly engaging with the apps [24]. In addition, concerns related to the ethics and reliability of apps have been raised by Huang et al [25], where only 1 app in their study was able to meet all 8 criteria for trustworthiness. This highlights the need for further investigation of the apps themselves as a key part of AP systems and their use in managing all types of diabetes. However, despite an extensive search of existing literature, to the best of our knowledge, there are no papers that explicitly explore users' perceptions of diabetes apps in relation to device integrations.

## Objectives

It is evident that mobile apps are becoming an integral part of diabetes self-care and management. However, while several studies have demonstrated their potential health benefits [20-22], to the best of our knowledge, there are no studies that examine in detail the integrations and potential suitability of diabetes apps as a collective to determine if they meet user needs and function appropriately as part of a wider AP system. As stated previously, social influence has a large impact on whether or not apps are used, along with reliability and trustworthiness being key factors in uptake [24,25]. There are also challenges in functionality and use being determined by different types of diabetes as well as the unique requirements for each individual and the different situations they find themselves in [19]. Therefore, there is a need to better understand the current landscape of device integrations and how well they meet users' needs.

As user reviews are a rich and useful source in exploring user feedback and needs for health-related apps (this is a common approach often used to examine a wide range of health apps, eg, focused on mental health [26,27], medication adherence [28,29], or diabetes [30]), the primary aim of this research was to investigate the reviews of diabetes management apps to determine wider themes and identify which functionality is important to users. We anticipate that as a result of the challenges that IoT systems like APs face, app reviews will highlight and reflect these challenges while also demonstrating which features are vital for end users' self-care and diabetes management.

Furthermore, with AP systems and the widespread use of DIY solutions to self-care, exploring integrations and connectivity with other devices, such as insulin pumps, CGMs, and smartwatches, will be important to ensure that systems work as expected. Due to the safety-critical nature of the diabetes



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management apps (safety-critical here meaning that a flaw in the system could lead to severe injury or even fatalities), it is crucial to ensure that systems are safe to use. Therefore, the secondary aim of this research is to identify the key issues users of the most popular apps face at the moment and what features are the most common sources of these issues. The primary contributions of this paper are (1) an in-depth investigation of user perceptions of diabetes apps and their associated integrations and (2) a summary of key features and issues with diabetes app functionality that will impact AP systems in the future.

The rest of the paper is structured as follows: first, we begin with the methodology of our study outlining the data collection procedure, including inclusion and exclusion criteria as well as keywords used in our search. Next, we present the key findings of our search, highlighting that the majority of reviews expressed a negative sentiment and providing insights into features common in diabetes apps in addition to issues with integrations. This is followed by the Discussion section, where we describe the principal findings, implications for AP systems, and limitations of our study, before finishing with concluding remarks.

## Methods

### Overview

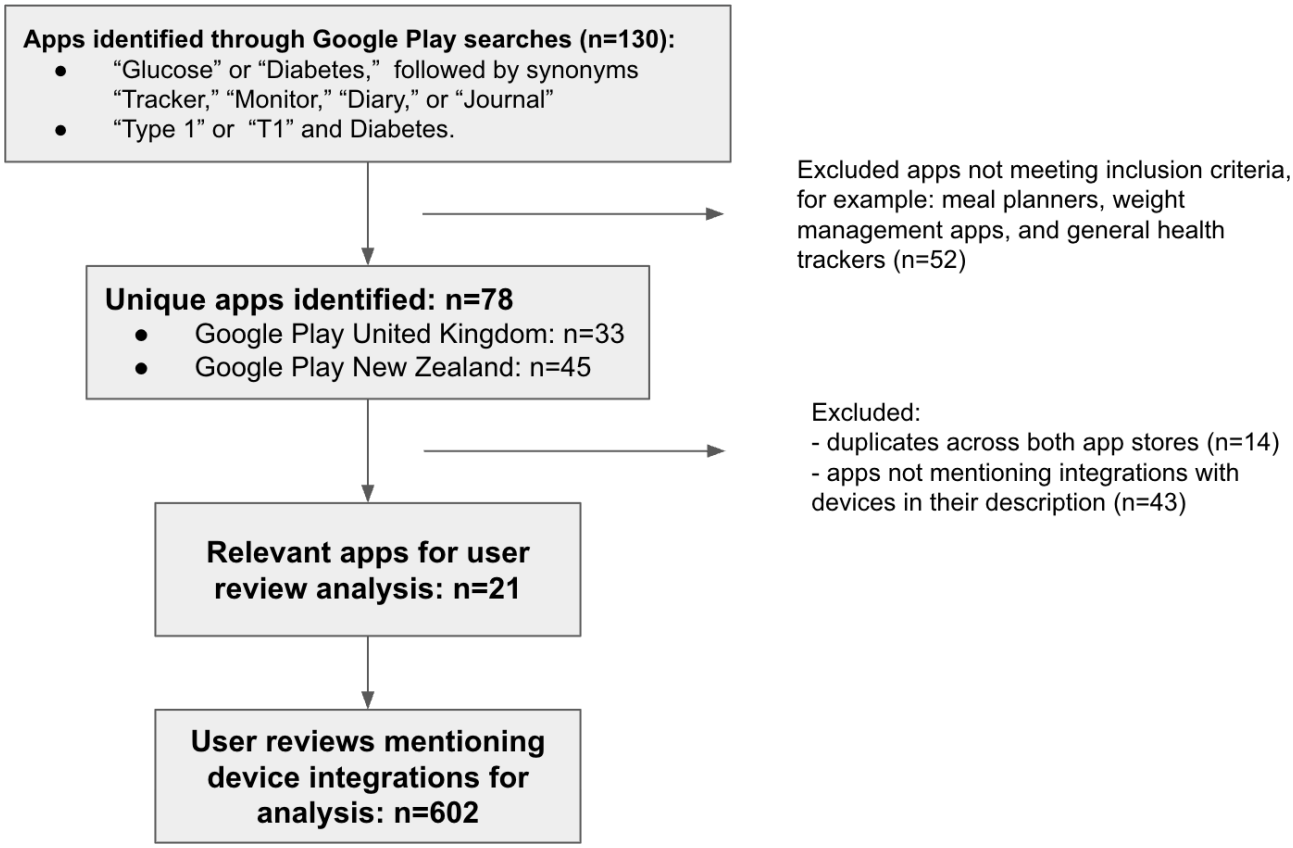
Following the procedures informed by similar app reviews [26], we decided to first identify relevant apps and then focus on their reviews. As users tend to post extreme reviews (either very positive or very negative [31]), public reviews are a great way of understanding factors that are important to users and identifying the most pressing issues. At the same time, by focusing only on reviews mentioning specific functionality, we can reduce the potential bias that the tendency to post extreme reviews could introduce. Our data collection, extraction, and analysis process are described in detail below.

### Data Collection

We used the New Zealand and the UK versions of Google Play to identify apps and reviews for analysis. We focused on Android apps predominantly, as Android phones are generally more affordable to the wider population and account for 70% mobile market share [32], which helps to capture the majority of users. However, while in both the United Kingdom and New Zealand, the market share of Android devices is closer to 50% [33,34], there is high duplication of apps across the Google Play and Apple App stores, with the most popular apps available on both platforms. Furthermore, Google Play reviews are easier to access and process for reviewing, as the Apple App Store does not allow copying of content.

Figure 1 summarizes our data collection process. First, to identify relevant diabetes apps, we used the following keywords in the web version of Google Play: (1) “Glucose” or “Diabetes,” followed by synonyms “Tracker,” “Monitor,” “Diary,” or “Journal” and (2) “Type 1” or “T1” and Diabetes.

**Figure 1.** An overview of the data collection process.




Our focus was to investigate apps that target core diabetes management activities such as tracking blood glucose levels and administering insulin, as they are more relevant to AP closed-loop systems. As a result, we included T1D as part of



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our keywords instead of T2D or gestational diabetes. Furthermore, there are several apps that aimed at T2D like the Type 2 Diabetic Cookbook [35] or Pregnant with Diabetes [36], which focus their functionality according to these conditions but do not provide functionality for diabetes management in general.

The searches resulted in a total of 130 apps, with 28 apps available in both the New Zealand and the UK Google Play app stores. Each author checked the descriptions of the apps to identify those that specifically mentioned device integrations (ie, apps that could connect and import data from other devices, eg, CGM, pumps, and wearable activity trackers), which resulted in 21 relevant apps. These apps and their functionality are summarized in Multimedia Appendix 1. Note that all the apps used in this study had both Android and Apple versions. Each app selected was also available in a wide variety of countries.

Next, for the subset of these 21 apps mentioning integrations, we downloaded user reviews during October and November 2023. The reviews had to meet the following inclusion criteria: (1) mentioned specific functionality or features. Reviews that simply provided praise ("Great app!") or criticism or complaints ("This app is awful!") were excluded, (2) published in the last 12 months, and (3) posted in English.

Given that the number of reviews varied across the apps, reaching over 26,000 for some popular apps such as OneTouch Reveal, we decided to limit the total number of downloaded reviews per app to 50 to avoid skewing the analysis toward features or issues characteristic to only a few popular apps (an approach informed by prior research [28]). Limiting the number allowed us to have a broad range of reviews across all apps.

When an app was available in both app stores and had features or content characteristic to this location, we collected reviews for both versions, for example, FreeStyle LibreLink – NZ and FreeStyle LibreLink - GB were treated as separate apps due to the limited number of reviews in the New Zealand app store. We believe this occurred because access to technologies is impacted by government funding, for example, CGM funding is still under review in New Zealand [37], while it is readily available in the United Kingdom [38] (although access to certain devices is limited). This allowed us to include popular apps that may have been unnecessarily affected by external factors such as funding schemes.

The reviews were manually copied from a desktop version of Google Play by the authors. In total, we downloaded 602 relevant reviews for 21 apps; 1 app (SocialDiabetes) did not have any reviews that met the inclusion criteria.

### Ethical Considerations

This work did not require an ethics application for several reasons. First, app review information is publicly available and published on the relevant app store, as a result, these data may be viewed by anyone with internet access. Furthermore, there is no direct interaction with participants, and sensitive or private information collected. Usernames were also omitted to help ensure reviews, and consequently, individuals are not identifiable.

### Review Annotation and Analysis

Next, we divided the reviews equally between the 2 authors. Each review was annotated by one author, and then the annotations were moderated by the other. For each review, we collected the following information: sentiment (positive, negative, neutral, and mixed), list of mentioned features, whether any integrations were mentioned (yes or no), whether any issues were mentioned (yes or no), details of any issues, and additional open-ended comments that summarized additional points covered in the review.

We used descriptive statistics to analyze the data and identify the main trends. We also analyzed all reviews thematically using the open-ended comments as initial codes. These comments were added during review annotation and moderation and were later reviewed and expanded by the authors. Through this process, we identified 11 feature categories that help to contextualize the findings in wider user experience (tracking, integration, data logging, notifications, accounts, user interface, data sharing, monitoring, compatibility, calculations, and data privacy) and additional concerns related to tracking others (often children) and general fear that unreliable apps can cause deaths.

## Results

### Overview

For the 602 reviews collected for diabetes apps, we were able to identify 11 feature categories (Table 1). Of the reviews collected, we found that over half (n=327, 54.3%) expressed a negative sentiment, while only 187 (31.1%) were positive. The remaining reviews were either neutral (n=15, 2.5%) or included mixed comments (n=73, 12.1%). Similarly, 301 (50.1%) reviews mentioned some type of device integration, and 62.8% (n=378) mentioned bugs or faults within the system. Detailed information about the 21 diabetes apps and reviews, including their version number, sentiment, features, integrations, and related issues, can be found in Multimedia Appendix 1.



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**Table .** Feature categories mentioned in user reviews (N=602)[a].

| Features | Definition | Values, n (%) |
|---|---|---|
| Integration | The ability to connect with external devices. | 259 (43) |
| Tracking | The ability to store data relevant to diabetes management. | 194 (32.2) |
| Data logging | The ability to add contextual information in the app. | 86 (14.3) |
| Notifications | All features related to alarms, alerts, reminders, and tips. | 70 (11.6) |
| User accounts | The ability to log in or out of associated accounts in order to access app functionality. | 38 (6.3) |
| User interface | Any information associated with the user interface. | 34 (5.6) |
| Data sharing | The ability to share static data with an external source. | 27 (4.5) |
| Monitoring | The ability to share dynamic data with an external source. | 15 (2.5) |
| Compatibility | Hardware or software issues between devices. | 15 (2.5) |
| Calculations | The ability to use the app to calculate bolus and other dosage levels. | 9 (1.5) |
| Data privacy | How much control and freedom the user has over where their data are stored and who it is shared with. | 8 (1.3) |

[a]Some reviews mentioned more than 1 feature type.

## Diabetes App Features

Table 1 gives an overview of the feature categories identified in the diabetes app reviews. The most common feature mentioned was device integrations (n=259, 43%), that is, the ability to connect, gather, and share data from external devices such as CGM, automated insulin pumps, smart pens, smartwatches, and so on. Users also highlighted how collecting data from these devices allowed them to make informed decisions about their insulin levels and diabetes management. One user said in their review:

> *FINALLY! A glucose app that actually works with my paired metre! I was considering buying a new metre and now I don't have the need. Additionally, this app creates charts and reports with useful DETAILS! My metre's companion app only shows daily numbers. I'm so happy I found this app!!* [Glooko - Track Diabetes Data]

After integrations, tracking was the next most commonly mentioned feature (n=194, 32.2%). It referred to functionality that allows users to record data either automatically or manually to manage their diabetes. In the reviews we collected, users mentioned medication, carbohydrates, blood glucose levels, weight, and activity tracking as relevant to their management. In addition, trends from these data were also useful to allow users to make data-informed decisions on their diabetes management. One review stated:

> *This is a great app for keeping track of your readings. I personally like the long-term charts which show trends and the times of your day that you have to pay a bit more attention to your sugar levels.* [Diabetes:M - Blood Sugar Diary]

While tracking and data logging features are related, data logging allows users the ability to provide contextual information around the data that they are collecting. In total, 86 (14.3%) reviews explicitly mentioned data logging. Some users liked taking photos of meals or entering manual readings from test machines, while others put in feature requests for the ability to make notes related to specific readings, for example, one review said:

> *... Please, I'm begging, give us a simple "Notes" section? I can write what exactly I ate, or that I accidentally skipped a meal/dose/whatever.* [mySugr - Diabetes Tracker Log]

Mentions of notifications appeared in 11.6% (n=70) reviews and covered a wide variety of information within the apps. Some notifications were simply reminders for entering meal information and so on, while others were alerts or alarms notifying users that their blood glucose levels were out of range. Users found these notifications helpful:

> *... The most useful for me are the ongoing notification & widget (both have trend arrows), it might seem simple but it really does help with trying to stay in range, also, a big plus is 3rd party apps allow you to see both ongoing notification & widget on a WearOS watch ...* [Gluroo Diabetes Logger]

However, others were frustrated by the inability to control these notifications, especially when it related to scheduling and editing the alerts. User reviews highlighted several examples of how



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such uncontrollable alerts could affect everyday life and that the one-size-fits-all approach is not adequate. For example, one user stated:

> *... Also, alarms override phone settings. Sitting in a wedding, or in church, you'll get a loud alarm. Only way to stop it is to turn off your phone ...* [Dexcom G7]

Many reviews were also quite emotional, highlighting users' frustration and the need for reliable devices that simply work:

> *Buggy, intrusive and a battery drain. Pairing is slow, connectivity is poor and readings are inaccurate. Sensors fail before even finishing warmup. Alarms blare all day and all night reporting false lows and connectivity alerts, even with my phone on vibrate or "Do Not Disturb." I was forced to turn all Dexcom notifications off in the system settings. This is a bad, dangerous app, clearly designed by someone who has never had to actually wear the sensor. People will DIE using this GARBAGE app.* [Dexcom G7]

Issues with the lack of control were also extended to other parts of the app. For example, another review described issues faced by shift workers:

> *When are you going to fix being able to adjust the hours of meals & sleep time out of the normal 9 to 5 hours for people that work a graveyard shift. App doesn't let you set your sleep time to be during the day, for people that have to work a graveyard shift, so it totally makes the app useless. Here we are a year later!!! and you haven't addressed my issues. not all people live a 9 to 5 life.* [OneTouch Reveal]

When user accounts were mentioned in reviews (n=38, 6.3%), they were usually in reference to issues with access. That is, users either had trouble registering or logging into an existing account. For example:

> *Had app before but it kept crashing at launch. Uninstalled it. Reinstalled recently. I keep getting stuck at login. It will not let me sign up or login. Uninstalled.* [One Drop: Better Health Today]

Comments directly related to the user interface appeared in 5.6% (n=34) of the reviews. Data visualization in the form of graphs and charts was important to end users so that results were easy to interpret and follow. Furthermore, many reviews highlighted users' resistance to interface changes, which were often seen as undesirable. For example, one review stated:

> *Was good until the last release, when the daily Time in target was removed, and the 24 hour rolling graph. Both my key measures were removed! Please bring these back.* [FreeStyle LibreLink - GB]

Similarly, the ability to share data with external sources was mentioned in 4.5% (n=27) reviews. For example, sharing an app-generated report with a doctor or nurse was considered useful:

> *I love this app it makes it so easy for me to show my doctor my progress my high and my lows because you carry your phone everywhere it's so accessible.* [iHealth Gluco-Smart]

Some apps provided users with the ability to not only share data but also monitor other users. For example, the ability for a parent to monitor a child's blood glucose levels while at school allows them to be kept informed of their time-in-range. Of the reviews collected, 2.5% (n=15) explicitly mentioned monitoring features:

> *It's a blessing. It was very difficult to record and track my mother's diabetes. It made it so easy. Thank you so much for this app. I would really recommend it.* [forDiabetes: diabetes tracker]

Surprisingly, one user mentioned in their review using one of the apps to monitor their cat, as the app synced well with their device and worked with custom ranges:

> *Simple diabetes tracking app. Just had to setup a custom range for my cat. I set 80 - 120 for before a meal and 80 - 300 after a meal for a generic range which I received from a vet. Works with alphatrak3 for pets.* [Blood Sugar Diary for Diabetes]

Compatibility was also mentioned in 2.5% (n=15) of reviews. While some issues were minor, such as phones no longer being able to access an app, others highlighted interoperability and cost issues in accessing diabetes technology:

> *My device is only compatible with the Clarity app and is incompatible with both the G6 and G7 CGM apps. I love using the Dexcom but the receiver is extremely expensive and inconvenient. Please add the OnePlus Nord N300 5G to the list of Dexcom accessible devices soon. Thank you!* [Dexcom Clarity]

Diabetes calculations were mentioned less frequently than initially anticipated (only n=9, 1.5% of reviews). We suspect this is because regulatory bodies such as the US Food and Drug Administration or Product Safety Australia have recalled apps, where these calculations have failed due to input errors [39,40]. However, users expressed that they hoped these calculators would come back as they found them useful, even though they knew why they were removed. For example, one user mentioned:

> *Best logging and calculating app I've found. Not perfect, but quite good. It was the only bolus calculator available until that feature was withdrawn due to U.S. regulations. Sad to see that gone.* [Diabetes:M - Blood Sugar Diary]

Similarly, data privacy was only explored in 1.3% (n=8) of the reviews collected. However, of those who did mention data privacy, permissions and how their data were shared, accessed, and used were important:

> *Consent for Private Data Collection Required to Use the App - No option to decline = Uninstalled* [SmartLog]

Another user highlighted that the app continued to run in the background despite not being given the appropriate permissions to allow this functionality:

> *I do not give this app permission to run in the background, yet it continues to do so. I have to force*



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*quit it to get it to stop.* [mySugr - Diabetes Tracker Log]

### Issues With Integrations

Given that the majority of reviews were either negative or mixed (ie, covering both good and bad features or experiences), it was no surprise that several issues were identified. In general, 378 (62.8%) reviews mentioned some issues, including 280 (46.5%) reviews focused specifically on issues related to device integrations. Table 2 summarizes the integration issues found in the user reviews.

**Table .** Integration issues mentioned in user reviews (n=378).

| Issue | Definition | Values, n (%) |
|---|---|---|
| Connectivity | The inability to connect with external devices. | 95 (25.1) |
| Data | The inability to store, manage, or access data. | 49 (22) |
| Alerts | The inability to notify users of important messages. | 35 (9.2) |
| Updates | The inability to update the software and associated hardware. | 31 (8.5) |
| Hardware | Hardware that does not respond as expected. | 24 (6.4) |
| Access | The inability to access the app, services, and associated hardware. | 1 (3.2) |

One of the most common issues found in the user reviews associated with integrations was the inability to connect with external devices. Several reviews discussed user's difficulty with connecting with medical devices such as insulin pumps or CGM in order to manage diabetes levels. One user mentioned:

> *When it works, it's really great, but it seems to struggle to work properly, plagued with signal losses. I'm not sure if it's the sensor or the software at this point. My friend's app also loses signal from a sensor on her arm to a phone in her pocket ...* [LibreLinkUp]

As highlighted in the previous review, connectivity issues also led to issues with the ability to store, manage, or access data. One of the primary benefits of the apps is to allow users to make data-informed decisions about their diabetes management. However, when data are not collected correctly, this leads to a lack of trust in apps:

> *The app leaves much to desire. No charts showing your readings so you can visually get an idea of what to expect out of your blood sugar trends. The tester is cheap junk. I've cross checked it multiple times with the most accurate tester on the market and sometimes it's over 70 mg/l higher. If I wasn't double checking between both testers, I very well could have taken a lethal dose of insulin. Absolutely do not recommend for more unstable type one diabetics like myself. It's honestly awful.* [One Drop: Better Health Today]

Further compounding these issues were alerts failing to notify users when their blood glucose levels were no longer in their optimum range. Delays caused by unreliable software or connection issues could be potentially dangerous, especially when a prompt remedial action was required:

> *Rarely has updated numbers, alerts can come after kid has been low for an hour.* [LibreLinkUp]

Software updates could also cause significant problems for users, sometimes causing them to be unable to continue using their system as expected:

> *Decided to stop working all of a sudden, will NOT reconnect with Bluetooth at all. Big stuff up on updates. Not good for people who need the software.* [SmartLog]

The above issues could have more serious consequences when the app was used on behalf of someone else. While there were just a few reviews describing such use (n=15, 3.9%), they highlight potential risks, as it is often vulnerable users who are monitored this way. Some of these reviews mentioned connection issues, data loss, and general lack of reliability, often caused by app updates:

> *This app has lost its credibility after the recent update (Sep 27, 2023). There's frequent signal loss, and the BGL doesn't update for as long as 1 hour! Alarms don't trigger in time. Many times, I received a low alarm after successfully treating a potential low. I hope the developers understand how crucial this is! My child is only 3YO, which makes it so important to be able to monitor her levels, even when she's not with me. It was a near flawless app before this update. Possible to roll back?* [Libre LinkUp]

Alongside these software problems, issues with the hardware devices themselves appeared in the user reviews. From problems with hardware not responding to issues with getting readings, it was clear that hardware reliability was crucial to the success of an app:

> *I'm on my 2nd 90-day G7 shipment. I've had one or two sensors fail before their expiration time & at least one that kept dropping its signal in each batch. I'm using the back of the arm, washing it with soap and water, & wiping my arm with alcohol and drying before inserting the sensor as instructed. I love the greater freedom that CGMs provide & Dexcom has*



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> *been great about replacing bad sensors, but they need to improve reliability…* [Dexcom G7]

Finally, access was a key issue mentioned in 3.2% (n=12) of reviews. This could be related to an inability to log into an account but also included features hidden behind paywalls, causing accessibility and equity concerns:

> *I purchased this app assuming it'd allow me to track and then share information with my physician. It would - if I agreed to pay an additional $60.00 per year for access to reports. I've submitted a request for a refund to google; I'm not buying an app just to be told to pay for a subscription. That's absurd.* [Diabetes & Diet Tracker]

The reviews mentioning the above issues also highlighted the need for good customer service. Many reviewers mentioned unresponsive developers when complaining about the various factors, which could further reduce the trust in the apps:

> *Would be a great app if the built in data imports worked. Until I can bring my data over I can't use this. Contacted support and still no contact 3+ weeks later. Appears to be a pointless app. Rechecked, imports still not working.* [Diabetes:M - Blood Sugar Diary]

# Discussion

## Principal Findings

### Overview

The aim of this study was to investigate the role device integrations play in the use of smartphone apps for diabetes management. Our results show that apps are used for a wide variety of reasons to assist with diabetes management. When working as expected, they are highly valued and useful to ensure that users remain "in range" and improve health outcomes. However, when issues occur, users highlight how this could have serious and dangerous impacts on their overall health—particularly in relation to insulin administration, as too much or too little can trigger adverse events with negative health effects. In the following sections, we discuss the implications of these findings and contribute to a better understanding of issues related to using popular diabetes apps as part of AP systems.

### Reliability, Trustworthiness, and Burden

Given the high number of negative and mixed reviews, it is evident that current apps do not adequately meet users' needs. In particular, issues occurring either with hardware, such as CGM sensors, or the software itself would cause users to not trust apps to accurately track their glucose levels. Some reviews even highlighted that this would cause users to stop using the app altogether, while others talked about measuring themselves in multiple ways to ensure that they had accurate results. One of the fundamental goals of these apps is to assist with self-care management and to consequently reduce the burden; however, by forcing users to measure and track themselves in multiple ways, the apps reviewed have failed in this regard.

In addition, once users see that the app is failing, for whatever reason, they tend to uninstall the app and look for an alternative. That is, once trust is lost, it is difficult to regain. This is reflective of other results related to software trustworthiness with health apps. For example, Wicks and Chiauzzi [41] highlight that while there is great potential for health-based apps, a lack of regulation and adequate verification processes means that apps do not behave as expected, leading to poor quality and a lack of trust.

As the internet became a prevalent place for information sharing, the Health on the Net Code was created as a code of conduct in the health or medical domain for sharing information on websites [42]. Huang et al [25] adapted the code for diabetes medication management apps and found that only 1 app of the 143 investigated met all criteria. Our results are reflective of this, in that user reviews show some apps to be unreliable and therefore untrustworthy. This emphasizes the need for appropriate regulation and verification processes to ensure that apps are fit for purpose and meet users' needs. Furthermore, as apps become part of AP systems and diabetics are more reliant on this technology, trustworthiness, reliability, and quality assurance will become increasingly important.

### IoT Challenges Related to Diabetes Apps and Devices

As stated previously, IoT systems come with inherent challenges for many different reasons. Lohiya and Thakkar [18] identified 12 key challenges for IoT, 6 of which are reflected in the reviews analyzed, namely, connectivity, device monitoring and sensing, device and data privacy, data analytics, security, and evolution of IoT devices. Below, we explore these 6 key challenges in relation to the reviews analyzed.

Connectivity issues in IoT systems relate to multiple devices being connected to the network, while device monitoring and sensing relates to sensors being able to respond to real-time data. In the reviews analyzed, which mention integrations specifically, users were often working with only 1 sensor (such as a CGM) being connected with 1 app; however, despite this simple setup, users still encountered significant issues in tracking real-time data. In addition, there were multiple data losses, which meant that users could not trust the information they were receiving from the system.

Device and data privacy refers to the accessibility of data or devices being shared only as the owner of that data allows. While some user reviews explicitly mentioned privacy concerns, it was surprising to find that there were more issues around an inability to share data with others, such as doctors or caregivers, in a useful and readable format. This was linked with the data analytics challenge, in which raw data are processed into understandable information. Despite privacy issues and the prevalence of dangerous data access permissions in diabetes apps [43], users appeared to be less concerned with data privacy than we anticipated and more concerned with the meaning that they could infer from that data for their diabetes management to share with others. This can be a serious issue, as data collected by diabetes apps can be considered sensitive, which can introduce potential vulnerabilities if that data are stored on external servers—as is the case with most health apps [44]. This



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also exposes users at risk of data leaks and other security vulnerabilities [45-47].

Security is a challenge for IoT systems, as devices must be able to communicate and share information within specific networks, and there already exist interoperability issues across different vendors and devices [48]. This is also the case for diabetes devices, for example, with a lack of compatibility between sensors and CGMs from different manufacturers unable to communicate. Given that commercial gains are at stake, it is unlikely that a unified ecosystem will develop in the near future, although DIY diabetes projects such as OpenAPS can work with different types of CGMs [7]. The above issues and challenges are reflected in the diabetes apps reviewed, we found that there were significant issues with access and updates that relate to this challenge, which echo similar issues noted for other health apps, for example, users of mental health apps reported being "devastated" after an app update wiped out their historic data [26]. Access issues often prevented users from being able to log in and retrieve their information from apps. Similarly, updates as part of the usual software maintenance process could lead to new issues being introduced. Security will be an ongoing issue for diabetes technology, as it is inherently sensitive information shared over the internet. In fact, even people directly involved in diabetes DIY using Nightscout see it as high risk and requiring expert involvement [49]. Therefore, there is an opportunity for apps developed by experts to support this type of AP solutions. However, as highlighted by the reviews, it will be important to ensure that prioritizing security will not impede access to the data itself.

The last IoT challenge we encountered in the reviews was an evolution of IoT devices, or rather interoperability challenges, when a lack of standard design makes it difficult to ensure devices are compatible with each other. This was evidenced by the number of different hardware systems mentioned in the reviews, such as CGM sensors and other testing devices. As DIY systems become more prevalent, app developers will need to ensure that they are clear about device compatibility for the systems they develop.

### *Implications for AP Systems*

As mentioned previously, AP systems use a combination of a CGM sensor, an automated insulin pump, and a website or smartphone app to create a closed-loop system that mimics a real-life pancreas [5]. As a result, the desirable features and challenges outlined in the user reviews—related to both the hardware and the app itself—will be relevant to AP system developers and the wider DIY community.

There are significant issues around the reliability, trustworthiness, and burden that smartphone apps create for diabetics. However, when they work well, they can lead to great health benefits as outlined in the reviews analyzed. AP systems that use apps like the ones investigated here will inherit the same issues if similar engineering processes are followed. Furthermore, the implications of inaccurate data on patient health and decision-making can negatively impact the user's health. This is compounded by the incorporation of artificial intelligence algorithms, which are used to decide what level of insulin to administer. Without reliable data, the AP system may deliver an incorrect dosage, leading to hypo- or hyperglycemic events. Ghassemi et al [50] emphasize the importance of rigorous validation for these systems to ensure the work as expected and avoid bias. It is evident that good quality assurance practices will be imperative to the success of AP systems to ensure that they are reliable and trustworthy and meet users' needs.

All current and proposed AP systems work by integrating a smartphone app as part of the closed-loop system. As phones are regularly updated, users must keep up with new app versions, changes to interfaces, and the cost barriers for newer phones. Similarly, older devices may struggle with battery life, which further impacts the use of older technologies as part of the AP system. This coupled with the regular maintenance required for pumps, and a continuous supply of CGM sensors significantly increases the burden on the end user. The need for user-friendly designs that are supported across multiple platforms and devices is necessary to ensure equitable access to the majority of diabetics.

Furthermore, as AP systems are themselves IoT systems, they inherit the challenges of IoT in addition to the issues outlined in the app reviews. As with most IoT systems, interoperability will be a key factor in their success. In the apps reviewed, hardware issues were mostly in relation to the single sensor and a single smartphone app—in contrast, AP systems may be far more complex, requiring communication between multiple sensors, pumps, and apps, leading to more potential problems. Therefore, the engineering of AP systems is an interesting and important avenue for future work.

## Limitations

The user reviews of diabetes apps were used in this research to determine whether apps meet user needs and how integrations are used. A limitation of this study is that we only investigated reviews published within the last year that explicitly mention features or functionality. There may be other themes that could have been discovered over a longer time period. Furthermore, we were unable to collect demographic data about reviewers, as they are anonymized. However, our data still give a good understanding of recent issues and features available in diabetes technologies, and the issues identified would occur regardless of the background of the user, which reduces the impact of this limitation.

Our focus on the app store means that our results reflect apps that are commonly available and attached to supported integrations. As a result, we do not investigate DIY solutions, as reviews are less readily available for these apps. Furthermore, there is the potential for bias toward extremely positive or negative comments [31] or toward more popular apps that receive significantly more user reviews. However, by limiting the number of reviews per app (by following an approach reported by Stawarz et al [28]) and focusing on reviews that explicitly mention features and functionality, we were able to reduce these biases.

Finally, our focus on user reviews allowed us to explore a wide range of apps and gather user experience data that would otherwise be difficult to access. While in-depth studies of



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individual apps would provide stronger data, this would not give us the same breadth of coverage or allow for the evaluation of such a diverse set of integrations. We believe that this provides the best possible analysis for integrations and the implications this may have for AP systems. Future research could explore the detailed implementation of various integrations within specific apps to better understand related issues and devise approaches to addressing them.

## Conclusions

Using user reviews as the basis for analysis, this research shows that the use of smartphone apps in self-care and diabetes management is a suitable solution, which can have positive health benefits for users. However, it is imperative that due to their safety-critical nature, such apps are reliable and trustworthy and meet users' needs in order to prevent and avoid adverse events. In addition, the apps must reduce the burden of self-care for diabetics to be appropriate for everyday use. The challenges and opportunities we have identified in the diabetes apps open up new avenues for research and provide warnings for those engineering AP systems to ensure that they do not inherit the same issues. Future work could include analysis of the apps themselves using a tool such as the Mobile App Rating Scale [51] to compare and contrast with our analysis here. In addition, we should explore the way in which AP systems are engineered and investigate interoperability issues, finding a balance between regulation and quality assurance practices.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Complete app and user review data with analysis.
[XLSX File, 103 KB - diabetes_v10i1e62926_app1.xlsx ]

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## Abbreviations

**AP:** artificial pancreas
**CGM:** continuous glucose monitor
**DIY:** do-it-yourself
**IoT:** internet of things
**T1D:** type 1 diabetes
**T2D:** type 2 diabetes


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# Experience of Using Wearable Devices for Dietary Management for Chinese Americans With Type 2 Diabetes: One-Group Prospective Cohort Study

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## Abstract

**Background:** Chinese Americans with type 2 diabetes (T2D) face significant challenges in dietary management, which is crucial for glycemic control. Wearable sensors, such as the electronic button (eButton) and continuous glucose monitor (CGM), offer a promising solution.

**Objective:** We aimed to explore the experience of using the eButton and CGM for dietary management among Chinese Americans with T2D.

**Methods:** Chinese Americans with T2D (N=11) participated in a one-group prospective cohort study, recruited via convenience sampling from the electronic medical records of NYU Langone Health. Participants wore an eButton on their chest to record their 10-day meals and a CGM for the 2 weeks and kept a diary to track food intake, medication, and physical activity. Individual interviews were conducted after 2 weeks to discuss their experience, barriers, and facilitators of use. Interview transcripts were thematically analyzed using ATLAS.ti (Scientific Software Development GmbH) software.

**Results:** Facilitators of using an eButton included the device's ease of use, ability to make participants more mindful, and influence on increased sense of control. Greater awareness of food intake enabled participants to eat smaller portions. Reported barriers included privacy concerns, difficulty positioning the camera for pictures, and the lack of a meal photo record to track glucose trends. For the CGM, facilitators included its comfort and ease of use, its ability to increase mindfulness of meal choices, and its motivating changes in eating behaviors. The most common barriers included the sensor falling off, getting trapped in clothes, and causing skin sensitivity.

**Conclusions:** Our findings suggest that it is feasible for Chinese Americans with T2D to use eButton and CGM for dietary management. When paired, these tools offer a promising method to help patients visualize the relationship between food intake and glycemic response. For clinical implementation, structured support from health care providers—such as dietitians or diabetes educators—is essential to help patients interpret the data meaningfully. Clinicians should also consider cultural factors, privacy concerns, and individual preferences when introducing wearable technologies, ensuring a personalized and patient-centered approach to diabetes care. Future studies should apply these devices to a larger sample over a longer duration to better inform effective diabetes management strategies.

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**KEYWORDS**

Chinese Americans; continuous glucose monitor; dietary management; eButton; type 2 diabetes; wearable devices; electronic button



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## Introduction

Type 2 diabetes (T2D) is becoming a growing public health concern in the United States and globally due to rapid cultural and social changes, such as rising urbanization, aging populations, and maladaptive lifestyle behaviors (eg, reduced physical activity and poor diet) [1]. This disease is associated with detrimental health outcomes, including stroke, cardiovascular disease, and kidney failure. The Centers for Disease Control reports the age-adjusted prevalence rate of T2D among Asian Americans is 9%, placing them at moderate risk [2]. Notably, the age-adjusted prevalence rate among Chinese Americans increased from 8.69% to 10.57% between 2011 and 2018, likely paralleling rising immigration levels [3]. Other studies have found that Chinese Americans are also at a higher risk for T2D than other racial and ethnic groups despite having a lower average BMI [4]. Chinese Americans' higher risk of developing T2D may be partly explained by eating certain cultural staple foods that typically elicit a high glycemic response, including rice, noodles, and steamed buns [5]. Moreover, unhealthy eating habits may be exacerbated by acculturation, as exposure to Western dietary patterns often includes foods with higher levels of fat, sugar, and sodium.

Diabetes dietary self-management is a critical part of managing the disease to achieve optimal glycemic control. The dietary recommendation guidelines proposed by the American Diabetes Association (ADA) [6,7] suggest that the daily intake of carbohydrates be less than 130 grams and that patients should avoid consuming food rich in starch. However, Chinese Americans' ability to practice these dietary management recommendations is challenging. It has been found that Chinese Americans' diabetes dietary self-management practices are poorer than those of Black and Hispanic Americans [8]. For instance, a study found unfavorable levels of diabetes self-management among Chinese American participants with T2D, reporting that only 36.8% followed dietary recommendations [9]. Chinese Americans' tendency to consume carbohydrate-heavy meals impedes their ability to follow nationally recommended fiber intake. For example, a review of Chinese immigrants' dietary behaviors in the United States found that fiber consumption ranged from 12 to 14 grams per day, which is less than the minimum recommended 25 grams per day for women and 38 grams per day for men [10]. Challenges to practicing diabetes dietary management are exacerbated by several cultural factors specific to Chinese Americans, for example, lack of culturally adapted dietary programs [5], disruptions in meaningful cultural meal practices that are normally carbohydrate-rich (such as rice), and eating with others in a communal manner coming from a collectivist culture [5].

Similar challenges in diabetes dietary self-management have been observed in other immigrant and ethnic minority populations. For example, Iqbal [11] conducted a scoping review of dietary behaviors among British South Asians with T2D and identified a range of cultural influences that complicate dietary self-management. These included strong cultural and religious norms surrounding food preparation and consumption, such as expectations to eat traditional high-carbohydrate meals (eg, white rice, roti, and sweets), reluctance to reject food offerings due to hospitality norms, and communal eating practices. Many participants expressed skepticism toward Western dietary advice and emphasized the importance of culturally tailored counseling. The study highlighted the need for diabetes education that respects cultural identity, incorporates traditional foods in a health-conscious way, and involves family members in intervention efforts. Many of these barriers have also been reported among Mexican Americans, who often face challenges reducing consumption of culturally important foods, such as tortillas, rice, and sweetened beverages, despite understanding dietary risks [12]. In African American communities, dietary self-management may be hindered by systemic issues, including food insecurity, neighborhood-level food access, and culturally embedded food preferences and preparation styles [13]. Collectively, these findings reveal that culturally responsive and community-informed strategies are essential to support dietary self-management in diverse populations with T2D.

Wearable devices can monitor a wide variety of physiological outcomes, including blood glucose, blood pressure, blood lipid levels, weight, waist circumference, and BMI. Among such technologies, studies have shown the continuous glucose monitor (CGM) to be an effective tool in capturing glucose patterns and positively influencing users' dietary choices. CGM technology is already well-established in the management of type 1 diabetes (T1D), where it has been shown to improve glycemic control, reduce hypoglycemic events, and enhance quality of life. A study has demonstrated improvements in time-in-range and reduced glucose variability when CGMs are paired with insulin delivery systems [14]. Similarly, the development of hybrid closed-loop systems, automated insulin delivery devices informed by real-time CGM data, has significantly advanced diabetes care for individuals with T1D [15]. These innovations have informed the growing use of CGM in T2D management, particularly among patients on insulin or with poor glycemic control. As such, CGM use has evolved from a primarily clinical monitoring tool to a behavioral intervention capable of enhancing patient engagement in both T1D and T2D contexts. For instance, Zahedani et al [16] integrated CGM data within a smartphone app that allowed users to log their food intake, physical activity, and body weight. The app provided daily insights, including glucose pattern tracking, macronutrient breakdown, glycemic index, glycemic load, and activity measures [16]. They found that CGM data integration within a smartphone app enhanced the metabolic health of patients with T2D by significantly improving hyperglycemia, glucose variability, and hypoglycemia. Moreover, users' body weight decreased, and users developed healthier eating habits, with reduced daily caloric intake and carbohydrate-to-calorie ratio and increased intake of protein, fiber, and healthy fats relative to calories [16].

Other dietary tracking tools have been developed to reduce dietary management challenges. For example, the electronic button (eButton), a wearable imaging device, can automatically record food data during a meal by taking food pictures every 3 - 6 seconds, which are then saved on a SIM card [17]. The recorded food picture data are processed to determine food names, volumes/portion size, and nutrient value (eg,



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carbohydrate grams) [18,19] Studies have established its acceptability and feasibility in real life for dietary assessments; however, the existing device has not been applied to dietary management for individuals with T2D [20,21].

Despite the advances that have been made in terms of using wearable devices in dietary management among patients with T2D, there are a very limited number of studies that consider applying such technology to Chinese American patients with T2D [22]. As Chinese Americans are at notable risk for developing T2D and endure challenges in managing their condition, it is critical to reduce diabetes disparities in this population by understanding how these technologies can be leveraged to improve dietary self-management. Moreover, while CGMs have shown promise in diabetes care, there is limited evidence on their integration with dietary tracking tools (eg, image-based wearable devices like the eButton) among Chinese Americans. Addressing this gap is important to advancing culturally tailored digital health solutions. Thus, this study aimed to explore the barriers and facilitators of using wearable sensors, specifically the eButton and CGM, for dietary self-management for this population. Our research question of interest was: What are the experiences of using wearable sensors (ie, eButton and CGM) for dietary self-management among Chinese Americans with T2D?

# Methods

## Study Design

The study was conducted from January 2022 to October 2023. We conducted a one-group, single-site, prospective cohort study among Chinese Americans. Following instructions on its use, participants were asked to wear a Freestyle Libre Pro CGM for 14 days, wear an eButton to record food images during meal times over 10 days, and record their food intake using a paper diary. On the first day of the study, participants were instructed to wear the eButton on their chest and turn on the camera during meals over the 10-day study period. In addition, our research staff put on the Libre Pro CGM for participants during a 14-day study period. At the end of the 14-day study, research staff removed the CGM from participants, downloaded the CGM and eButton image data, and reviewed the CGM results alongside participants' food diaries and eButton pictures to help identify potential factors influencing their glucose levels. Following this review, individual interviews were conducted. This protocol enabled a comprehensive assessment of participants' dietary behaviors and glucose patterns, which informed the subsequent qualitative interviews.

## Participant Eligibility

### *Inclusion Criteria*

Participants were eligible to participate in the study if they met the following inclusion criteria: (1) aged ≥18 years old, (2) diagnosed with T2D at least 1 year prior, (3) self-identified as first- or second-generation Chinese immigrants, (4) felt comfortable communicating in English, and (5) had access to a computer and internet connection. While we acknowledge that there is a group of Chinese Americans who are limited in English proficiency, for the limited scope and timeline of this study, we will only focus on those who feel comfortable communicating in English.

### *Exclusion Criteria*

Participants were ineligible for participation in the study if they met any of the following criteria: (1) planning frequent travel or vacations or intending to relocate in the next 5 weeks, (2) having serious diabetes-related complications, physical illness, or a mental illness (eg, schizophrenia, bipolar disorder, or substance abuse) that would preclude participation, or (3) having severe cognitive impairments (eg, dementia or intellectual disability).

## Participant Recruitment

We applied convenience sampling to recruit study participants. Eligible participants were recruited using NYU Langone Health electronic health records patient portal (MyChart, Epic Systems Corporation). MyChart recruitment through the NYU DataCore analytics team involves sending a message about the study through the patient portal "MyChart" to patients who meet inclusion criteria. Individuals responded "interested" or "not interested." Interested individuals were contacted by our research staff for further screening. Qualified individuals who provided consent were invited to the research facilities to learn more about study procedures and conduct research activities. The final sample size was determined based on data saturation; no new themes emerged, which is considered the gold standard of the qualitative method [23,24].

## Qualitative Interviews

At the end of the 14-day study, participants participated in a semistructured individual interview that included open-ended questions to tell us about their experience using eButton and the CGM. The semistructured individual interview is guided by the Healthy Eating guidelines of the Association of Diabetes Care and Education Specialists (ADCES) 7 Self-Care Behaviors [25]. The interviews were conducted in a private room, audio recorded using 2 digital recorders, and lasted approximately 30 minutes each. Participants were informed that they would not be judged on what they had done or said related to the use of the eButton and CGM and that there was no right or wrong answer. Participants were encouraged to talk about what they believed and what they felt when they used the eButton and CGM.

## Relevant Areas Explored in Interviews (Topic Guide)

Data were collected by qualitative interviews based on a topic guide [26]. The topic guide addressed participants' eButton experiences (eg, what they liked/disliked, what could be improved for future designs), their CGM experiences (eg, what they liked/disliked and opinions on the CGM report), their previous diabetes self-management practices, their previous experiences with measuring food portion sizes and carbohydrate grams, their opinions on eButton and wearing frequency, their opinions on diabetes/nutrition education (and frequency of sessions), and their insight on which populations would benefit from using eButton and CGM together.

The interview topic guide was modified over the course of the study, using an iterative process informed by the content from



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previous interviews [27]. For example, we incorporated more questions on "Would you like to use other health monitors (eg, Fitbit for tracking physical activities)? Do you think it will increase the burden for you if using multiple health monitors?" after several participants discussed how wearing the CGM and eButton impacted their daily activities.

### Data Analysis

The recorded content was transcribed using Landmark transcription (Landmark Associates Inc) software. Landmark is a specialized human transcription and translation service for qualitative research [28]. This service allows users to transcribe their data through a secure, HIPAA (Health Insurance Portability and Accountability Act)–compliant platform with 99% guaranteed accuracy. Each transcription file is encrypted with a unique key, which is also encrypted by a separate master key that rotates regularly.

Following transcription using Landmark, a research assistant double-checked the interview transcripts to further deidentify any remaining personal identifiable information. Once personalized information was confirmed to be deidentified, a coding book was developed. Two research assistants read the interview transcripts independently, identifying main themes and subthemes. After discussing these results with a third expert in diabetes management, the research assistants created a codebook in an Excel (Microsoft Corp) spreadsheet to develop the coding framework and refine codes where necessary.

Using ATLAS.ti version 23.2.1 software, the 2 trained research assistants thematically analyzed the qualitative transcripts. Each research assistant independently coded the transcripts using the Excel codebook as a guide and then compared their coding results. Furthermore, a set of pregenerated (a priori) codes (eg, eButton pros/cons, CGM pros/cons) was imported into ATLAS software and described to guide the analysis process. Also, new codes (a posteriori) that emerged during analysis (eg, previous diabetes management behaviors) were described. Moreover, each broad topic in the guide was taken as an overarching category (deductive coding), which was then refined based on the analyzed transcripts (inductive coding) [26]. If new codes emerged, all of the documents were rechecked and coded accordingly. Similarities and differences in coding outcomes were discussed between 2 research assistants (and with the third expert in diabetes management using wearable devices) until a consensus was reached. Once codes were analyzed and reviewed in all interview documents, reports were created showing the frequency with which the codes were used to label data segments in the main themes and subthemes. This step assisted in identifying the most common experiences of participants with wearing the eButton and CGM.

In addition, descriptive analysis was conducted for demographic variables using SPSS version 28.0 (IBM Corp). Continuous variables (eg, age and education) were described using mean (SD). Categorical variables (eg, sex and employment) were described using frequency and percentages. After identifying the qualitative findings, we also reported the counts for the number of themes and subthemes.

### Ethical Considerations

The study was approved by the institutional review board at NYU Langone Health (i21-01714). All participants provided written informed consent to participate in this study. Information about study subjects was kept confidential and managed in accordance with the requirements of the HIPAA of 1996. Participants were compensated with a $100 gift card for their participation in the entire study. There were no costs that the participant incurred as a result of participating in the study.

## Results

### Sample Description

We enrolled 12 eligible Chinese Americans with T2D, 1 withdrew from the study, and 11 completed all data collection. The 11 participants who completed the study are all Chinese Americans, with 8 males and 3 females, the age group ranging from 42 to 77 years (Table S1 in Multimedia Appendix 1). The facilitators and barriers to using the eButton and CGM were summarized in Table S2 in Multimedia Appendix 1.

### Experience of Using eButton Device

Participants recounted their experiences of using eButton for the duration of the study period, discussing their perceived advantages and disadvantages of the device, as well as suggestions for improved functionality. Among 11 participants who discussed the eButton advantages, participants perceived that it was very easy to use (n=6) and facilitates mindfulness (n=6), which helps to increase participants' sense of control over their eating habits and portion sizes. However, major barriers to using eButton included the lack of privacy from the camera (n=4), difficulties in staging the camera (n=5), and the device's obtrusive appearance (n=4). Participants suggested that the functionality of the eButton device could be improved by including several features, such as having reminders/notifications to turn off the camera (n=2), incorporating language translations (n=1), synching the data to their iPhones (Apple Inc; n=5), and saving pictures of meals to enable record-tracking (n=3).

### Participants' Perceived Advantages of eButton Ease of Use

More than half of the participants (n=6) in this study noted the very simple, straightforward nature of using the eButton device and were satisfied with the lack of complicated instructions. Much of this ease is due to the device's ability to collect dietary intake data by automatically taking pictures, leaving the participants with no effort to manually record the information. For instance, one participant describes the benefits of eButton's effortless utility:

> *The fact that [eButton] is not very impactful was probably the best thing. The only thing is that you have to remember to have it… and then put it on, so that was nice.* [ID 1001]

eButton is easy to use, as it minimally interferes with participants' daily lives. Users simply place it on their chest, and the device does the rest of the work for them, eliminating any tedious work on the user's end. Another participant



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appreciated not having to be overly conscious about tracking information and found it convenient to leave data collection to the eButton:

> *eButton is very easy to use for me, and all you do is just make sure you charge the battery before you use it every time you finished the filming.* [ID 1005]

eButton's uncomplicated functionality alleviates any inconveniences with using the device in an effective manner. Participants admired this ease of use and noted it as playing a major role in their positive experience with eButton.

### Increased Mindfulness and Sense of Control of Eating Habits

Even though eButton currently only functions as an assessment tool without providing any real-time feedback, participants think it can serve as a reminding tool for eating habits, specifically their meal portion sizes. For example, a participant appreciated how eButton held them accountable with their carbohydrate consumption by gradually becoming more aware of the amount they were eating:

> *eButton in a sense actually makes you conscious. So, when I wear eButton it reminds me that "oh, how much is this rice? How much is that cake?" It's almost like somebody is sitting there reminding you just by wearing it. So maybe I shouldn't eat that much.* [ID 1016]

Simply wearing the eButton makes users more conscious about their eating choices and feel responsible for making a healthy change to their dietary behavior. Furthermore, participants found that this increased mindfulness helped them to maintain steady blood glucose levels throughout the day by deliberately controlling their meal portion sizes. If they were presented with the option of consuming an unhealthy food item, they realized that they could exercise willpower and decide to forego eating it or simply have a smaller amount:

> *You know right away this meal doesn't do you any good, and you can stay away from it. And then next time you have it, you either have a smaller portion or just don't have it at all. And that way, it can help your blood glucose stay stable.* [ID 1013]

eButton is pivotal in diabetes self-management by holding users accountable for their eating habits, and by doing so, helps them to pay closer attention to the content and size of their meals.

### Participants' Perceived Disadvantages of eButton

#### *Lack of Privacy*

Several participants noted the inconvenience of having the eButton device record and take pictures of every object in its periphery. Some participants' family members were also concerned about being taped, as it made them feel uncomfortable. Thus, participants had to be extra cautious of what was being recorded to respect their own and their family's privacy. Doing so was particularly challenging because the eButton has a very small camera and dim lighting, so participants often forgot to turn off the recording. One participant describes the burden of this faulty feature:

> *... afterwards you have to remind yourself to turn it off. Then you walk around in the house with [eButton] recording everything with other people around. Then it's a little intrusive. I worry if something is caught on camera.* [ID 1016]

Five other participants expressed concerns about the eButton's working status, as they faced problems with knowing whether the device was on or off. This was particularly stressful to some because they were not confident about whether they were recording their meals properly and/or taping something they were not supposed to.

The lack of privacy presents a barrier to participants feeling completely at ease when using eButton in fear of not knowing what is being caught on camera. This barrier may or may not prevent them from wanting to use eButton as often, unless there is a way to remind them to turn off the camera.

#### *Difficulties in Staging the Camera*

The eButton camera's small size poses not only an issue, but also the challenge in staging it to take pictures of the meals. The device's placement on the user's chest makes it difficult to position it in such a way to capture a high-quality image:

> *The placement of eButton, even with the Velcro stickers, was still incredibly difficult because every time I thought I was aiming it at a good angle, when I looked at the images, it turns out it wasn't a good angle.* [ID 1017]

Failing to take high-quality pictures may prevent eButton users from keeping an accurate track of the food they are eating, as the bad angles may exclude certain parts of a meal placed in front of them.

#### *Bulky and Obtrusive Appearance*

Participants' experiences with eButton were also negatively affected by the device's bulky physical appearance, as it hindered their ability to interact seamlessly in their day-to-day interactions. One participant criticized the eButton's placement on their chest that made it socially awkward when speaking with others.

In addition, when asked how long they would feel comfortable wearing the eButton, several participants noted that the obtrusive appearance of the device prevents them from wanting to wear it for extended periods of time.

> *It depends, because if it's something unobtrusive and beautifully designed that you can wear every day that would be nice… but if it's that big clunky thing, that's more complicated… if [eButton] is small and you could make it like an accessory, like a brooch.* [ID 1011]

eButton's relatively large size may be bothersome and should be designed more discreetly to facilitate participants' ease and comfort with using the device.



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## Participants' Suggestions for Future eButton Features

### *eButton Reminders for Participants to Turn Off the Device*

While the eButton's functionality has some disadvantages, participants thoughtfully reflected on some of the ways in which future iterations of the device's features can be improved to address their concerns. First, the eButton's relatively small, inconspicuous camera made it challenging for participants to remember when to turn off the device, thus causing privacy issues. To combat this inconvenience, participants (n=2) suggested that the eButton should send a notification that reminds the user when to stop recording their meals to prevent them from taping unrelated content. For instance, 1 participant suggested the following:

> *Because usually you wear something and then you forget. And you're doing something else. You watch TV and you talk to people… you have to find a way to turn it off. A reminder. Either a beep or something. An alert so now I realize I should turn it off.* [ID 1016]

A notification, either in the form of a friendly reminder or noise, would be beneficial to alerting users when to stop recording. Hence, they can be saved from potentially embarrassing themselves and/or wasting the camera's battery.

### *Incorporate Language Translations*

Since all the participants in this study identified as Chinese Americans, most of them felt that their experience using eButton would be improved if it met their bilingual needs with language translations. One participant even described how they would appreciate advanced features, including the ability to incorporate voice activation in different languages:

> *Maybe it can also link iPhone translate. It could be multi-language. That would be really nice too. And also, maybe it could do voice activate or voice control. That would be even better.* [ID 1013]

Having the ability to translate languages and activate voice control techniques would potentially reduce the language barrier that Chinese Americans often endure.

### *Sync Data to Participants' iPhones*

In addition to incorporating advanced language translation features, participants believed that eButton could be made more feasible for users if it could sync the dietary intake data to users' iPhones and other smartphone devices. In doing so, users can access their data at any time they wish, rather than waiting to schedule and attend an appointment with their doctor to acquire the results. For example, 1 participant explained that syncing the data to their personal devices would be much more convenient for them:

> *Linking [eButton] up to an iPhone would be a lot easier and convenient. Because everybody pretty much has an iPhone or smartphone. That way it'd be easier for them to use.* [ID 1013]

The ability to link up the iPhone to the eButton is helpful to inform users of their dietary intake data in real-time, as many people often have their smartphones with them as they go about their daily lives.

### *Save Pictures of Meals*

Finally, participants (n=3) in this study suggested that future iterations of eButton should include a record-tracking feature allowing users to save pictures of their daily meals.

> *If [the eButton] were just taking pictures of what I was eating, and when I was eating it, and keeping – so I would be able to see what I had and then what my body's response in the blood glucose would be [what I'm] interested in.* [ID 1019]

Having this record-tracking feature would be especially advantageous for users to refer to the content of their meals rather than relying on their memory. Knowing what they ate would enable users to make connections to how their dietary choices influenced their glucose levels. Consequently, users may be more motivated to change their unhealthy eating habits upon understanding the patterns in their diet and its repercussions on blood sugar levels.

## Experience of Using CGM

Participants described their experiences of using CGM for the duration of the study period, discussing their perceived advantages and disadvantages of the device. Among 11 participants who discussed the CGM advantages, some participants perceived that it is more comfortable and easier to use compared to finger sticks (n=5) and increases mindfulness (n=3), which helps to facilitate positive changes to their eating behaviors (n=5). However, barriers to using CGM included its susceptibility to falling off and/or breaking easily (n=1), its tendency to get trapped in clothes (n=1), and the risk of causing skin sensitivity issues (n=1).

### *Participants' Perceived Advantages of CGM*

#### Comfortable and Easy to Use Compared to Finger Sticks

The participants in this study discussed some of their painful experiences with using traditional finger sticks as a means to self-monitor their blood glucose levels. They recounted the difficulty and discomfort in pricking themselves several times per day. Having experienced this invasive procedure consistently, participants were quick to praise CGM's ability to noninvasively monitor their glucose:

> *I think it's a fantastic device. I wish I could continue using [CGM] because I know that the inconvenience of using the blood glucose meters, you know, having to prick my finger three times a day, ugh, it's a nuisance. [CGM] has alleviated the nuisance of having to take my blood glucose every day for three times a day. It makes it easier for me to live my life ideally.* [ID 1017]

The use of CGM saves participants from having to endure the pain and discomfort from continuously pricking such a sensitive area of their body. CGM's advanced technology allows users to be at ease when monitoring their blood glucose with simply having the device inserted under their skin in a pain-free manner.



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#### Increased Mindfulness

Prior to using CGM, participants in the study were not much likely to be aware of the harms from consuming carbohydrate-rich foods, including noodles, rice, and buns. They tended to underestimate the amount of sugar within these foods and were shocked to realize how high their glucose levels spiked as a result of eating them:

> *Okay, I tell myself: "Don't drink any soda. Don't eat too much sugar." But it's not the case like that. You have to more consider the food, what you eat, like carbohydrates and noodles. That, I didn't know that, you know. I do know they're a carbohydrate, but I didn't know that high… when I see the graph, my reaction very surprised me because it was high… from the chart CGM shows me it's very useful. So I tell myself: "Be careful [with] what you should eat, you should change your lifestyle a little bit in order to live healthy."* [ID 1005]

Being able to look at the graph generated by the CGM and interpret the glucose reading provides users with greater insight into how their body responds to the food's nutrient content:

> *I can get to see like every 15 minutes. You don't get that from a glucose meter. The glucose meter only tells you at that moment, but this is like every 15 minutes. Actually, [CGM] helps me understand a lot more. You probably can pinpoint it to which food spikes [your glucose] the most. Some foods are really good or bad. [CGM] really gives me a much clearer picture of it, so I think it's great.* [ID 1013]

Consequently, users are more readily able to identify which specific foods may have contributed to a glucose spike, thus improving their understanding of how they may need to make dietary changes.

#### Facilitate Positive Change for Future Eating Behaviors

The ability for CGM users to recognize which foods may be contributing to increased blood glucose levels may motivate them to facilitate positive changes to their eating behaviors to prevent future glucose spikes. For instance, a participant noted that viewing a lower glucose reading on the CGM graph motivated them to choose lighter foods:

> *And then you have the charts, and your mind is like, "Oh, in the future, I can choose this type of food. It makes me lighter."* [ID 1001]

### Participants' Perceived Disadvantages of CGM

#### *Prone to Falling Off and/or Breaking*

While CGM has several advantages, there are a few notable downsides to using the device because of its fragile build. For example, 1 participant in the study denounced the CGM's susceptibility to falling off and/or breaking easily. This was the case with 1 participant who accidentally broke the device after going into the ocean:

> *You can't go in the ocean with [CGM] because… I'm pretty sure that's what broke the first one… like I taped it up and I covered it, but… I'm pretty sure that the salt water or the waves or something just, it can't handle it.* [ID 1001]

Users may have to exercise extra caution in handling CGM and might face limitations in terms of specific activities they can engage in (eg, swimming).

#### *Tendency to Get Trapped in Clothes*

Another barrier to using CGM is the tendency of the device to get trapped in clothes. Users may find it difficult to take on or off their clothing items, especially if they are tight. The conspicuous nature of the device may make the experience of using CGM less comfortable as users become aware of the CGM on their body:

> *Sometimes you take off the sweaters, [CGM] got trapped a little bit. You feel there's something I have to, yeah, take off.* [ID 1016]

CGM users may have to rely on wearing looser-fitting clothing to allow the CGM sensor to prevent getting caught.

#### *Skin Sensitivity Issues*

Finally, wearing the CGM may put users at risk of experiencing skin irritation, whether it is a mild rash or a more painful allergic reaction to the adhesive. Skin sensitivity issues are problematic because this could worsen the users' quality of life and may even prompt the user to discontinue using the CGM, which may impede their diabetes self-management. For example, one participant noted their concern:

> *My only concern is my sensitivity to the tape.* [ID 1006]

Being sensitive to the CGM could possibly deter users from keeping the device on. This problem should be addressed by CGM manufacturing companies to make the adhesives more skin-friendly and avoid dermatological discomfort.

## Discussion

### Principal Findings

This study aimed to explore the experience of using eButton and CGM for improving dietary self-management among Chinese Americans with T2D, a population that has been shown to have greater challenges in dietary management. Participants reported a largely positive experience using the eButton, finding it very easy to use and feeling that it enhanced their mindfulness and sense of control over their eating habits. Participants were also pleased with using CGM, as this device was reported to be more comfortable and easier to use compared to traditional finger sticks, increase mindfulness, and facilitate healthier changes for future eating behaviors. However, the eButton's lack of privacy, difficulty in staging its camera, and its obtrusive appearance made the experience of dietary self-management less enjoyable. Furthermore, the CGM had several setbacks, including its susceptibility to breaking and/or falling off, its tendency to get trapped in clothes, and its causing some skin sensitivity. Prior studies exploring the experience of CGM use among patients with T2D have reported similar drawbacks, such as skin irritation, rashes, and even bleeding at the attachment site [29].



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While there is limited research that explores the experience of using wearable devices for dietary management among Chinese Americans with T2D, existing literature on using such technology among other racial/ethnic minority populations for dietary management demonstrates similar findings. For example, Sabben et al [30] found that some barriers to wearing a CGM among African Americans were related to technical issues (eg, losing signal and malfunctioning), not finding a comfortable and discreet place on the body for the sensor, concerns about infections, and finding the device too complicated to use. Despite these challenges, participants indicated the benefits of CGM, including the convenience of having the longitudinal data available to their health care teams, which helped streamline some of the conversations during doctors' appointments, as the health care professional could review the data ahead of time [30]. Moreover, Peyyety et al [31] found that the CGM size and visibility are potential barriers to continued usage. Participants reflected on the stigma surrounding T2D and how wearing a CGM could draw unwanted attention to their diagnosis, thus making them uncomfortable and potentially limiting their social interactions with others. However, in terms of feasibility, they also found that participants overwhelmingly favored the convenience of using CGM over finger sticks, similar to what participants in our study had confessed [31]. Similarly, Litchman et al [32] found that a combination of CGM with an online peer support community was feasible, acceptable, and satisfactory for Hispanic adults with T2D. In addition, our study also shows that participants reported a positive experience using the eButton, particularly that it is very easy to use without extra effort for participants to record food intake, as the eButton can automatically record food data by taking food pictures. Although studies have established its acceptability and feasibility in real life for dietary assessments, this is the first study to apply this tool to individuals with T2D [20,21]. This novel application suggests that the eButton may be a feasible and acceptable tool for dietary self-management in this population, particularly when integrated into culturally tailored diabetes care.

Beyond the US context, international research further supports and enriches our findings. Babazadeh et al [33], in a study of Iranian adults with T2D, identified predictors of self-care behaviors and glycemic control, such as self-efficacy and perceived barriers, factors also reflected in our participants' experiences. Some participants in our study (n=5) described how the ability to recognize which foods caused increases in their blood glucose levels through reviewing CGM report data helped them make positive changes for future eating behaviors to prevent future glucose spikes.

Moreover, a qualitative study by Chowdhury et al [34] in rural Bangladesh identified key barriers and facilitators influencing dietary self-management behaviors among patients with T2D, including gaps between knowledge and implementation, cultural dietary practices, resource limitations, and the role of social and religious support systems. While our participants used wearable devices like CGMs and eButtons to enhance dietary awareness, cultural eating practices—such as sharing carbohydrate-heavy meals with family—sometimes conflicted with the feedback these tools provided. In contrast to our US-based setting, where device usability, appearance, and privacy were key concerns, patients in Bangladesh struggled more with access to healthy foods, structured care, and educational resources. Chowdhury et al [34] emphasized the value of delivering self-management support through trusted, locally embedded health care structures—suggesting that future interventions involving wearable technologies may be more effective when paired with culturally familiar and community-based delivery models in Chinese American populations as well.

## Limitations

The main limitation of our study is the small sample size (n=11) that was enrolled from just a single health care system (ie, NYU Langone), which constrains the transferability of our findings. The limited number of participants may not capture the full range of experiences or perspectives relevant to the topic. Consequently, the themes identified may reflect the specific contexts and individual narratives of our participants, rather than being broadly representative.

Another important limitation is our inclusion of only English-speaking participants. This criterion may have excluded individuals from linguistically diverse backgrounds, who may experience unique barriers or hold different cultural beliefs that influence their engagement with the topic under study. As a result, the findings may not adequately reflect the experiences of non-English-speaking or limited-English-proficiency populations, which is particularly important in multicultural or multilingual settings.

Together, these limitations suggest that while our study provides valuable in-depth insights, caution should be taken when applying these findings to broader or more diverse populations. Future studies with larger, more linguistically and culturally diverse samples are needed to enhance the richness and applicability of the findings across different contexts.

## Strengths

However, our study has notable strengths, including the fact that the collection of dietary intake data was recorded using the eButton, so participant recall bias was not an issue. Moreover, the creation of a comprehensive interview guide that was iterated throughout the process of interviewing participants was helpful to address their experiences, perspectives, and opinions. This approach gave us more flexibility in exploring unexpected insights. In addition, to the best of our knowledge, this is the first study to apply the eButton and CGM to dietary self-management for Chinese Americans with T2D. Our findings suggest that applying eButton in conjunction with CGM may be a promising educational tool to allow individuals with diabetes to understand how their dietary intake impacts their postprandial glucose levels and glucose variability, particularly the consumption of high-carbohydrate food.

## Perspective for Clinical Practice

This study highlights the potential clinical value of integrating visual dietary data from the eButton and CGMs to help dietary management challenges for Chinese Americans with T2D. Although the eButton is not yet widely available or integrated into routine care, this technology offers a compelling glimpse into how future tools might support dietary self-management



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by allowing patients to see the direct relationship between food intake and glycemic response. In practical terms, the eButton captures timestamped images of all meals and snacks, while the CGM continuously records glucose levels throughout the day. When these 2 data sources are aligned, they provide a visual and numerical timeline of how specific foods influence postprandial glucose. For instance, a patient might review their CGM data and observe a glucose spike after lunch. By examining the corresponding eButton images, the patient, ideally with the support of a diabetes educator or dietitian, can identify which foods or portion sizes may have contributed to the spike. This integrated approach can make dietary self-management more intuitive and personalized, moving beyond generic dietary advice. As a result, patients can build self-efficacy and make dietary decisions more concrete.

However, it is important to recognize that the ability to derive meaningful insights from these devices depends on structured support. Our study reviewed the CGM data at the end of 14-day use alongside the eButton and food diary data to help participants understand how that eating habit impacts glucose levels. Therefore, expecting patients to independently interpret and synthesize complex, multimodal data may lead to confusion, frustration, or disengagement. As such, health care providers must play an active role in facilitating data interpretation, whether through in-clinic discussions, digital dashboards, or annotated feedback reports. Embedding this support into clinical workflows, especially in the context of culturally responsive care, can help ensure that technology enhances rather than complicates the self-management process.

Clinicians should also remain attentive to the practical and psychosocial limitations reported by participants. Concerns about privacy, comfort, stigma, and device visibility are important considerations, particularly among culturally and linguistically diverse populations who may already face barriers to care. Introducing wearable technologies should therefore be approached through shared decision-making, tailored to each individual's preferences, lifestyle, and social context.

We need to admit that in this pilot study, we only used the Professional (blinded) version CGM to help participants understand the relationship between food intake and glucose changes. Even though it still helps participants realize that high-carbohydrate intake has a significant impact on glucose changes. In addition, while the integration of CGM and eButton data is not yet standard practice, it represents a promising direction for more personalized and responsive dietary support, as suggested by the participants in this study. As digital health tools continue to evolve, their successful adoption will depend not only on technological innovation but also on human-centered implementation in clinical care.

## Future Research

Future research should examine the application of eButton and CGM in dietary self-management among a larger sample size of Chinese Americans with T2D. It would also be beneficial to test the effectiveness of these two devices in racial/ethnic minority populations, particularly among African Americans and Hispanics, due to the high prevalence of T2D in these groups [35].

## Conclusions

In summary, our findings suggest that it is feasible and acceptable for Chinese Americans with T2D to use the eButton and CGM for dietary management, as both of these devices were overwhelmingly well-received by the participants. Participants perceived the eButton and CGM as tools for diabetes self-efficacy since taking pictures of meals heightened their awareness of food portion sizes and observing blood glucose trends improved their understanding of what foods might be contributing to higher glycated hemoglobin levels. However, meaningful use of these devices requires structured clinical support to help patients interpret complex data, highlighting the need for culturally responsive integration within health care settings.

Future studies should add certain features (eg, saving pictures) of eButton, integrate the unblinded version of CGM to provide real-time glucose values, use larger sample sizes, include non-English speaking Chinese patients, and include a longer duration of wearing eButton and CGM to inform effective dietary management for Chinese Americans with T2D. Ultimately, integrating wearable technologies like the eButton and CGM with tailored clinical guidance holds promise for advancing personalized, culturally appropriate dietary self-management strategies in this population.

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## Conflicts of Interest

None declared.

Multimedia Appendix 1



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Demographic information of participants (N=11) and summary of participants' facilitators and barriers to using eButton and continuous glucose monitor.
[DOCX File, 18 KB - diabetes_v10i1e73381_app1.docx ]

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## Abbreviations

**ADA:** American Diabetes Association
**ADCES:** Association of Diabetes Care and Education Specialists
**CGM:** continuous glucose monitor
**eButton:** electronic button
**HIPAA:** Health Insurance Portability and Accountability Act
**T1D:** type 1 diabetes
**T2D:** type 2 diabetes


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Original Paper

# Exploring the Needs and Preferences of Users and Parents to Design a Mobile App to Deliver Mental Health Peer Support to Adolescents With Type 1 Diabetes: Qualitative Study

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## Abstract

**Background:** Beyond physical health, managing type 1 diabetes (T1D) also encompasses a psychological component, including diabetes distress, that is, the worries, fears, and frustrations associated with meeting self-care demands over the lifetime. While digital health solutions have been increasingly used to address emotional health in diabetes, these technologies may not uniformly meet the unique concerns and technological savvy across all age groups.

**Objective:** This study aimed to explore the mental health needs of adolescents with T1D, determine their preferred modalities for app-based mental health support, and identify desirable design features for peer-delivered mental health support modeled on an app designed for adults with T1D.

**Methods:** A semistructured qualitative focus group study was conducted with adolescents with T1D and parents of adolescents with T1D. Data were collected through pre–focus group surveys, including sociodemographic background, diabetes status, health care experiences, and focus group sessions, including their opinions on peer support and technology. A thematic analysis following an inductive and iterative process was performed to develop themes and subthemes from the collected information.

**Results:** Focus group participants included 10 adolescents (mean 16, SD 1 years; 8/10, 80% female; who had been living with diabetes for an average of 9, SD 5 years) and 10 parents (mean age 51, SD 7 years; 9/10, 90% female). Four core themes emerged: (1) experience: navigating adolescence with T1D, (2) empowerment: support systems that enabled better management of their T1D, (3) obstacles: societal barriers that affect adolescents' T1D management, and (4) innovation: adolescent-driven preferences for digital peer support platforms.

**Conclusions:** App-based peer support offers a promising avenue for addressing the mental health needs of adolescents with T1D. Understanding the unique support needs of these adolescents and using this information to suggest design considerations for a mental health peer support app is an important step toward addressing their complex emotional and social challenges.

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**KEYWORDS**

peer support; type 1 diabetes; digital interventions; diabetes distress; depression; mental health; focus groups; disease management; adolescent; parent; mobile app; mHealth; type 1; diabetes; qualitative study; physical health; psychological; emotional health; mental health support; thematic analysis; data collection; mobile health

## Introduction

Managing type 1 diabetes (T1D) extends beyond physical health to include a significant psychological component [1]. This psychological aspect is often due to diabetes distress (DD), a state of emotional burden directly related to the demands of living with diabetes [2]. DD is influenced by various factors, including the complexity of diabetes management, social dynamics, and puberty-related changes (both physical and psychosocial) that occur during adolescence [3]. For example, adolescents may feel shame and stigma from visible self-care tasks, which are sometimes mistaken for illicit drug use, leading to questioning by authority figures and reluctance to engage in public self-care needs [4].

In Canada, accessing psychological support is inconsistent across provinces [5]; therefore, obtaining treatment for DD may pose a significant challenge. Barriers include uncertainties about where to seek help [6], long waiting times [7], a shortage of mental health care professionals [6], concerns about stigma [8], geographic or demographic disparities (impacting youth, rural communities, and Indigenous populations) [6], and the financial burden of services not covered by private insurance plans [5].

Peer support may present a potential solution for adolescents with T1D, especially when facilitated through digital platforms [9]. This age group is highly attuned to technology, often preferring digital interactions over in-person ones [10]. Digital platforms offer the privacy and flexibility that adolescents value, allowing them to seek support without the discomfort or stigma of face-to-face encounters. In addition, these platforms provide the convenience of accessing support at any time and from any location, which is particularly important given the financial and geographic barriers to accessing traditional mental health services [10]. These platforms also allow adolescents with T1D to tailor support to their specific needs and preferences, providing a space to share experiences, express empathy, and exchange bidirectional assistance in managing their condition [9]. However, these digital platforms should be codesigned with the target population to be effective [11].

T1D REACHOUT (The University of British Columbia) is a peer-led mobile app to support mental health, cocreated by researchers and adults with T1D living in British Columbia, Canada [12]. It offers support mechanisms, including (1) one-on-one support through a self-selected peer supporter, (2) group texting support through a 24/7 chat room, and (3) face-to-face group sessions through video huddles. The app is developed using a participatory approach, ensuring that the target population's preferences and unique challenges were at the forefront of its design. While the direct impact of this participatory approach on the app's effectiveness requires further empirical validation, the literature on digital health suggests that user engagement in design processes can enhance the relevance and usability of interventions [11,13,14].

Tailoring the T1D REACHOUT app's functionalities to adolescents with T1D may address some of the dimensions of DD. Focus groups were selected as the primary method for user engagement because they provide a dynamic environment for participants to discuss shared experiences and preferences [15]. The group setting encourages interaction, allowing adolescents to build on each other's ideas and reveal insights that might not emerge in one-on-one interviews.

Therefore, the aims of this study were three-fold: (1) to explore the mental health needs of adolescents with T1D in British Columbia; (2) to determine their preferred modalities for app-based mental health support delivery; and (3) to identify the desirable design features for a peer-delivered mental health support app for adolescents, using the existing T1D REACHOUT app as a model.

## Methods

### Study Design

We conducted a semistructured qualitative study involving focus groups with a convenience sample comprising either adolescents living with T1D or parents of adolescents with T1D from families receiving care at BC Children's Hospital (BCCH) or in the Interior Health. Our findings are reported following the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [16], given in Multimedia Appendix 1.

### Ethical Considerations

Ethical approval for this study was obtained from the University of British Columbia–Children's & Women's Health Centre of British Columbia Research Ethics Board (H21-01806; approval date: January 25, 2022; principal investigator: MG). Additional approvals were secured from the Interior Health Authority (IHA) and Vancouver Island Health Authority (VIHA) research ethics boards.

All participants provided informed consent (some adolescents provided assent with their parent or guardian providing consent, while others consented directly) before participating in the study. Initial consent discussions were conducted through Zoom videoconferencing software (Zoom Video Communications) or telephone to explain the study objectives and address participants' questions. Informed consent and assent were documented electronically using the REDCap (Research Electronic Data Capture; Vanderbilt University) eConsent [17,18].

All focus group recordings were automatically transcribed by the Zoom videoconferencing software and deidentified before analysis by replacing identifiable information, such as names, with participant IDs. Study data were stored securely, and only study team members could access them.



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Participants received a CAD $25 (approximately US $18) e-gift card as a token of appreciation for their time and participation in the focus groups.

## Sampling and Recruitment

Recruitment began in March 2022 and concluded in February 2023. To be eligible, adolescent participants had to meet the following inclusion criteria: (1) being aged 15-18 years; (2) having physician-diagnosed T1D; (3) having access to a smart device or computer; and (4) residing in the IHA region, VIHA region, or receiving care at BCCH. The decision to include diverse locations was made to capture a broader range of perspectives, with the aim of achieving a more comprehensive representation of our participants. For parents or guardians, inclusion criteria were as follows: (1) having a child with T1D aged 15-18 years; (2) having access to a smart device or computer; and (3) residing in British Columbia.

We used diverse recruitment methods: invitation emails were sent from the BCCH Diabetes Clinic to families who had authorized contact for research, and families attending the BCCH Diabetes Clinic were recruited in person; invitation letters were sent from Diabetes Educational Centers in IHA and VIHA to eligible families; and promotional flyers at diabetes clinics, social media posts on T1D-specific Facebook groups, and referrals from pediatric endocrinologists who identified participants likely to benefit from the study were also used.

## Data Collection

### *Prestudy Survey*

Participants completed a prestudy survey using the REDCap platform [17,18], administered after the informed consent process. The surveys captured the demographic and care context and the T1D challenges to contextualize the focus group results; the survey data were not analyzed thematically but served as background information only to facilitate focus group stratification and contextualize discussions. These pre–focus group surveys (given in Multimedia Appendices 2 and 3) assessed sociodemographic background, diabetes status, health care experiences, opinions and experiences with peer support, and technological preferences. Parent surveys assessed sociodemographic background, their child's treatment-related information, and health care coverage.

### *Focus Groups*

Subsequently, participants were scheduled for focus group sessions with peers from the same health region and age group (parents, adolescents aged 15-16 years, or adolescents aged 17-18 years). Focus group sessions were conducted between May 2022 and February 2023. Each focus group session lasted approximately 90 minutes and was conducted with 2-8 participants. The focus groups were facilitated by 2 female researchers with complementary expertise (more details are provided in the *Ensuring Rigor and Trustworthiness* section). The facilitators (TST or TIY) led groups using a focus group guide (Table 1), which was designed based on the study's goals and existing literature on similar populations [4,14]. The focus group guide underwent a walk-through with the research team before data collection to ensure its clarity and relevance. This process allowed us to refine the questions, ensuring they were appropriate and aligned with the objectives of the study.

**Table 1.** Focus group guide: questions used to guide the adolescent and parent focus groups.

| Focus groups | Questions |
|---|---|
| Adolescents | • As someone living with T1D[a], what kind of emotional or mental health support do you need?<br>• When you are frustrated with having T1D, who do you turn to for support?<br>• What topics or situations do you find yourself needing the most support for?<br>• How receptive would you be to getting support from other people with TID your own age?<br>• What are your thoughts about seeking support from slightly older people with T1D (ages 19-30 years)?<br>• What T1D-specific social media networks have you used before (Connected in Motion, JDRF[b], Facebook groups, or any online communities)?<br>• Demo the REACHOUT App—then ask "What did you like about the REACHOUT App?"[c]<br>• How important would it be to have health care professionals (ie, nurses, dieticians, psychologists) involved in REACHOUT NexGEN? |
| Parents | • What do you worry about the most raising an adolescent with T1D?<br>• What kind of support do you need with regard to being a parent of an adolescent with T1D?<br>• When you are frustrated with T1D-related issues, who do you turn to for support?<br>• What topics or situations do you find you need the most support around?<br>• What are the issues or situations that you and your daughter/son have the most conflict about (related to T1D management)?<br>• What T1D-specific social media networks have you used before (Connected in Motion, JDRF, Facebook groups, or any online communities)? |

[a]T1D: type 1 diabetes.

[b]JDRF: Juvenile Diabetes Research Foundation.

[c]We showed participants a video of the app. Afterward, we asked the questions "What did you like about the app?" and "How important would it be to include certain features?"



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Adolescent and parent focus group questions differed slightly but focused on similar topics, with the adolescent focus groups viewing a demonstration of the existing REACHOUT app. While focus groups were structured with core and follow-up questions, organic discussions were encouraged to gain further insights and clarity on specific ideas. Focus groups were conducted online through Zoom videoconferencing software, and at the beginning of the session, the facilitator discussed the session rules and privacy and confidentiality.

The focus group size was designed to allow for diverse input while maintaining a manageable and comfortable setting. The target size was 4-6 participants per group, which is generally recommended in the literature to promote rich discussion while allowing everyone to participate [15]. However, due to logistical constraints, some groups were smaller than anticipated. While smaller groups may limit diversity of opinion, they may foster a more intimate and open environment, encouraging participants to share more personal insights. Combining groups from the same age range might have enhanced the diversity of viewpoints; however, separate groups were maintained based on scheduling and participant preferences, with the smaller groups offering a more personalized discussion.

The focus groups are intended to identify key user preferences and insights that will inform future redesign efforts. The insights from the focus group will form part of the revised requirements for the app redesign based on the adult app [12].

### *Data Processing and Analysis*

Survey responses were analyzed using descriptive statistics using SPSS Statistics for MacBook (version 29.0; 2023; IBM Corp), with frequency data expressed as count (%) and continuous data expressed as mean (SD).

To ensure the accuracy of the focus group data, audio recordings of the focus groups were automatically transcribed by Zoom, deidentified by removing names, and then further verified by TIY. A thematic analysis of the resulting transcripts followed an inductive and iterative process to develop themes and subthemes [19]. Two coders, TIY and PJ, independently coded each of the transcripts using NVivo 12 (Lumivero). The coders compared their results throughout the coding process, ensuring consistency and accuracy. In cases of disagreement, coders reviewed the relevant data together and reassessed their coding decisions. If a consensus could not be reached, TST or MG made the final decision after reviewing the codes in the context of the research questions and focus group guide. After completing the first round of coding from the last focus group, we determined that thematic saturation had been reached and decided to end the recruitment and data collection process [20]. Finally, the study team convened to discuss and establish a unified codebook, organizing the identified themes and subthemes.

### *Ensuring Rigor and Trustworthiness*

We ensured the rigor and trustworthiness of our research through triangulation, combining prestudy surveys and focus groups to capture diverse perspectives. Peer debriefing by 2 independent coders (TIY and PJ) validated themes, ensuring consistency and accuracy. Thematic saturation confirmed no new significant themes emerged.

We documented each research step to maintain transparency and reduce bias, enhancing credibility. The team's positionality also strengthened the process: TT, with over 25 years of experience in qualitative methodologies, provided theoretical expertise; TIY, an MSc student with an MBBS, contributed clinical insights and methodological knowledge; and SP and PJ, a medical student and graduate, respectively, added relevant academic and practical experience.

## Results

### Participants

Out of 48 adolescents with T1D and 26 parents of adolescents living with T1D who expressed initial interest in the study, 16 of the former and 17 of the latter consented, and 10 of both groups participated in the focus group discussions. Reasons for nonparticipation (n=54) included the inability to reestablish contact after initial consent (28/54, 52%), loss of interest (7/54, 13%), scheduling conflicts (11/54, 20%), and "no show" to focus group session despite previous confirmation (8/54, 15%). Participants included parent-child dyads, parents without their children, and children without their parents.

### Prefocus Group Survey

The mean age of adolescent participants was 16 (SD 1) years and they had been living with diabetes for an average of 9 (SD 5) years (Table 2). Parent participants had a mean age of 51 (SD 7) years and were mostly (9/10, 90%) female (Table 3).



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**Table 2.** Characteristics of adolescent participants (n=10).

| Variables | Values |
|---|---|
| **Age (years), mean (SD)** | 16 (1) |
| **Age at diagnosis (years), mean (SD)** | 9 (5) |
| **Sex, n (%)** | |
| Male | 2 (20) |
| Female | 8 (80) |
| **Racial background, n (%)** | |
| White | 8 (80) |
| East Asian | 1 (10) |
| Other | 1 (10) |
| **Insulin delivery system, n (%)** | |
| Multiple daily injections | 5 (50) |
| Insulin pump | 5 (50) |
| **Blood glucose monitoring device, n (%)** | |
| Continuous glucose monitor | 6 (60) |
| Flash glucose monitor | 2 (20) |
| CGM[a]+lancets and strips | 2 (20) |
| **Continuous or flash glucose monitor type, n (%)** | |
| Dexcom G6 | 8 (80) |
| Freestyle libre | 2 (20) |
| **Diabetes care provider, n (%)** | |
| Endocrinologist | 6 (60) |
| Family physician | 2 (20) |
| Diabetes nurse | 1 (10) |
| Other | 1 (10) |

[a]CGM: continuous glucose monitoring.



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**Table 3.** Characteristics of parent participants (n=10).

| Variables | Values |
|---|---|
| **Age (years), mean (SD)** | 51 (7) |
| **Sex, n (%)** | |
| Male | 1 (10) |
| Female | 9 (90) |
| **Racial background, n (%)** | |
| Arab | 1 (10) |
| White | 9 (90) |
| **Education, n (%)** | |
| High school graduate | 1 (10) |
| Some college or technical graduate | 5 (50) |
| College graduate | 1 (10) |
| Graduate or professional degree | 3 (30) |
| **Total household income (CAD $)[a], n (%)** | |
| $20,000-$29,999 | 1 (10) |
| >$90,000 | 9 (90) |
| **Child's insulin delivery system, n (%)** | |
| Multiple daily injections | 2 (20) |
| Insulin pump | 8 (80) |
| **Child's blood glucose monitoring device, n (%)** | |
| CGM[b] | 6 (60) |
| Flash glucose monitor | 2 (20) |
| CGM+Lancets and strips | 2 (20) |
| **Extended health care coverage, n (%)** | |
| Yes | 8 (80) |
| No | 2 (20) |
| **Counseling services coverage[c], n (%)** | |
| Child only | 1 (13) |
| Family | 2 (25) |
| No coverage | 2 (25) |
| I don't know | 3 (38) |

[a]CAD $1 = US $0.76.

[b]CGM: continuous glucose monitoring.

[c]Only participants with extended health coverage (n=8) were asked this question.

## Focus Groups

We conducted 5 focus groups: 2 groups consisted of parents, with 1 group comprising 6 participants, and the other having 4 participants; the remaining 3 groups were composed of adolescents, with 1 group of 3 participants aged 15-16 years, another group of 5 participants aged 17-18 years, and the final group including 2 participants aged 15-16 years.

Four overarching themes were identified, with 3 themes exploring the support needs of adolescents living with T1D and 1 theme exploring their preferences for a peer-led mental health support app. These themes were (1) experience: navigating adolescence with T1D, (2) empowerment: support systems that enabled better management of their T1D, (3) obstacles: societal barriers that affect adolescent's T1D management, and (4) innovation: adolescent-driven preferences for digital peer support platforms. These 4 themes were then further categorized into subthemes.



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## Theme 1: Experience—Navigating Adolescence With T1D

Subthemes included (1a) challenges beyond physical health, (1b) balancing T1D management and independence in adolescent-parent relationships, and (1c) transitioning toward managing diabetes independently.

### *Subtheme 1a: Challenges Beyond Physical Health*

Most adolescents described diabetes as a "lonely" condition and reported difficulty finding peers with the same emotional struggles. Adolescent concerns included fear of hypoglycemia in unfamiliar situations, anxiety about long-term complications, and challenges of everyday activities such as driving or writing exams. Even when feeling anxious, some adolescents were still reluctant to discuss these worries with health care professionals, family, and friends.

> *I don't have anyone to talk to, and I just like to go through it, which probably adds a lot more stress to me having to be all alone going through that.* [Adolescent 1]

Adolescents also described specific instances where they felt isolated, such as during school trips or exams, when managing diabetes became a visible and misunderstood challenge among peers.

> *My friends don't get why I always carry snacks or why I sometimes leave during class—it makes me feel different and not in a good way.* [Adolescent 3]

Parents expressed different concerns, such as shielding their children from worry while encouraging responsible diabetes management.

> *I don't want to scare her into worrying about, you know, potential problems with losing limbs or heart attacks or strokes, or the absolute worst possible things.* [Parent 4]

### *Subtheme 1b: Balancing T1D Management and Independence in Adolescent-Parent Relationships*

Encouraging adolescents to prioritize diabetes care created a complicated dynamic between adolescents and parents. While parents wanted to instill a sense of responsibility in their children, they did not want to be perceived as overbearing (ie, "helicopter parents").

> *I find that there was a period where my son would systematically forget to bolus for his meals, and as a parent, I just had to nag him and nag him, and I think that hurt our relationship.* [Parent 3]

Communication with parents was particularly challenging when adolescents felt overwhelmed by constant reminders and pressure regarding management.

> *I don't want to bring up my care and then have them like be more stressed and be on me more because their way of supporting me is like bugging me.* [Adolescent 9]

However, parents also mentioned that when they engaged in constructive communication, they improved their relationship with their children.

### *Subtheme 1c: Transitioning Toward Managing Diabetes Independently*

As adolescents approached adulthood, some parents recognized the need to relinquish some diabetes-related responsibilities and shift them onto their children.

> *There definitely was a transition period where I had to let him take over, and it wasn't perfect. In fact, it was a scary thing to do, but I find that eventually, by backing away and letting him take charge, he did take charge, and he's much, much better today.* [Parent 5]

This sentiment was echoed by several adolescents, particularly those traveling far from home to attend university.

> *I'm going away for university next year, and I feel like it's because my parents—I've kind of been able to prove to my parents that I can be independent, but I was doing that by kind of like trial and error.* [Adolescent 1]

In contrast, other adolescents were not ready to assume complete management control and chose to remain at home close to their parents.

## Theme 2: Empowerment—Support Systems That Enable Better Management of Their T1D

Subthemes included (2a) the role of online support systems, (2b) family and community support as foundational support systems, and (2c) interest in peer connections.

### *Subtheme 2a: Role of Online Support Systems*

Both adolescents and parents discussed the value of online support systems for connecting with others living with T1D or caring for a child with T1D. These platforms helped reduce isolation and foster companionship with individuals who understood their experience. Adolescents highlighted the importance of online communities to share experiences with peers managing T1D, while parents appreciated the role of these communities in providing access to advice from other caregivers.

> *I find that if I look online, and I see discussion of other people and their struggles with diabetes, I feel a little bit less lonely, but it still isn't quite the same as having someone to talk to and relate to.* [Adolescent 10]

> *I have found some Facebook support groups, and I've been looking at them, and in many ways, some of them I have vented on there, and I have learned a lot.* [Parent 4]

While these digital environments offered the space to exchange thoughts and frustrations about T1D, some adolescents found these online groups overwhelming, primarily when discussions evolved into emotion-heavy topics such as long-term complications.



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### *Subtheme 2b: Family and Community as Foundational Support Systems*

Family members were described as the cornerstone of support. Adolescents noted that siblings often stepped in to help with reminders or provided companionship during health care appointments. Parents, on the other hand, saw themselves as "safety nets," providing structure to daily management tasks.

> *If I have any new issues that I realized have come up that I need help Problem Solving, my mom is definitely my go-to person since she knows the situation well.* [Adolescent 8]

Although many adolescents leaned on parents and friends for support, talking about diabetes with loved ones was not always satisfying. Instead, some adolescents valued connecting with other T1D peers who could offer empathy and understanding and exchange practical information.

Parents accessed community support by connecting with other parents of children with T1D and exchanging tips and information.

> *It's super important to feel supported and just be able to have another mom say to you, oh, this is where you get this, this is where you get the small juice boxes that, you know, all the little tips and tricks that.* [Parent 3]

### *Subtheme 2c: Interest in Peer Connections*

Adolescents expressed a strong desire to connect with young adults with T1D (ie, near-peers) who have successfully achieved independence in managing their diabetes, while parents echoed this need from their perspective, hoping to reduce adolescents' feelings of loneliness.

> *It would be nice to talk to someone my age who gets it—like what it's like to have T1D during a school trip or stuff like that.* [Adolescent 5]

> *I want to know how older diabetics are achieving independence and what role diabetes plays in their life.* [Parent 8]

They sought insights on managing diabetes in the work and school setting. Parents were equally eager to help their children link up with relatable peers to reduce feelings of loneliness and isolation during a challenging period in life.

> *I'm looking also for her to find peers who have a similar medical condition so that she doesn't feel like she's so alone as a teenager.* [Parent 7]

## Theme 3: Obstacles—Societal Barriers That Affect T1D Management

Subthemes included (3a) insurance-related obstacles, (3b) stigma and discrimination surrounding diagnosis, and (3c) lack of understanding by the public.

### *Subtheme 3a: Stigma and Discrimination Surrounding Diagnosis*

Adolescents recounted situations where they felt unfairly scrutinized by authority figures, such as being accused of using illicit drugs (use of needles for insulin administration). Stigma and discrimination often originated from individuals outside the immediate family and peer group; however, these negative comments sometimes also came from friends. Anticipating these situations, many patients and families guarded their diagnosis from others. Those who disclosed their condition often found themselves mistaken for having type 2 diabetes and were targets of pejorative stereotypes (eg, poor lifestyle habits).

> *You've probably seen like hundreds of jokes that are like, oh, if you eat that, you're gonna get diabetes and then, of course, that makes you feel bad because there's that stigma, and that's just so not true.* [Adolescent 9]

Some parents reported concealing their child's diagnosis until it was essential to disclose it, such as when starting a new job.

> *It wasn't easy for my son to get a job because of, you know, the circumstances around his health.* [Parent 3]

Because of the stigma around diabetes, parents needed to advocate for their children in the school and work setting and encourage them to advocate for themselves.

### *Subtheme 3b: Insurance Coverage Obstacles*

Participants also expressed frustrations with navigating insurance coverage.

> *I don't understand how insurance works. I don't know how they're going to cover the cost of my diabetes supplies. I don't know what they cover; I don't have that information.* [Adolescent 9]

For many parents, securing lifesaving supplies for their children was an arduous process that involved hours on the phone.

> *It takes two hours and three hours of my day to stay on top of things and get updates from insurance companies and stay on hold, and all of this, and I feel like if there's a shortcut of information, that would be amazing.* [Parent 3]

They also invested considerable time on the internet searching for pertinent information. Adolescents reported a general lack of knowledge regarding the policies and procedures of medical insurance and the costs of diabetes supplies. Not surprisingly, these frustrations were noted by participants preparing to leave home to attend university.

### *Subtheme 3c: Lack of Understanding by the Public*

Both adolescents and parents reported negative experiences when talking to the general public about diabetes. Not only did individuals without T1D make inaccurate assumptions and demonstrate a lack of knowledge and sensitivity, but also these conversations often required exhausting explanations and effort.

> *Explaining it to somebody creates more work for the diabetic than it does to help them because, first, you need to explain it before, and you can tell them what's bothering you about it, so they understand how everything works. So, it creates more work, so sometimes it's easier just to not open up the conversation.* [Adolescent 1]



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Consequently, participants avoided situations or interactions where the topic of diabetes could emerge.

> *It's pointless to go to others because I would have to teach them, so my daughter and I just talk about it amongst ourselves.* [Parent 4]

### Theme 4: Innovation—Adolescent-Driven Preferences for Digital Peer Support Platforms

Subthemes included (4a) information security and accuracy, (4b) enhancing user interface and user experience, and (4c) add-ons for optimizing interactions.

#### *Subtheme 4a: Information Security and Accuracy*

Many participants expressed concern about exchanging inaccurate and potentially harmful medical advice about insulin pumps, dosages, dietary restrictions, and so on.

> *Information about managing your pump and insulin, bolusing, and how you will lose a dress size in a matter of two weeks, there's a lot of curiosity around that, so I'm concerned about that.* [Parent 4]

One suggestion to reduce this risk was to have health care professionals moderate group chats.

> *I think there could be some privacy issues, and what can be talked about. I don't know if it's kind of overkill but there could be like mediators, especially on chats that might be covering more sensitive topics.* [Adolescent 9]

#### *Subtheme 4b: Enhancing the User Interface and User Experience*

Participants expressed positive feedback about the planned REACHOUT NexGen platform, appreciating its concept, components (group chat, personal messaging, and access to trained near-peer mentors), and potential benefits for peer discussions. Parents wanted the platform to be user-friendly, straightforward, and enjoyable for adolescents, while adolescents focused more on aesthetics, user experience, and navigation assistance. Specifically, they suggested a more welcoming color palette and an introductory tutorial guiding users through its various components.

> *For the like homepage sort of thing, it looks kind of like intense, like it looks like Microsoft teams, which is kind of like intimidating.* [Adolescent 1]

> *Just like the design of the homepage a little bit maybe. I don't know, I'm not good with design, but maybe it could change a little bit just to make it look more visually appealing.* [Adolescent 2]

#### *Subtheme 4c: Add-ons for Optimizing Interactions*

Participants recommended features to incorporate into an ideal digital support platform, such as the ability to pin messages or chats on the platform's home screen and complete phone calls or video calls on the platform. These features, currently absent in the adult version of REACHOUT, were proposed to enrich user interactions and connectivity.

> You know in iMessage, for example, you are able to pin a certain conversation, so it becomes like a bubble at the top of your list, so it's like a priority almost. [Adolescent 7]

> If there could be video calls or even phone calls, it would be nice, so you don't have to get off the app if you want to speak to someone on the phone. [Adolescent 1]

## Discussion

### Principal Findings

This study explored the support needs of adolescents with T1D, focusing on the psychosocial challenges they face during an already demanding stage of life characterized by puberty-related changes, academic pressures, peer dynamics, and increased conflict with parents. In doing so, it provided specific design insights for app-based peer support, including features such as moderated chats for safety and video calls to foster emotional connection. These findings address gaps in the literature by demonstrating how technology can be tailored to meet adolescents' unique support needs and highlight ways to adapt an existing app (T1D REACHOUT), initially designed for adults, to better serve the adolescent population with T1D.

### Comparison With Previous Work

Other studies [4,21,22] have also observed concerns about diabetes management, fear of long-term complications, strained relationships with parents, and transition into adulthood. For example, Castensøe-Seidenfaden et al [21] identified key worries among 9 adolescents aged 15-19 years and 13 parents, including safety in managing diabetes, independence, and apprehensions about future health complications.

Our results also revealed the pivotal role of support systems. Over and above family support, which has been shown to have a positive impact on mental health in adolescents with T1D [23,24], our participants voiced a clear desire to connect with peers with T1D. As adolescents approach adulthood, they gravitate more strongly toward their friends for support rather than their parents [25], as noted in subtheme 1b, where adolescent participants expressed being overwhelmed by their parents. In the context of T1D, peer support offers a space to exchange viewpoints and experiences regarding specific challenges, foster mutual understanding, and encourage collaborative problem-solving [26,27].

Furthermore, engaging in peer activities bolsters adolescents' capacity for empathy and support [28]. It can play a significant role in alleviating stress and anxiety during times of transition, as noted in subtheme 2c, where adolescent participants expressed desires to connect with peers and near-peers. Previous research among adolescents with T1D has found a link between peer support and improved diabetes outcomes. For example, Doe [29], in a study of 90 adolescents aged 15-18 years, observed a significant association between peer support and better glycemic control. Similarly, in a study by Raymaekers et al [30] involving a large cohort of 467 individuals, including adolescents (14-17 years) and emerging adults (18-25 years), it was found that increased emotional support from peers predicted lower levels of diabetes-related distress.



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Our findings also highlight the specific ways adolescents wish to connect with peers with T1D, such as through moderated digital platforms that enable both group and one-on-one interactions. This expands upon previous work by Doe [29], which linked peer support with better glycemic control but did not explore the exact mechanisms or features adolescents preferred for peer interactions. Finally, our data provide insights that inform the design and implementation of a peer-delivered mental health support mobile app for adolescents. Using the principles of human-centered design [31], we were able to transform insights from theme 4 into actionable design strategies for our app; this included refining the app through a streamlined interface, clear color schemes, clutter reduction, user tutorials, message pinning, enhanced connectivity through calls, and moderated chats for safety. Although the integration of features such as phone and video calls has predominantly been used to provide support between scheduled visits with the diabetes care team and to facilitate online clinic appointments with health care providers [32], our findings suggest that these modes of communication may also foster a sense of companionship and emotional connection with peers. Similarly, other studies have identified app-related preferences for this T1D age cohort, such as user-friendliness, ease of navigation, and safe participation by moderating peer discussions [13,14,33]. For example, the self-compassion chatbot (called "COMPASS") app [33], designed for adolescents aged 12-16 years with T1D, demonstrated improvements in psychosocial well-being among adolescents with T1D, but participants in our study advocated for safe discussions with their peers and features that can assist in easy navigation, such as a search bar function.

While there are existing platforms that adolescents with T1D have already leveraged to obtain peer support (eg, Reddit, Discord, and TikTok), these online environments lack two core features: (1) access to focused one-on-one support delivered by a trained near-peer and (2) health care professional–monitored chat rooms and discussion boards [34]. Over and above same-age peers, adolescents have expressed a desire for support from young adults with T1D who have more years of life experience to share [4]. Furthermore, adolescents seek security in knowing safeguards are in place to prevent the exchange of medically contraindicated information [35]. In response to this gap, our platform, REACHOUT NexGEN, will incorporate these critically important features. For example, T1D REACHOUT, the adult version of the app, uses trained moderators and health care professionals to oversee chat rooms and discussion boards, ensuring that the information exchanged is accurate and safe [12]. This moderation system helps protect users from receiving inaccurate advice, a concern that was echoed in our study by adolescent participants who emphasized the importance of safeguards. By adopting these practices, REACHOUT NexGEN will offer a safe and secure space for adolescents with T1D to connect with both peers and near-peers, therefore addressing their need for support while safeguarding their well-being.

## Limitations

This study has limitations. First, one of our focus groups (adolescents aged 15-16 years) had only 2 participants, which may have hindered in-depth discussion; however, we obtained some useful points from the discussion, and we ran another focus group with more participants from this age group. Second, most of our participants were female and may have been more inclined to openly discuss health issues [36] and engage in research studies [37]. The majority of the participants were female, which may have influenced the support needs emphasized in our findings. Female adolescents are often more likely to articulate psychosocial challenges and emotional well-being, which may have led to a stronger focus on these areas [36]. Female adolescents with T1D often experience higher levels of DD due to a combination of hormonal fluctuations once they reach menarche, which complicates blood glucose management and psychosocial factors, including body image concerns and increased risk of eating disorders [38]. Conversely, the lack of male representation may mean that certain challenges, such as stigma around discussing diabetes among male peers or unique preferences for technological interactions, were underrepresented. A more gender-diverse sample could provide a more balanced perspective on the support needs of the broader adolescent population with T1D. Also, our focus group participants lacked sociodemographic diversity and may not reflect the larger adolescent population with T1D [39]. Finally, the variation in focus group sizes, influenced by participant preferences and scheduling constraints, may have limited broader discussions and diversity of perspectives. While smaller groups fostered personalized interactions, future studies should aim to balance participant preferences with recommended group sizes to enhance discussion dynamics.

These factors all potentially limit the generalizability of our findings. Future studies should explore strategies to engage a more heterogeneous sample by actively collaborating with community organizations, advocacy groups, or cultural associations representing various demographic groups, as this could contribute to a more nuanced understanding of the complexities within different demographic groups.

## Conclusions

This study confirmed the existing and compelling evidence of the need for mental health support for adolescents with T1D. It also showed that adolescents are interested in the potential benefits of app-based peer support for providing emotional assistance. Further research is required to evaluate the platform's feasibility and effectiveness to uncover potential challenges, refine design features based on user feedback, assess user engagement and satisfaction, and evaluate the app's sustained impact over time.

## Acknowledgments

The authors thank the participants for their time and for sharing their insights. The study was supported by a 2022 BC Children's Hospital Research Institute Digital Health Research Accelerator Seed Grant (to MG and TST) and a 2020 BC Children's Hospital



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## Data Availability

The datasets generated and analyzed during this study are not publicly available due to the privacy and confidentiality requirements of the research ethics board.

## Authors' Contributions

TIY contributed to investigation, formal analysis, writing–original draft. PJ contributed to formal analysis, writing–review & editing. SP contributed to investigation, writing–review & editing. NCW contributed to methodology, project administration, writing–review & editing. SA contributed to funding acquisition, methodology, writing–review & editing. TST contributed to conceptualization, funding acquisition, methodology, supervision, writing–review & editing. MG contributed to conceptualization, funding acquisition, methodology, supervision, writing–review & editing.

## Conflicts of Interest

SA participated on advisory boards for Dexcom, Abbott, Novo Nordisk, Eli Lilly, Sanofi, and Insulet.

Multimedia Appendix 1
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[DOCX File , 25 KB - diabetes_v10i1e64267_app1.docx ]

Multimedia Appendix 2
T1D REACHOUT NexGEN Study: adolescent focus group participant questionnaire.
[DOCX File , 44 KB - diabetes_v10i1e64267_app2.docx ]

Multimedia Appendix 3
T1D REACHOUT NexGEN Study: focus group parent questionnaire.
[DOCX File , 28 KB - diabetes_v10i1e64267_app3.docx ]

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## Abbreviations

**BCCH:** BC Children's Hospital
**CGM:** continuous glucose monitor
**COREQ:** Consolidated Criteria for Reporting Qualitative Research
**DD:** diabetes distress
**IHA:** Interior Health Authority
**REDCap:** Research Electronic Data Capture
**T1D:** type 1 diabetes
**VIHA:** Vancouver Island Health Authority


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Original Paper

# Examining How Adults With Diabetes Use Technologies to Support Diabetes Self-Management: Mixed Methods Study

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## Abstract

**Background:** Technologies such as mobile apps, continuous glucose monitors (CGMs), and activity trackers are available to support adults with diabetes, but it is not clear how they are used together for diabetes self-management.

**Objective:** This study aims to understand how adults with diabetes with differing clinical profiles and digital health literacy levels integrate data from multiple behavior tracking technologies for diabetes self-management.

**Methods:** Adults with type 1 or 2 diabetes who used ≥1 diabetes medications responded to a web-based survey about health app and activity tracker use in 6 categories: blood glucose level, diet, exercise and activity, weight, sleep, and stress. Digital health literacy was assessed using the Digital Health Care Literacy Scale, and general health literacy was assessed using the Brief Health Literacy Screen. We analyzed descriptive statistics among respondents and compared health technology use using independent 2-tailed *t* tests for continuous variables, chi-square for categorical variables, and Fisher exact tests for digital health literacy levels. Semistructured interviews examined how these technologies were and could be used to support daily diabetes self-management. We summarized interview themes using content analysis.

**Results:** Of the 61 survey respondents, 21 (34%) were Black, 23 (38%) were female, and 29 (48%) were aged ≥45 years; moreover, 44 (72%) had type 2 diabetes, 36 (59%) used insulin, and 34 (56%) currently or previously used a CGM. Respondents had high levels of digital and general health literacy: 87% (46/53) used at least 1 health app, 59% (36/61) had used an activity tracker, and 62% (33/53) used apps to track ≥1 health behaviors. CGM users and nonusers used non-CGM health apps at similar rates (16/28, 57% vs 12/20, 60%; *P*=.84). Activity tracker use was also similar between CGM users and nonusers (20/33, 61% vs 14/22, 64%; *P*=.82). Respondents reported sharing self-monitor data with health care providers at similar rates across age groups (17/32, 53% for those aged 18-44 y vs 16/29, 55% for those aged 45-70 y; *P*=.87). Combined activity tracker and health app use was higher among those with higher Digital Health Care Literacy Scale scores, but this difference was not statistically significant (*P*=.09). Interviewees (18/61, 30%) described using blood glucose level tracking apps to personalize dietary choices but less frequently used data from apps or activity trackers to meet other self-management goals. Interviewees desired data that were passively collected, easily integrated across data sources, visually presented, and tailorable to self-management priorities.



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**Conclusions:** Adults with diabetes commonly used apps and activity trackers, often alongside CGMs, to track multiple behaviors that impact diabetes self-management but found it challenging to link tracked behaviors to glycemic and diabetes self-management goals. The findings indicate that there are untapped opportunities to integrate data from apps and activity trackers to support patient-centered diabetes self-management.

***(JMIR Diabetes 2025;10:e64505)*** doi:10.2196/64505

**KEYWORDS**

diabetes; self-management; mobile health; health technology; continuous glucose monitors; digital health literacy

## Introduction

### Background

Adults with diabetes can significantly lower their risk of diabetes complications such as nerve damage, kidney failure, blindness, myocardial infarction, and stroke by maintaining healthy daily diabetes self-management behaviors [1-3]. Diabetes self-management behaviors span multiple domains, including taking medications on a consistent schedule, engaging in regular physical activity, maintaining a healthy diet, self-monitoring blood glucose levels and blood pressure, practicing good sleep hygiene, and managing stress [4,5]. Adults with diabetes navigate these self-management behaviors to make daily decisions unique to their treatment regimens—such as adjusting medication doses and food intake after exercising. Successfully changing and sticking with healthy self-management routines is challenging for many people [6,7]. These demanding tasks can also lead to overwhelming diabetes distress, which can result in less motivation to stick to healthy regimens as well as higher blood glucose levels [8].

Technologies such as mobile apps, wearable activity trackers, and wearable continuous glucose monitors (CGMs) are available to support adults with diabetes; however, little is known about how adults with diabetes use CGMs in combination with mobile apps and activity trackers for other diabetes self-management domains. With 1 in 5 Americans reporting that they use a smartwatch or fitness tracker [9], there are increasing opportunities for adults with diabetes to use these devices for diabetes management, as evidenced by their incorporation into diabetes treatment guidelines [10]. While CGM use has been linked to lower glycated hemoglobin levels among people with type 2 diabetes who use insulin [11,12], available evidence is not clear on whether using CGMs enables patients to improve medication taking or other diabetes self-management behaviors [13,14]. There is mixed evidence on whether using activity trackers results in lower blood glucose levels for adults with diabetes [15-17]. It remains unclear whether and how adults with diabetes connect data from these apps with information from their CGMs to guide daily behavioral routines. Other domains, including stress and sleep—increased stress has been linked to higher blood glucose levels among adults with type 1 and 2 diabetes [18]—are included as behaviors that are important to address in treatment guidelines [5], but we do not know whether adults with diabetes use technologies to track these behaviors and link them with their diabetes information.

### Objectives

In this mixed methods study, we aimed to assess how adults with diabetes use and combine blood glucose level and self-management behavior tracking technologies to inform their day-to-day diabetes self-management and reach their personal health goals. Our research question focuses on understanding how adults with diabetes with differing clinical profiles and digital health literacy use and integrate data from multiple behavior tracking technologies for diabetes self-management.

## Methods

### Study Population

Individuals aged 18 to 75 years with diabetes (type 1 or 2) who were prescribed at least 1 diabetes medication were eligible for this study. The age cutoff for the study was set at 75 years because diabetes management goals change once individuals are beyond a certain age, including more liberal blood glucose level targets that emphasize safety. This could affect the appropriateness of certain technologies, such as CGMs, and how individuals use them.

The exclusion criteria included a diagnosis of gestational diabetes without another diabetes diagnosis, a diagnosis of schizophrenia or any other kind of “serious mental illness,” and diagnoses of “serious medical illnesses” (eg, cancer, chronic obstructive pulmonary disease, and end-stage kidney disease).

### Recruitment

Potentially eligible participants were either referred by health care providers (n=2) or recruited via a posting on the University of Pittsburgh Pitt+Me research registry, which was available from March to November 2023. The posting contained information about the purpose of the study; eligibility criteria; and what participation involved, including with regard to completing the survey on the internet and potentially being invited for an interview. The target audience included individuals diagnosed with diabetes who are currently prescribed at least 1 diabetes medication. Potential participants who had responded to the posting were contacted via telephone by a study team member to confirm eligibility and obtain verbal consent (refer to the *Ethical Considerations* subsection for details). The study team member then administered the survey over the telephone or via a web-based Qualtrics (Qualtrics International Inc) form. After completing the survey, potential interview participants were purposefully recruited to represent a variety of experiences with technology and diabetes-related factors such as diabetes type, diabetes medication use (insulin



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or oral), and CGM use (current or prior), as well as demographic factors, including age, sex, and racial identity and ethnicity.

### Closed-Ended Survey Questions

The web-based survey (Multimedia Appendix 1 [19,20]) included 46 questions about sociodemographic characteristics; functional challenges to using apps (vision or dexterity problems); and diabetes management, including blood glucose level monitoring patterns. The survey took approximately 10 (median 9.31, IQR 11.85-18.66) minutes to complete; included free-text, multiple-choice, and Likert-scale response options; and was developed internally by the research team through multiple versions. We assessed current or previous participant experience with 6 types of mobile apps for diabetes self-management behaviors that correspond to key self-management domains in American Diabetes Association diabetes management guidelines [5]: blood glucose level monitoring, diet, exercise, weight loss, sleep, and stress and mindfulness. While current and previous technology use represent different use patterns, we decided to group these patterns together because these data could be used to craft interventions that incorporate different domains that adults with diabetes have demonstrated interest in tracking. We also asked about current and former use of wearable blood glucose level and activity trackers. We used questions from previously validated surveys, including the Brief Health Literacy Screen [19,21] for general health literacy, which is scored on a scale ranging from 3 to 15, with scores of ≤9 reflecting marginal or inadequate health literacy [22,23]; and the Digital Health Care Literacy Scale (DHLS) [20] reflecting the ability to use mobile apps (scored from 0 to 12, with higher scores indicating higher digital health literacy).

### Interviews

Semistructured interviews were conducted using a secure videoconferencing platform (Zoom; Zoom Video Communications, Inc) from May to November 2023. All interviews were conducted by a study team member with a doctorate degree in nutritional sciences, subject matter expertise, and training and experience in conducting interviews. Another study team member who is a primary care physician and expert in health literacy also participated and asked follow-up questions ad hoc. A trained research assistant took notes during the interviews and wrote reflexive memos summarizing each interview afterward. The interview guide (Multimedia Appendix 2) included questions for participants about their experiences using health technology to track data and make diabetes-related behavior changes. The guide was developed by study team members, pretested with 3 adults (who were not included in the data analysis), and revised based on their responses. In the final guide, participants were first asked to describe how they tracked information during a typical day and their experiences with diabetes-related mobile apps (6 types: blood glucose level monitoring, diet, exercise, weight loss, sleep, and stress and mindfulness) and wearable blood glucose level and activity trackers. We then asked participants to describe how they learned to use these apps and trackers; what features helped them manage diabetes; what aspects of the tools or training could have been more helpful; whether they combined information if they used >1 tool; and why they stopped using the tool, if applicable. In addition, participants were asked whether they shared blood glucose level data with members of their health care team or others (eg, family members); and to describe these experiences and how, if at all, they could be enhanced. The interviews took 45 to 60 minutes to complete and were recorded and transcribed. Transcripts were reviewed for accuracy by the research assistant.

### Data Analysis

#### *Survey*

Descriptive statistics—frequency (percentage) for categorical variables and mean (SD) for continuous variables—were used to assess patient characteristics and summarize other data (eg, health technology use, general health literacy, and digital health literacy). Participant use of each of the 6 types of apps and 2 types of wearables was tallied by category. We then categorized participants as 0, 1, or >1 app and wearable used. Health technology use was compared among participant groups (eg, age and insulin use) using independent 2-tailed *t* tests for continuous variables and chi-square for categorical variables. Data are presented as frequency (percentage) or mean (SD), unless otherwise noted. To capture as many aspects of technology use among adults with diabetes as possible, we did not exclude participant responses if they did not complete all questions in a particular section. Data were analyzed using SPSS (version 28.0; IBM Corp) and Stata (version 18.0 for Mac; StataCorp LLC).

To analyze the association between health literacy and app use, we used a cutoff score of ≤9 as a marginal or inadequate score based on prior literature [22,23]. As there are no defined tiers for low, marginal, or high levels of digital health literacy in the DHLS, we created categories for this score, including ≤9 (marginal or inadequate digital health literacy) and ≥10 (adequate digital health literacy) based on the distribution of scores among the survey respondents. We tested the association between digital health literacy and total app use using Fisher exact tests with an assigned $\alpha$ of .05.

#### *Interviews*

We used content analysis to summarize themes by interview topic [24,25]. An initial inductive codebook was developed based on the anticipated categories of information that would be gathered during the interviews. Members of the research team separately coded 3 transcripts, compared results as a group, and then adjusted the codebook to include deductive emerging themes. After reaching sufficient agreement on the dually coded transcripts, single-user coding was applied to the remaining transcripts. Team members separately reviewed coded passages and potential themes, which were then presented and discussed as a group until consensus was reached. Analysis was conducted using NVivo software (version 14 for Mac and Windows; Lumivero).

### Ethical Considerations

This study was deemed exempt by the University of Pittsburgh Institutional Review Board (22120073-001).



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For the survey consent process, a study team member contacted interested individuals and confirmed their eligibility. The team member then outlined the goals of the study, the processes for completing the survey, the possibility of being contacted for a postsurvey interview, the potential risks and benefits of participation, the processes for protecting confidentiality and data safety, and the option of declining participation at any time. These parameters were reviewed with interview participants, who were selected from the survey respondents, at the beginning of their interviews.

Study data—including survey responses and interview quotes—were deidentified, labeled with a study ID number, and stored on Health Insurance Portability and Accountability Act–compliant servers. All personally identifying information was removed from transcripts.

Participants received US $10 in compensation for completing the survey and US $30 in compensation for completing the interview.

## Results

### Survey

A total of 61 adults with diabetes completed the survey. Of the 61 respondents, 60 (98%) owned a smartphone, and 54 (94%) used web-based resources to look up health information. As shown in Table 1, of the 61 respondents, 21 (34%) were Black, and 23 (38%) were female. Approximately half (29/61, 48%) were aged 45 to 70 years, and most (50/61, 82%) had some college education. A majority (44/61, 72%) had type 2 diabetes, 59% (36/61) used insulin, and 56% (34/61) reported having current or prior experience with using a CGM. Respondents had overall high levels of general health literacy (mean 13.1, SD 2.6; possible scores: 3-15) and digital health literacy (mean 10.6, SD 2.1; possible scores: 0-12). The characteristics of the interview participants are presented in Table 2.



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**Table 1.** Survey respondent characteristics.

| Characteristics | Values |
|---|---|
| **Age group (y; n=61), n (%)** | |
| 18-44 | 32 (52) |
| 45-70 | 29 (48) |
| Female sex (n=61), n (%) | 23 (38) |
| **Race and ethnicity (n=61), n (%)** | |
| Asian | 4 (7) |
| Black or African American, non-Hispanic | 21 (34) |
| White, non-Hispanic | 35 (57) |
| Multiple | 1 (2) |
| **Education (n=61), n (%)** | |
| High school graduate or GED[a] | 11 (18) |
| Some college | 23 (38) |
| College graduate or higher | 27 (44) |
| **Time since diabetes diagnosis (y; n=61), n (%)** | |
| ≤1 | 3 (5) |
| 1-3 | 11 (18) |
| 3-5 | 10 (16) |
| >5 | 37 (61) |
| **Diabetes type (n=59), n (%)** | |
| Type 1 | 15 (25) |
| Type 2 | 44 (75) |
| **Insulin frequency (among those who used insulin; n=36), n (%)** | |
| Once daily | 7 (19) |
| Twice daily | 7 (19) |
| ≥3 injections daily | 15 (42) |
| Insulin pump | 7 (19) |
| Take noninsulin diabetes medications (n=61), n (%) | 43 (70) |
| **CGM[b] use (n=56), n (%)** | |
| Currently | 32 (57) |
| Previously | 2 (4) |
| Never | 22 (39) |
| **Brief Health Literacy Screen (possible scores: 3-15; n=60)** | |
| Score, mean (SD; range) | 13.1 (2.6; 6-15) |
| Inadequate health literacy (score: ≤9), n (%) | 6 (10) |
| Adequate health literacy (score: ≥10), n (%) | 54 (90) |
| **Digital Health Care Literacy Scale (possible scores: 0-12; n=61)** | |
| Score, mean (SD; range) | 10.6 (2.1; 2-12) |
| Marginal digital health literacy (score: ≤9), n (%) | 11 (18) |
| Adequate digital health literacy (score: ≥10), n (%) | 50 (82) |

[a]GED: General Educational Development Test.

[b]CGM: continuous glucose monitor.



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**Table 2.** Interview participant characteristics.

| Characteristics | Values |
|---|---|
| **Age group (y; n=18), n (%)** | |
| 18-44 | 6 (33) |
| 45-70 | 12 (67) |
| Female sex, n (%) | 9 (50) |
| **Race and ethnicity (n=18), n (%)** | |
| Asian | 2 (11) |
| Black or African American, non-Hispanic | 7 (39) |
| White, non-Hispanic | 9 (50) |
| Multiple | 0 (0) |
| **Education (n=18), n (%)** | |
| High school graduate or GED[a] | 4 (22) |
| Some college | 7 (39) |
| College graduate or higher | 7 (39) |
| **Time since diabetes diagnosis (y; n=18), n (%)** | |
| ≤1 | 1 (6) |
| 1-3 | 2 (11) |
| 3-5 | 0 (0) |
| >5 | 15 (83) |
| **Diabetes type (n=18), n (%)** | |
| Type 1 | 2 (11) |
| Type 2 | 16 (89) |
| **Insulin frequency (among those who used insulin; n=11), n (%)** | |
| Once daily | 5 (45) |
| Twice daily | 1 (9) |
| ≥3 injections daily | 5 (45) |
| Insulin pump | 0 (0) |
| Take non–insulin diabetes medications (n=18), n (%) | 16 (89) |
| **CGM[b] use (n=13), n (%)** | |
| Currently | 9 (69) |
| Previously | 0 (0) |
| Never | 4 (31) |
| **Brief Health Literacy Screen (possible scores: 3-15; n=18)** | |
| Score, mean (SD; range) | 12.0 (2.5; 7-15) |
| Inadequate health literacy (score: ≤9), n (%) | 2 (11) |
| Adequate health literacy (score: ≥10), n (%) | 16 (89) |
| **Digital Health Care Literacy Scale (possible scores: 0-12; n=18)** | |
| Score, mean (SD; range) | 10.6 (2.5; 2-12) |
| Marginal digital health literacy (score: ≤9), n (%) | 4 (22) |
| Adequate digital health literacy (score: ≥10), n (%) | 14 (78) |

[a]GED: General Educational Development Test.

[b]CGM: continuous glucose monitor.



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As shown in Table 3, of 53 survey respondents, 43 (87%) reported currently or previously using health apps in 1 of 6 categories or wearable activity trackers. There was variability in completing survey items on specific types of apps or wearable activity trackers (combined app and wearable activity tracker use: n=53; wearable activity tracker use: n=60). Of the 6 types of health apps plus wearable activity trackers surveyed, on average, 2.6 (SD 2.0; range 0-7) types were used. Nearly half (25/53, 47%) of the respondents used ≥3 types of apps and wearable activity trackers. The most frequently used apps were those related to blood glucose level monitoring (37/61, 61%), followed by those related to food (23/61, 38%) and weight (18/61, 30%). Nearly three-fifths (36/61, 59%) of the respondents reported using a wearable activity tracker, including 28% (17/61) who used an exercise app. A similar percentage of CGM users (20/33, 61%) and nonusers (14/22, 64%) used wearable activity trackers. The use of blood glucose level monitoring apps was more common among CGM users than nonusers (28/34, 82% vs 5/22, 23%; $P<.001$) as well as more common among insulin users than nonusers (27/36, 75% vs 10/25, 40%; $P=.006$). However, non-glucose monitoring app use (39/61, 74%) was similar among CGM users and nonusers (16/28, 57% vs 12/20, 60%) as well as among insulin users and nonusers (20/33, 61% vs 12/20, 60%), but there was a trend toward lower use among those aged 45 to 70 years compared to those aged 18 to 44 years (14/27, 52% vs 18/26, 69%); however, these results were not statistically significant ($P=.20$). Participants also reported sharing self-monitored data with their health care providers at similar rates across age groups (17/32, 53% for those aged 18-44 y vs 16/29, 55% for those aged 45-70 y; $P=.87$). Details of health technology use (current or previous) among interview participants are presented in Table 4.

**Table 3.** Health technology use (current or previous) among survey respondents.

| | Respondents, n (%) |
|---|---|
| **Blood glucose level monitoring apps (n=61)** | |
| CGM[a] or glucometer app | 31 (51) |
| Another website or app | 6 (10) |
| Food tracking app (n=61) | 23 (38) |
| Weight tracking app (n=61) | 18 (30) |
| Exercise app (n=61) | 17 (28) |
| Stress-related, mindfulness, or meditation app (n=61) | 14 (23) |
| Sleep app (n=61) | 13 (21) |
| Wearable activity tracker (n=61) | 36 (59) |
| **Combined total app types and wearable activity tracker use (n=53)** | |
| 0 | 7 (13) |
| 1 | 13 (25) |
| >1 | 33 (62) |
| Have tried to share information from apps with health care provider (n=61) | 33 (54) |
| A health care provider recommended health app or wearable activity tracker (n=49) | 18 (37) |
| “Have you ever completed a telehealth video visit?” (n=54) | 42 (78) |
| “Do you use online resources (websites, search engines) to look up health information?” (n=54) | 51 (94) |
| “I own a personal computer, laptop computer, or tablet” (n=54) | 52 (96) |

[a]CGM: continuous glucose monitor.



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**Table 4.** Health technology use (current or previous) among interview participants.

| | Participants, n (%) |
|---|---|
| **Blood glucose level monitoring apps (n=18)** | |
| CGM[a] or glucometer app | 9 (50) |
| Another website or app | 4 (22) |
| Food tracking app (n=18) | 9 (50) |
| Weight tracking app (n=18) | 6 (33) |
| Exercise app (n=18) | 3 (17) |
| Stress-related, mindfulness, or meditation app (n=18) | 6 (33) |
| Sleep app (n=18) | 6 (33) |
| Wearable activity tracker (n=18) | 11 (61) |
| **Combined total app types and wearable activity tracker use (n=17)** | |
| 0 | 0 (0) |
| 1 | 5 (29) |
| >1 | 12 (71) |
| Have tried to share information from apps with health care provider (n=18) | 12 (67) |
| A health care provider recommended health app or wearable activity tracker (n=10) | 4 (40) |
| “Have you ever completed a telehealth video visit?” (n=11) | 8 (73) |
| “Do you use online resources (websites, search engines) to look up health information?” (n=11) | 10 (91) |
| “I own a personal computer, laptop computer, or tablet” (n=11) | 11 (100) |

[a]CGM: continuous glucose monitor.

As seen in Table 5, combined wearable activity tracker and app use was higher among those with DHLS scores of ≥10, particularly for those using >1 tracker or app, but this did not reach statistical significance (*P*=.09).

**Table 5.** Digital Health Care Literacy Scale (DHLS) scores and app use among survey respondents.

| | Respondents with DHLS scores of ≤9, n (%) | Respondents with DHLS scores of ≥10, n (%) | *P* value |
|---|---|---|---|
| **Total app types used (range 0-6)** | 11 (100) | 42[a] (100) | .35[b] |
| 0 | 4 (36) | 6 (14) | |
| 1 | 3 (27) | 14 (33) | |
| >1 | 4 (36) | 22 (52) | |
| **Wearable activity tracker use** | 11 (100) | 49 (100) | .1[c] |
| No | 7 (64) | 17 (35) | |
| Yes | 4 (36) | 32 (65) | |
| **Combined total app type and wearable activity tracker use (range 0-7)** | 11 (100) | 42 (100)[a] | .09[b] |
| 0 | 3 (27) | 4 (10) | |
| 1 | 4 (36) | 9 (21) | |
| >1 | 4 (36) | 29 (69) | |

[a]Not all participants completed all app use survey questions; hence, the total number of respondents for total app type and wearable activity tracker use are different.

[b]Fisher exact test.

[c]Fisher exact test for 2 × 2 contingency tables (2-sided).



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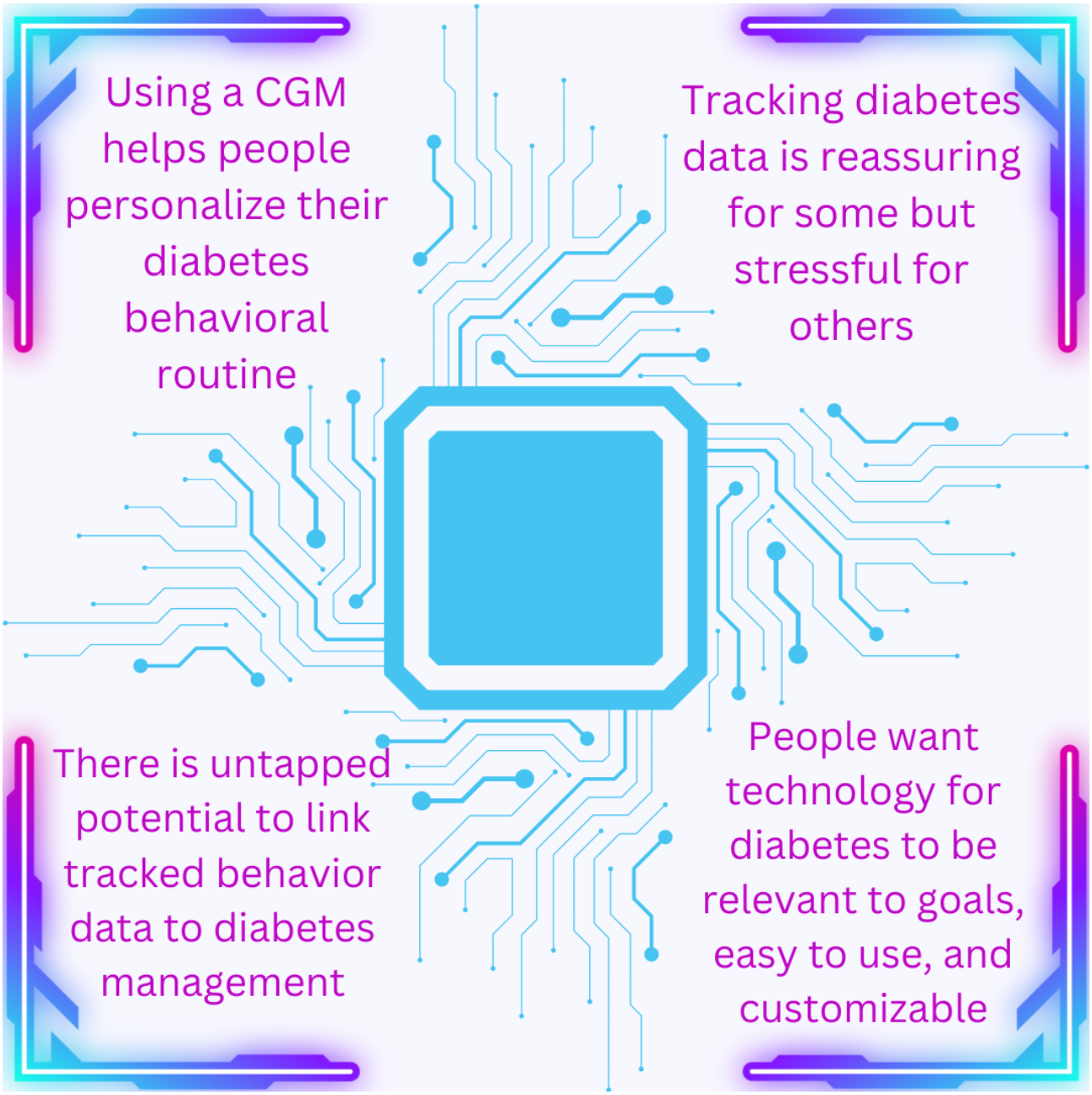
## Interviews

### *Overview*

Of the 61 survey respondents, 18 (30%) were invited to complete semistructured interviews examining how technologies were and could be used in daily diabetes self-management. As shown in Table 2, most interviewees (16/18, 89%) had type 2 diabetes, with 45% (5/11) of the interviewees who used insulin requiring ≥3 injections daily. They had high levels of digital health literacy on the DHLS as well as high levels of overall health literacy on the Brief Health Literacy Screen. Half (9/18, 50%) of the interviewees used a CGM or glucometer app, 67% (12/18) shared data with a health care provider, 73% (11/18) had used telehealth, and 91% (10/11) used web-based resources.

Four major themes emerged from the interviews, as shown in Figure 1 and described in the following subsections.

**Figure 1.** Main themes from semistructured interviews. CGM: continuous glucose monitor.




### *Theme 1: Using a CGM Helps People Personalize Their Diabetes Self-Management Behavioral Routine*

Despite the fact that CGM apps are focused on guiding insulin dose adjustments, many interviewees described using CGM data to guide day-to-day diabetes health behaviors such as eating choices and physical activity patterns:

> *So I get to choose what to eat knowing what my blood sugar is...When I see my blood sugar's closer to 200 then I will eat less fruits or sugary food in the morning and really more eggs or something like that.* [Male, aged 45-59 y, with type 2 diabetes]

> *Yes, like when I was going to the gym and I was working with this workout group and we were weightlifting, my sugar would go up even though I*



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> *didn't eat anything. Like I could start at 90. And by the end of the workout, my sugar was like at 145-150. And I was noticing that happen[ing]...then like on my drive home it was start[ing] to go down but after we worked out with the weights my glucose would always go up.* [Female, aged 26-44 y, with type 1 diabetes]

Others with type 2 diabetes discussed how the use of their CGM allowed them to be more flexible in terms of when and how often they checked their blood glucose levels:

> *My doctor absolutely would prefer that I'm, you know, pricking 4 times a day. That's just not feasible with the lifestyle that I live. It's just not possible. So the [continuous] glucose monitor helps in that...Sometimes like if I'm feeling weird, I'll do it [check the app] more times. Sometimes, I'll do it less times.* [Female, aged 26-44 y, with type 2 diabetes]

Notably, many participants discussed tailoring the more generic lifestyle behavior advice they receive from clinicians to identify what personally impacts their blood glucose levels. Interviewees described how using CGMs allowed for personalized understanding of the extent to which certain eating patterns impacted their blood glucose levels, which was "better than a dietitian." They described CGM data as liberating because these data gave them insights into their body's responses to foods that they previously felt were "off-limits":

> *It's the dietitians I think, are very, to some extent they're helpful. But I actually found the CGM much more helpful...I like Chinese food. And what I was told was at the beginning, that probably you can't eat that anymore, in that you have to decrease that. But that's not entirely true...actually I'm able to actually eat certain types of foods. And I got that information more from my CGM than dietitians.* [Male, aged 45-59 y, with type 2 diabetes]

> *It [the CGM] tells me, depending on what I'm going to eat, what I have a taste for, what my taste buds are, yes, no. The numbers will help me and let me know. Okay, I can have this, but not too much of it.* [Female, aged 26-44 y, with type 2 diabetes]

### *Theme 2: Tracking Additional Data for Diabetes Management Is Reassuring for Some, While Others Feel That It Increases Stress*

Interviewees expressed an array of views on how increasing the amount of data available affects their confidence managing diabetes. Some found it reassuring to have extra data:

> *I told you I was a numbers guy. I'm also kind of a fanatic on schedule, and it was nice, because [the CGM] kind of put you into a schedule.* [Male, aged 60-70 y, with type 2 diabetes]

> *Even though the days and the moments I use it [the CGM] fluctuate, I still use it way more than I took the time out to finger stick myself. So even in the days that I've only, you know, scanned 3 times. That still gives me a good idea of you know where I stand with my numbers and was able to keep me, you know, mentally aware that, hey? You're still, you know, you're still on track. It's still on track.* [Female, aged 26-44 y, with type 2 diabetes]

Others who tried tracking health data described feeling stressed or overwhelmed by the additional data:

> *Each one of us have obsessive compulsive things. And one of the things that bothers me is when I look at the green area in that [CGM app] graph, and I see myself go outside of the green area, it kind of bothers me so I always want to stay within that green area or close to it. I like to see it all green, when I see some yellow I don't like that. I'll accept it. And they say yep, that's because of this food that I ate. But usually I don't like it.* [Male, aged 45-59 y, with type 2 diabetes]

> *So I wait to put my new [CGM on], and getting that first number, I get anxious to see what it is, what it's going to be. And you know, did I wonder? Like, oh, did I? You know, did I do good today with eating? You know I took my medicine, and you know it should be this, but what if it's that?* [Female, aged 26-44 y, with type 2 diabetes]

> *I think it's obsessive to be looking at that [activity tracker] all day...I'm not one of those people that wants to count their steps. You know, I might want to count them one day, and then the next day I don't. So, you know, so I don't want to be focused on a watch...it's just too much for me.* [Female, aged 49-59 y, with type 2 diabetes]

Some people described having extra data from wearable monitors as relieving stress because they were better able to share their data with others:

> *Every time I scan...my wife gets to see what my blood sugars are. She has the app...So as soon as I scan, it shows up on her phone. It's one of the alerts in her phone, and then she sees the range as well. So she sees all of the information. So she does remind me and then sometimes she'll text me and say your sugar's really high or something and I say "Yeah I just had this type of meal."* [Male, aged 45-59 y, with type 2 diabetes]

The ability to share wearable activity tracker and app data with health care providers was also described as stress relieving because interviewees felt that this made it easier for health care providers to understand how diabetes management was going at home:

> *When I come in for an appointment, [the physician will] download 2 weeks' worth of data. So she's connected to my system all the time. And her reaction was, "Wow, you're 90 plus percent compliant."* [Male, aged 60-70 y, with type 2 diabetes]

> *So the conversations we would have when I go to my appointments...is basically them asking me, okay, what are you doing differently? Your levels are like, really good. There's no adjustments that need to be made...And then, if they see anything real low on a specific day, they'll ask me, okay, well, what was*



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> *going on this day, you were really low. And so there, if there's any adjustments need to be made, they'll tell me right then and there.* [Female, aged 26-44 y, with type 2 diabetes]

### *Theme 3: There Is Untapped Potential to Link Data on Commonly Tracked Lifestyle Behaviors to Diabetes Self-Management*

Interviewees mentioned using wearable activity trackers and mobile apps to track multiple aspects of their lifestyle, including healthy eating, physical activity, sleep, and stress levels. While they often discussed links between stress or sleep and blood glucose levels, they rarely discussed linking or comparing tracker data on these behaviors with blood glucose level monitor data:

> *So I'm one of those people who, you know, who may eat more chips because I'm just feeling down, or I'm just having a stressful day, something like that. And so when that happens when I'm stressed a lot, that's what messes with my eating, and then it messes with my blood sugar, and then my readings are very high, because I ate the wrong thing all day, or I've eaten a wrong...I've eaten a candy bar before I went to bed.* [Female, aged 45-59 y, with type 2 diabetes and no CGM experience]

> *I do see it [sleep] in my app, my health app, and it shows up that once in a while. That's a once every four weeks my phone tells me that "oh you reached your goal for tonight." But it does make me more mindful that yeah, I'm not sleeping as much as I need to be.* [Male, aged 45-59 y, with type 2 diabetes]

> *There was a lot of good information [in] there of "Try this or do this, or make sure you're..." I mean, everything from what you're eating to socializing. So, I think...what can I, what can I do to sleep better? And how does how does that sleep really affect my diabetes?* [Male, aged 60-70 y, with type 2 diabetes discussing a subscription-based lifestyle and weight management app]

### *Theme 4: People Prefer to Use Diabetes Management Apps and Wearables When It Is Relevant and Customizable to Their Self-Management Priorities With Data That Are Easily Collected and Integrated in One Place*

Interviewees preferred customizing whether, when, and how they tracked certain diabetes lifestyle data based on their personal goals or situation at the time:

> *It came to a point where I was no longer interested or cared about how many steps I took because, you know, again, most of my day is spent in the car. So like, I wasn't really stepping. If that makes sense, it wasn't, you know, you would see different friends and stuff on social media. And, "Oh, I had 10,000 steps," and it's like, yeah, I barely made a thousand a day. So like, yeah, bump this.* [Female, aged 26-44 y, with type 2 diabetes]

> *I think they [specific app] probably try to do too much with exercise logging. So I don't even, I just ignore that feature. 'Cause doctors really want me to focus on caloric intake.* [Male, aged 60-70 y, with type 2 diabetes]

> *I'll use it [a food and activity tracking app] for myself sometimes to track what I'm eating, and when I was focused on losing weight. And I haven't really been focused on it because I'm focused on something else right now.* [Female, aged 45-59 y, with type 2 diabetes]

If they did use trackable data, interviewees wanted to control how frequently they were prompted to track data and what types of prompts they received:

> *So again, you know I'm technical, technically savvy, whatever you want to call it. And I thought that the app would be perfect for me, thinking, by my lifestyle being on the go and stuff like that. But, it really wasn't. So one of one of the biggest things that I didn't like about it, is it overrides. It was overriding anything [settings] that I had on my phone at the time...It was just like, you know, bust through...I didn't know about the alarms and things so it's going off, you know, during times where it's inappropriate.* [Female, aged 26-44 y, with type 2 diabetes discussing the mobile app that accompanies the CGM]

Interviewees preferred that their data were easy to visualize and interpret:

> *The application that [the CGM company] provides does provide a graphing capability. So I can graph or print the numbers out for the 3 months time period, and take those along with me for [the physician] to look at...It'll tell you what your actual numbers were, for the average ones for the day, what the average was for the last 30 days, the last 90 days. And it'll do a trend line for you. Tell you the time in within range. So all that information is there, and we do share it.* [Male, aged 60-70 y, with type 2 diabetes]

> *Yeah. I love [the CGM]. Yeah, I love, It makes things so much easier to put in perspective, like with the graphs and stuff.* [Male, aged 45-59 y, with type 2 diabetes]

Interviewees felt that the lower the burden of tracking, the better. They expressed a preference for passive collection of data. Manual data entry was viewed as a difficult habit to maintain:

> *I don't [track] anymore with the [manual entry] activity trackers because they're more cumbersome than anything, and like I said, that's why the [watch with activity tracker capability] is working, because it's just tracking without me being actively needing to work it out. I used the [food and activity tracking app] more for the, for the nutritional information...but then after a month it's just too cumbersome to log every single thing over there.* [Male, aged 45-59 y, with type 2 diabetes]



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Interviewees preferred seeing data from multiple behaviors in one place, which was described as reducing the burden of data use and, in some cases, helping them make connections between health behaviors and blood glucose levels:

> *So everything is very integrated in my phone, [the health app] even brings my medications, even brings my labs [and] tests. You know, I look at my sleep and go through the sleep. I look at my steps but because I'm not actively physically active, it's more of "okay, here's the information." It's nice to see.* [Male, aged 45-59 y, with type 2 diabetes]

> *Yes, I have [the CGM] connected to the [CGM] app, and then [other app] is connected to the watch. I just noticed when I was putting in my weight on the [wearable activity tracker] it has the glucose readings on that as well. I guess they're connecting...it is helpful because they have like the charts. So it's just nice to see like it's all in range or it's going up and down.* [Female, aged 26-44 y, with type 1 diabetes]

## Discussion

### Principal Findings

In this web-based survey of diverse adults with diabetes and moderate to high digital health literacy, we found that nearly two-thirds (33/53, 62%) used technology to track >1 lifestyle factor impacting their daily diabetes self-management. This included individuals who did not use CGMs and those with varying levels of digital health literacy. It is important to note that participants self-selected to participate in the survey, which was posted on the web, and this may have skewed the sample toward those with higher digital health literacy. Wearable activity trackers were equally used among CGM users and nonusers. Mobile apps used to track blood glucose levels and eating were more common than those used for stress or sleep; however, approximately a quarter of the respondents tracked their stress (13/61, 21%) and sleep (14/61, 23%) levels using apps. In the sample of interviewees with overall higher digital health literacy, we found that current technology offers adults with diabetes an opportunity to customize general diabetes lifestyle advice to their needs and, for some, reduces stress around diabetes management. Given that these adults with diabetes who were able to respond to a web posting to participate in a research study were tracking multiple behaviors, there may be untapped potential, at least among technology-savvy adults with diabetes, to link data from tracking sources to diabetes self-management. Participants desired that apps and wearable activity trackers passively collect, integrate, and graphically display data from various sources in one place and allow customization to their changing personal goals over time.

### Comparison to Prior Work

Our results echo those of prior qualitative studies that identified factors impacting the use of specific individual apps or activity trackers among adults with diabetes. These factors include ease of use, customizable user experiences, health care provider perceptions and guidance, and seamless connectivity. They impacted app and activity tracker use among diverse groups of adults with diabetes (including those on insulin) [26-30]. Our study uniquely focused on how adults with diabetes combined multiple types of diabetes self-management technologies rather than using a particular app or activity tracker. In particular, we were interested in how many people used >1 app because that could present an opportunity to understand how they integrate data from these different sources, particularly because some trackable behaviors (eg, sleep) can impact trackable blood glucose levels or other trackable behaviors (eg, physical activity).

In addition, while some prior studies addressed factors that affect CGM app use [30], our study examined the interface between CGM data, which are more voluminous than those generated by other apps, and diabetes self-management behavior data, which are often tracked on a daily basis. CGM data can be used for overviews, beyond minute-to-minute readings, which could make CGMs and behavior tracking apps easier to use together. There is untapped potential to connect these data sources and, particularly, to help adults with diabetes link data that they are tracking on stress and sleep to their tracked blood glucose levels.

Our results highlight the highly individualized impact of trackable lifestyle data on diabetes self-management behaviors beyond just tracking blood glucose levels. Interviewees who used CGMs described many uses beyond insulin dose adjustments, including using CGMs to guide and personalize their diabetes self-management routines. In this way, additional lifestyle data from novel trackers that cover other domains of diabetes self-management could add more insights and personalization to an individual's daily diabetes management. In particular, a better understanding of the relationship between personal data patterns and blood glucose levels could increase the sense of ownership of adults with diabetes over their diabetes self-management [31-33] and enhance intrinsic motivation for change [33-35].

### Future Directions

Our study has important implications for how adults with diabetes can use and integrate multiple technologies for diabetes self-management. Participants in our study used apps for tracking multiple behaviors across different age groups and treatment regimens; therefore, technologically focused diabetes self-management education programs could be expanded to accommodate the growing number of non–insulin users who integrate wearable activity tracker, CGM, and app data to manage their condition. These programs could be focused on addressing known barriers among adults with diabetes to using technology for diabetes self-management, including a lack of understanding of how to use personal health data, low digital health literacy, and a lack of knowledge and overall awareness of digital tools used for diabetes [36,37]. Newer platforms that allow users to combine inputs from multiple sources of health data and understand the relationships between these domains have been shown to be acceptable to users [38] and effective in some cases for short-term treatment outcomes in people with type 1 [39,40] and type 2 [41-45] diabetes, although there was heterogeneity in the types of data and interventions included. Taken together, these findings demonstrate the opportunity to incorporate multiple data sources more deliberately in



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personalized diabetes self-management education and diabetes self-management apps.

### Strengths and Limitations

Our study has several strengths, such as the inclusion of a diverse cohort of adults with diabetes, including people who did not use insulin—especially because more individuals (including those not on insulin) are qualifying for wearable devices such as CGMs and are using health tracking apps.

Our study also has multiple limitations. First, it relies on a convenience sample that is not necessarily representative of the general population of adults with diabetes. In particular, participation was self-selected by people who could use the internet to respond to the study invitation, which could have led to the higher levels of digital health literacy in this sample and may have contributed to higher app and activity tracker use than the general population of adults with diabetes. Second, the experiences of adults with type 1 diabetes and low health literacy are not well represented in the qualitative interview data. Third, because our main goal in this exploratory study was to describe emergent patterns and not quantify associations at this level, we did not collect information about other comorbidities, employment status, geographic location, current blood glucose control, or other factors that might confound technology use. Fourth, the low numbers of participants in the low health literacy and digital health literacy categories limited our power to assess the associations between literacy and technology use. Finally, most of the respondents (58/61, 95%) were aged >25 years; therefore, the results may not be generalizable to teenagers or emerging young adults. The results of this study could guide topics and sampling strategies for future studies that include a wider population-based sample.

### Conclusions

We found that a diverse cohort of adults with diabetes used several wearable and mobile app technologies to track multiple aspects of their daily routines relevant to diabetes self-management. They were interested in digital tools that were easy to use, integrated data across multiple platforms, and aligned with their personal priorities in customizable ways. Our findings have important implications for the ways in which adults with diabetes can be empowered to manage their health successfully and experience the benefits of health technologies.

## Acknowledgments

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## Data Availability

The datasets generated and analyzed during this study are not publicly available because the small sample size and detailed qualitative responses could make participants identifiable. Requests for deidentified survey data can be sent to the corresponding author and will be considered on a case-by-case basis.

## Authors' Contributions

All authors contributed to the conceptualization, methodology, formal analysis, and writing (original draft as well as review and editing) of this paper. TB, SG, JK, and AMR were responsible for data curation. SG, JK, CL, and AMR were responsible for funding acquisition. TB, SG, and JK were responsible for investigation. TB and JK were responsible for software. SG, JK, MZ, CL, and AMR were responsible for resources. CL and AMR were responsible for supervision. TB, SG, JK, MZ, CL, and AMR were responsible for visualization.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Key survey items.
[DOCX File , 23 KB - diabetes_v10i1e64505_app1.docx ]

Multimedia Appendix 2
Interview guide.
[DOCX File , 21 KB - diabetes_v10i1e64505_app2.docx ]

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## Abbreviations

**CGM:** continuous glucose monitor
**DHLS:** Digital Health Care Literacy Scale

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Original Paper

# Digital Innovation and Integrated Care in People With Diabetes in Western Sydney: Retrospective Cohort Study

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## Abstract

**Background:** The COVID-19 pandemic catalyzed the adoption of digital technologies in health care. This study assesses a digital-first integrated care model for type 2 diabetes management in Western Sydney, using continuous glucose monitoring (CGM) and virtual Diabetes Case Conferences (DCC) involving the patient, general practitioner (GP), diabetes specialist, and diabetes educator at the same time.

**Objective:** This study aims to assess the effectiveness of the innovative diabetes clinics in Western Sydney.

**Methods:** In 2020, a total of 833 new patients with type 2 diabetes were seen at Western Sydney Diabetes (WSD) clinics. An early cohort of 103 patients was evaluated before and after participation in virtual DCC, incorporating CGM data analysis, digital educational resources, and remote consultations with a diabetes multidisciplinary team. Assessments were conducted at baseline and 3-4 months post DCC.

**Results:** The integration of CGM and virtual consultations significantly improved glycemic control. Hemoglobin $A_{1c}$ ($HbA_{1c}$) levels decreased notably from 9.6% to 8.2% (average reduction of 1.4%; 95% CI 1.03-1.82; $P$<.001). Time in range (TIR) as measured by CGM increased substantially from 46% to 73% (95% CI 20-32; $P$<.001), and the glucose management indicator (GMI) improved from 7.9% to 7% (average reduction of 0.9%; 95% CI 0.55-1.2; $P$<.001). Despite no significant change in the total daily insulin dose, the proportion of patients on insulin therapy rose from 27% to 39% ($P$<.001), indicating more targeted and effective diabetes management.

**Conclusions:** Our findings demonstrate the effectiveness of a digitally enabled integrated care model in managing type 2 diabetes. The use of CGM technology, complemented by virtual DCCs and digital educational tools, not only facilitated better disease management and patient engagement but also empowered primary care providers with advanced management capabilities. This digital approach addresses traditional barriers in diabetes care, highlighting the potential for scalable, technology-driven solutions in chronic disease management.

***(JMIR Diabetes 2025;10:e64832)*** doi:10.2196/64832

**KEYWORDS**

CGM; T2DM; digital innovation; integrated care; effectiveness; type 2 diabetes care; type 2 diabetes; Australia; diabetes; adoption; digital technologies; diabetes management; continuous glucose monitoring; glucose monitoring; diabetes specialist; diabetes educator; cohort; virtual consultations; daily insulin dose; insulin; disease management; patient engagement; primary care; chronic disease management



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## Introduction

Diabetes presents a significant global health challenge. Rates of diabetes have increased dramatically in recent years, with disadvantaged regions bearing a greater burden when compared with wealthier areas of the world [1,2]. Western Sydney is a large geographic region in Sydney with 1 million residents. It is one of the most culturally diverse areas in Australia and has a number of suburbs with extremely disadvantaged populations. The rates of diabetes in Western Sydney are up to double those of higher-income areas in the city [1].

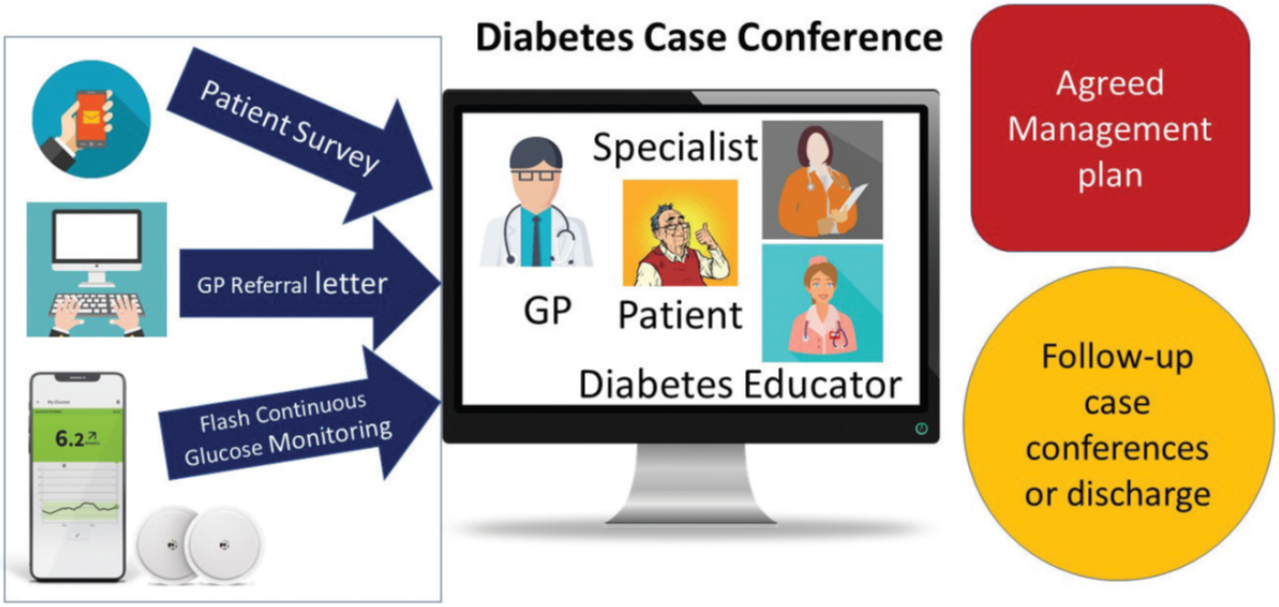
Western Sydney has an estimated 100,000 people with diabetes in the region. This equates to 13.1% of the adult population of 760,000 [2], with a total population of 1 million people in the region. This represents an unsustainable burden of disease that cannot be managed through existing specialist services that focus on treating individual patients. These traditional services, which usually require ongoing specialist care for every person diagnosed with diabetes, are too labor-intensive for the relatively small specialist workforce in the region. Recognizing this, Western Sydney Diabetes (WSD), an integrated care initiative located in the region, has pioneered a hybrid model of integrated care, designed to address the complex needs of patients with type 2 diabetes [3]. This model leverages digital technologies—including CGM, virtual multidisciplinary DCC, and a suite of digital educational resources—to enhance the coordination between primary and specialist care and empower general practitioners (GP) with the tools and knowledge to manage diabetes more effectively. The program was first modeled before the pandemic with local providers and has since been expanded to include a range of hybrid services that can be provided virtual or face to face.

Central to this program is the upskilling of the community workforce. WSD has been working with community medical staff since the program was started in 2014, with a focus on integrated care that crosses the specialist and GP boundaries. Previous evaluations have shown the benefits of involving GPs and other community health care staff in the care of people with diabetes and in better integrating these services with the hospital team [4].

In addition, WSD has adopted the innovative use of continuous glucose monitoring (CGM) in the program. CGM devices measure glucose tissue levels every minute and can be left on for 2 weeks at a time. This contrasts with traditional self-monitoring of blood glucose, whereby patients conduct finger-prick tests on their own blood several times a day. While initially controversial for type 2 diabetes, CGM has become a proven tool in treatment, with a range of research demonstrating the utility of this device for diabetes management [5,6]. By integrating real-time glucose data into patient care, WSD facilitates a comprehensive, collaborative treatment planning process. This process not only involves the patient and their GP but also draws on the expertise of dietitians, diabetes educators, and other clinicians.

WSD has also developed a comprehensive educational program for patients and providers. This includes diabetes case conferencing (DCC), which is a core component of the clinical care offered by WSD. DCC involves bringing together the patient, community providers, and hospital specialist team to discuss the patient's case and make a plan for their treatment. This process aims to upskill the GP and team as well as provide gold-standard care for the patient. Previous evaluations have proven the benefit of this process not just for individual patients but for the GP's practice of medicine as well [4,7]. The DCC model of care is depicted below in Figure 1.

**Figure 1.** Western Sydney Diabetes model of care explained, patients referred by the general practitioner or other specialists are triaged, following triaging patients have preclinic work up including continuous glucose monitoring insertion before the case conference (adopted from Western Sydney Diabetes website).






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WSD also conducts a yearly virtual diabetes masterclass series and in-person masterclass, which draws over 1000 registrants from across Australia. In addition, WSD has developed over 130 short educational videos for patients and providers to improve the understanding of diabetes [8]. These form a key component of the educational tools that WSD has developed to upskill practitioners in their work and help patients with self-management. All patients are provided with access to these digital tools when attending WSD clinics.

This combined clinical model, including a range of education and integration pieces, has not been formally evaluated. Previous studies have shown that individual aspects of this clinical model are effective, but existing data does not demonstrate any benefits to the model as a whole. Therefore, this study aims to retrospectively analyze the outcomes for patients managed under WSD's innovative clinical model, focusing on the use of CGM and other technological solutions in regular practice for individuals with complex type 2 diabetes. By examining the model's efficacy in improving patient care and enhancing GP capacity, the research seeks to provide valuable insights into the potential of integrated, technology-enabled care models to address the diabetes burden in high-prevalence regions.

## Methods

### Study Design and Participants

This retrospective cohort study analyzed patient records from the WSD complex diabetes clinics for the first quarter of 2022. Eligible patients had participated in at least one initial and one follow-up appointment at a WSD hybrid clinic, used CGM, and were subsequently discharged to their GP for ongoing diabetes management. Discharge criteria included the patient's stability and the GP's readiness to assume care, reflecting WSD's objective to enhance GP capacity for diabetes management in the community.

### Data Collection

Data were extracted from the electronic medical records, focusing on clinical and demographic information, medication regimens, CGM data, and dietary interventions. Specifically, we extracted hemoglobin $A_{1c}$ ($HbA_{1c}$), total daily dose of insulin, and CGM metrics including time in range, glucose management indicator, and time above and below range. In addition, we collected detailed information about medication usage. A convenience sampling method was used, culminating in the collection of 103 patient records. Data were securely stored in a dedicated database for analysis.

We did not have specific inclusion or exclusion criteria beyond the sampling methodology. All patients with sufficient follow-up data who had been discharged by the clinic were included.

CGM data were gathered by clinical staff trained in CGM use and analysis. WSD exclusively used the Abbott Libre system during this period, and reports were extracted for all patients from the LibreView cloud system (Abbott Diabetes Care). A trained clinician then extracted the data from these reports and entered it into our research database.

### Statistical Analysis

Data analysis was conducted using Stata 15 (StataCorp). We used *t* tests and chi-square tests to compare pre- and postintervention clinical metrics for continuous and categorical variables, respectively. Key CGM metrics analyzed included time in range (TIR) and the glucose management indicator (GMI). Changes in medication, especially insulin dosages, were also examined.

### Qualitative Analysis

In addition to quantitative metrics, the study includes an informal qualitative review of CGM's clinical utility in managing type 2 diabetes, assessing its impact on patient care and treatment outcomes. This qualitative review was conducted as a series of informal interviews with patients and GPs involved in the clinic. Themes from these discussions were collated and reported back by the WSD team.

### Ethical Considerations

This study was approved by the Western Sydney Local Health District Human Research Ethics Committee (approval 23/02578). The project was granted a waiver of consent as participants were deidentified before analysis.

## Results

### Patient Demographics and Baseline Characteristics

The study analyzed 103 patient records, with 81 patients having complete $HbA_{1c}$ data both at baseline and follow-up. Table 1 provides a comprehensive overview of patient demographics. Patients were followed up between 3 to 6 months after their first attendance at the WSD clinic.



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**Table 1.** Demographics and diabetes medications at baseline for the sample.

| Variables | Male (n=61) | Female (n=42) | Total (N=103) |
|---|---|---|---|
| Age (years), mean (SD) | 65.1 (10) | 61.1 (13.1) | 63.4 (11.5) |
| **Diabetes medications at baseline, n (%)** | | | |
| Metformin | 42 (68.9) | 34 (81) | 76 (73.8) |
| Sulfonylurea | 24 (39.3) | 4 (9.5) | 28 (27.2) |
| DPP4I[a] | 27 (44.3) | 11 (26.2) | 38 (36.9) |
| SGLT2I[b] | 33 (54.1) | 12 (28.6) | 45 (43.7) |
| GLP1RA[c] | 13 (21.3) | 13 (31) | 26 (25.2) |
| Insulin | 33 (54.1) | 29 (69) | 62 (60.2) |
| Mean insulin TDD[d] in units, mean (SD) | 33.6 (42.5) | 39.9 (41) | 36.2 (41.8) |
| Mean baseline $HbA_{1c}$[e] in %, mean (SD) | 9.5 (1.5) | 9.9 (1.7) | 9.7 (1.6) |

[a]DPP4I: Dipeptidyl Peptidase-4 Inhibitor.

[b]SGLT2I: Sodium-Glucose Cotransporter-2 Inhibitor.

[c]GLP1RA: Glucagon-Like Peptide-1 Receptor Agonist.

[d]TDD: total daily dose.

[e]$HbA_{1c}$: Hemoglobin $A_{1c}$.

## Glycemic Control

A significant reduction in $HbA_{1c}$ levels was observed, decreasing from an average of 9.6% at baseline to 8.2% at follow-up. This change represents a mean reduction of 1.4% (95% CI 1.03-1.82%; *P*<001).

## CGM Metrics

CGM data highlighted an improvement in TIR, which increased from 46% at baseline to 73% at the follow-up (95% CI 20%-32%; *P*<001). In addition, the GMI decreased from 7.97% to 6.94%, a reduction of 1.03% (95% CI 0.55%-1.2%; *P*<001), indicating enhanced glucose control. Time above range (TAR) high and TAR-very high reduced by 10.06% and 16.95%, respectively. Time below range (TBR)-low and TBR-very low also reduced by 0.1% and 0.44%, respectively (Table 2).

**Table 2.** Changes in continuous glucose monitoring metrics comparing the initial review and before discharge.

| CGM[a] metrics | Initial review, mean (SD) | Before discharge, mean (SD) | Change | *P* value |
|---|---|---|---|---|
| Sensor active time (%) | 75.44 (20.84) | 78.61 (20.39) | 3.17 | .84 |
| Glucose variability (%) | 28.94 (7.85) | 27.34 (5.92) | –1.6 | .16 |
| Glucose Management Indicator (GMI; %) | 7.97 (1.31) | 6.94 (0.71) | –1.03 | <.001 |
| Average blood glucose (mmol/L) | 10.74 (3.20) | 8.5 (1.51) | –2.24 | <.001 |
| Time in range (TIR) 3.9-10 mmol/L (%) | 46 (27.69) | 73 (15.97) | 27 | <.001 |
| Time above range (TAR) – high 10.1-13.9 mmol/L (%) | 31.32 (14.88) | 21.26 (10.90) | –10.06 | <.001 |
| Time above range (TAR) – very high>14 mmol/L (%) | 20.98 (22.22) | 4.03 (8.25) | –16.95 | <.001 |
| Time below range (TBR) – low 3.1-3.8 mmo/L (%) | 1.29 (2.63) | 1.19 (2.55) | –0.1 | .98 |
| Time below range (TBR) – very low <3.0 mmo/L (%) | 0.6 (1.83) | 0.16 (0.93) | –0.44 | .07 |

[a]CGM: continuous glucose monitoring.

## Medication Adjustments

Substantial changes in medication regimens were noted post consultation. The use of sulfonylureas decreased significantly, with only 17% (5/28) of patients continuing this medication at follow-up. Conversely, 32 patients had a glucagon-like peptide-1 receptor agonist (GLP1 RA) added to their regimen, while 9 discontinued its use. The proportion of patients on insulin therapy increased from 60% to 73%, although the average total daily insulin dose did not show a statistically significant change (average decrease of 5 units, *P*=.10).

## Patient and GP Experiences

Both patients and GPs expressed highly positive feedback regarding their experiences with the virtual clinic model. The use of CGM was particularly highlighted as beneficial. Patients reported improved understanding and management of their condition, attributing this to the insights gained from real-time



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glucose monitoring. GPs noted the virtual clinic facilitated more effective communication, and collaborative care planning, and enhanced their ability to manage diabetes in a primary care setting.

## Discussion

### Principal Findings

This study provided evidence of improvements in patient outcomes associated with the WSD model of care. This included improvements in CGM parameters, medication usage, and other key diabetes markers. While the study was limited, lacking a control group, the findings suggest that this model of care may be beneficial for similar clinical areas in the future.

The integration of CGM and virtual DCC within the WSD care model has marked a paradigm shift in managing complex type 2 diabetes. This innovative approach, blending digital health technologies with a collaborative care framework, has led to remarkable glycemic improvements, significantly surpassing outcomes commonly associated with telehealth interventions alone [9,10]. The essence of this success lies in the holistic care model, with CGM acting as a linchpin for real-time glycemic insight, thereby revolutionizing both self-management practices and clinical decision-making. The feedback in our informal review underscores the value of integrating digital health technologies in chronic disease management, aligning with the study's aim to evaluate the impact of a technologically enabled care model on diabetes management.

CGM has emerged as a critical tool in diabetes care, functioning as a “truth detector” by providing detailed insights into glucose fluctuations directly linked to lifestyle choices [11]. This real-time data empowers patients to observe the immediate impact of their dietary and exercise habits, facilitating more informed lifestyle adjustments and significantly improving glycemic control. However, CGM’s role in enabling efficient remote monitoring underscores its indispensability in our virtual care framework, aligning with the efficacy of telehealth in diabetes management demonstrated by previous studies [9].

Ehrhard NM [12] in a 52-week randomized controlled trial (RCT) showed $HbA_{1c}$ reduced by 1% at 12 weeks with CGM compared with 0.5% with self-monitoring of blood glucose (SMBG). Furthermore, Vigersky et al [13] showed that after 12 weeks of intervention using CGM or SMBG, $HbA_{1c}$ reduced by 0.8% in the CGM group and 0.2% in the SMBG group at 52 weeks. A recent systematic review and meta-analysis of 12 RCTs comprising 1248 participants by Jancev et al [14] showed CGM use resulted in an improvement of 6.36% for TIR and a 0.31% reduction in $HbA_{1c}$.

The DCC component has been crucial in eliminating geographical barriers and fostering seamless collaboration between primary care providers and specialists. GPs can attend the appointments virtually, with patients joining either from their own homes, the GP clinic, or the specialist clinic. Administration support has been crucial to allowing this hybrid model to be successfully implemented [7]. This model not only guarantees continuity of care but also serves as an invaluable educational platform for GPs, bolstering their ability to manage complex type 2 diabetes cases more effectively. The educational aspect of DCC, alongside the practical insights gained from CGM data, illustrates the power of this model to scale diabetes management efforts, catering to a wider patient demographic in the evolving landscape of digital health care.

The Australian National Diabetes Strategy (2016-2020) [15] addressed key areas such as integrated care fostering shared care and a patient-centered approach. Several services, such as the Hunter New England diabetes service, which covers a very large geographic region roughly the size of Greece but with a population of just under 1 million, and WSD were highlighted in this strategy as exemplars of diabetes management and engagement with community [16]. Similar to WSD’s evaluation, the Hunter New DAP [17] case conferencing study showed improvement in $HbA_{1c}$ by 0.4%. Another similar model in the southwest of Sydney demonstrated equivalent benefits in their patient cohort [18].

Another RCT demonstrated benefits for video case conferencing similar to those seen in this study [14]. WSD’s previous evaluations have also shown that with DCC patients were more empowered in shared decision-making and perceived as receiving good ongoing care further enhanced by the digital education bundles [15]. Table 3 shows the improvements associated with video conferencing for various studies on type 2 diabetes.



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**Table 3.** Related researches show improvement in hemoglobin A1c (HbA1c) and other variables using virtual health in type 2 diabetes mellitus.

| Study | $HbA_{1c}$ improvement (%) | Blood pressure (mm Hg) | BMI ($kg/m^2$) | Study size, n |
|---|---|---|---|---|
| Abrahamian et al [19] | • 0.3% | • 156→148<br>• 88→83 | Nil | 154 |
| Basudev et al [20] | • 0.6 (1.7%)<br>• Control group 0.8 (1.9%) | • 6 (16) systolic<br>• 2 (18) control group | Nil | 208 |
| Zhou et al [21] | • –2.4% (P <.001)<br>• Control -0.62 | • 3<br>• Control 2 | —[a] | 108 |
| Sood et al [22] | • –1.01%<br>• Control -0.68%<br>• P=.19 | — | — | 182 |
| De Groot et al [23] | • –0.486%<br>• P<.001 | • -0.875<br>• P<.01 | — | 8410 |

[a]Not applicable

Like these previous studies, our investigation supports the use of DCC and CGM in the treatment of diabetes. While the study design does not allow for inferences about specific modalities of care, the integrated nature of the clinic is clearly important to improve the health of people with diabetes. In our previous clinical evaluations, we have shown an improvement associated with DCC of 0.87% in terms of $HbA_{1c}$. That the improvement in this study is higher demonstrates the importance of innovative models of care and incorporating CGM into this process [4].

This care model is aimed at collaborating with community providers to improve the connection between specialist and community health services, and to upskill community health care workers to improve diabetes management more broadly. Our informal qualitative review indicated that this was occurring, with these findings supported by previous work, which has demonstrated the benefits more fully.

This study had many limitations. The inclusion criteria mean that only patients who improved were included in the cohort by definition. Therefore, it is not possible to draw concrete inferences about the improvements seen in this study and the measures used. There is no control group, and therefore there is no ability to draw causal inferences. The qualitative review was informal and lacked sufficient rigor to make clear statements about clinician or patient insights into the clinic. The sample size was relatively large, and the measurements were all objective; however, the retrospective nature of the study also limits the conclusions that can be drawn.

The study's limitations highlight the necessity for broader, comparative research to affirm these findings across varied health care contexts. The considerable baseline $HbA_{1c}$ levels also suggest that the dramatic improvements observed may not be universally achievable, indicating a need for tailored interventions based on patient baseline characteristics. There were also issues with the deployment of these interventions, highlighting the need for additional administrative support when implementing a complex technological program such as this.

## Conclusion

In conclusion, the WSD model shows that collaborative programs are implementable even in high-risk complex clinics. This integrative model is likely to have benefits more broadly for people with diabetes and community health care providers. Embracing and refining such innovative care approaches holds the promise of scaling diabetes management capabilities, potentially improving health outcomes for a broader spectrum of patients with type 2 diabetes. As we move forward, our focus will also extend to objectively measuring patient health outcomes in relation to engagement levels and social determinants, aiming to further enhance the care model's efficacy and reach.

## Conflicts of Interest

None declared.

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## Abbreviations

**CGM:** continuous glucose monitoring
**DCC:** diabetes case conferencing
**GLP-1 RA:** glucagon-like peptide-1 receptor agonist



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**GMI:** glucose management indicator
**GP:** general practitioner
**HbA1c:** hemoglobin A1c
**RCT:** randomized controlled trial
**SMBG:** self-monitoring of blood glucose
**TAR:** time above range
**TBR:** time below range
**TIR:** time in range
**WSD:** Western Sydney Diabetes

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# Continuous Glucose Monitoring in Primary Care: Multidisciplinary Pilot Implementation Study

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## Abstract

**Background:** Continuous glucose monitoring (CGM) is used to assess glycemic trends and guide therapeutic changes for people with diabetes. We aimed to increase patient access to this tool by equipping primary care physicians (PCPs) to accurately interpret and integrate CGM into their practice via a multidisciplinary team approach.

**Objective:** The primary objective of this study was to evaluate the feasibility and effectiveness of integrating CGM into primary care clinics using a multidisciplinary approach that included a clinical pharmacist (PharmD) and a certified diabetes care and education specialist (CDCES).

**Methods:** Eighteen PCPs received a 1-hour video training module from an endocrinologist teaching a systematic stepwise approach to CGM interpretation. Patient inclusion criteria included type 2 diabetes mellitus, ≥18 years old, hemoglobin $A_{1c}$ ($HbA_{1c}$) ≥8% or concern for hypoglycemia, and no previous CGM use or an endocrinology visit in the past year. Patients saw physician extenders (CDCES or a PharmD) for professional CGM placement and education on nutrition, medication administration, and physical activity goals based on the PCP's recommendations. The CDCES or PharmD reviewed CGM data with patients and collaborated with PCPs to adjust the care plan, informed by the systematic stepwise approach to CGM interpretation. Patients either converted to personal CGM if desired or had a second professional CGM device placed after ≥1 month from the initial professional CGM placement and obtained a postintervention $HbA_{1c}$ measurement at ≥3 months from the initial $HbA_{1c}$ measurement. The primary outcomes were time in range, $HbA_{1c}$, and average time from referral to the first CGM device placement. Follow-up continued with the CDCES or PharmD until patients met the study discharge criteria of $HbA_{1c}$ level ≤7%. Paired *t* tests with 1-sided *P* values were used to assess changes in glucose metrics from the initial to postintervention measurements. The McNemar test was used to determine the significance of change in patients meeting the goal of ≥70% time in the target range of 70-180 mg/dL.

**Results:** The CGM users (n=46) had a mean (SD) age of 62.39 (14.57) years, and 14/46 participants (30%) were female. The mean (SD) time in range increased by 28.06%, from 43.25% (33.41%) at baseline to 71.31% (25.49%) postintervention (*P*<.001), due to reduced hyperglycemia. The proportion of CGM users meeting the consensus target of the time in range ≥70% increased from 23.81% to 57.14% (*P*<.001). Postintervention $HbA_{1c}$ decreased by an average of 2.37%, from 9.68% (1.78%) to 7.31% (1.32%; *P*<.001).

**Conclusions:** The integration of CGM into primary care clinics to increase patient access is feasible and effective using a multidisciplinary approach.



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**KEYWORDS**

continuous glucose monitoring; diabetes education; primary care physicians; multidisciplinary team; type 2 diabetes

## Introduction

In the United States, 38.4 million people (11.6% of the US population) are living with diabetes [1]. As the eighth leading cause of death in the US [2], diabetes continues to be a significant health concern, with increased needs for large-scale, comprehensive strategies for diagnosis and medical management [3]. The 2025 American Diabetes Association Standards of Care in Diabetes [4] recommend quarterly hemoglobin $A_{1c}$ ($HbA_{1c}$) testing, in addition to blood glucose monitoring and continuous glucose monitoring (CGM) for people who are treated with any type of insulin therapy. CGM is a technology that has transformed modern diabetes care, elucidating daily glycemic trends in a way that neither $HbA_{1c}$ nor blood glucose monitoring testing can, by characterizing glycemic profiles in real time over the course of the day and glycemic trends over periods of time [5]. The use of CGM increases the time spent in the target range of 70 - 180 mg/dL (time in range) while reducing $HbA_{1c}$ [6]. This is achieved through coupling the proper interpretation of CGM results with medication and lifestyle adjustments recommended by health care providers [7]. As CGM is traditionally used by endocrinologists [8], the integration of CGM into patient care is often slowed by the shortage of endocrinologists [9]. In addition, many individuals living with diabetes are cared for by primary care physicians (PCPs) rather than endocrinologists [10]. It is thus of paramount importance to develop approaches that enable the integration of CGM into primary care, so that access to CGM is equitably afforded to all people living with diabetes and not just those under the care of an endocrinologist.

Integrating CGM into primary care holds a promising future but has some nuances that must be addressed to be successful [11]. First, patients must have access to CGM technology. Implementing a care team that is trained to interpret CGM is pivotal to any workflow that incorporates CGM into primary care and reduces therapeutic inertia [12]. Additionally, the care team, including PCPs, must be formally educated on how to interpret and use CGM data to optimize clinical care [13]. Although any PCP can prescribe CGM, they must understand how to interpret results and adjust the care plan based on the data provided by CGM, in order for the use of CGM to be clinically effective. In this pilot program, we addressed these concerns by implementing a systematic workflow with a multidisciplinary team including PCPs, a certified diabetes care and education specialist (CDCES), and clinical pharmacist (PharmD) who were all taught a systematic and stepwise approach to CGM interpretation by an endocrinologist. The CDCES and PharmD regularly communicated with the PCPs regarding clinical management. The goal of this study is to demonstrate feasibility of a systematic workflow that enables the integration of CGM into primary care while alleviating the burden on PCPs, and as a result improve diabetes management strategies in a primary care setting.

## Methods

### Ethical Considerations

Per our institutional policy, this met the definition of quality improvement and not human subjects research, and therefore, did not require institutional review board review or oversight. Participants had the ability to opt out and were not compensated. Data were deidentified.

### Participants

Eighteen PCPs as well as the participating CDCES and PharmD from two academic-affiliated community-based outpatient primary care clinics within multispecialty urban practices were offered a 1-hour recorded training module led by an endocrinologist regarding a systematic and stepwise approach to CGM interpretation, based on published methodology [14], followed by a live question and answer session with an endocrinologist. The CDCES was a registered nurse, and the PharmD operated under a collaborative practice agreement. PCPs who successfully completed training on CGM interpretation could refer eligible patients to the CDCES or PharmD, who then collaborated with the PCP to modify the diabetes treatment regimen. Patient inclusion criteria included type 2 diabetes mellitus, age ≥18 years, $HbA_{1c}$ ≥8%, or concern for hypoglycemia (Table 1). The exclusion criteria included the past use of CGM or an endocrinology visit in the past year. Three patients were included with $HbA_{1c}$ <8% due to concern for hypoglycemia.



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**Table .** Patient demographics.

| Category | Patients, n (%) |
|---|---|
| Age group, years | |
| 30 - 39 | 4 (9) |
| 40 - 49 | 7 (15) |
| 50 - 59 | 10 (22) |
| 60 - 69 | 9 (19) |
| >70 | 16 (35) |
| Sex | |
| Male | 32 (70) |
| Female | 14 (30) |
| Duration of disease | |
| <1 year | 6 (13) |
| 1 - 5 years | 13 (28) |
| 6 - 10 years | 17 (37) |
| >10 years | 10 (22) |

## Systematic Workflow

Before referral, the PCP provided basic CGM education to the patient and explained the clinical benefits of wearing a professional CGM device (Figure 1). The PCP explained the roles of the CDCES and PharmD to provide further CGM education and manage follow-up in collaboration with the PCP. The CDCES or PharmD met with the patient for 30 - 60 minutes to provide basic diabetes education on nutrition and lifestyle, discuss potential options for medication adjustment based on the PCP's recommendations, and the plan to monitor glycemic trends with CGM. A tailored plan was created to help patients effectively manage their diabetes through mutually agreed upon self-care behaviors such as healthy coping, healthy eating, physical activity, medication monitoring, problem solving, and risk reduction. Food logs were reviewed with patients to allow them to understand how food choices impact their glucose levels. The CDCES provided education on balanced and carbohydrate-consistent meals. Education on concepts were discussed, including decreased portion size, increasing nonstarchy vegetables, moderate carbohydrate portions, modifications of meal order (eating protein before carbohydrate when possible), and increasing intake of nutrient-dense food options. Patient-specific titration of medications including insulin, GLP-1 receptor agonists, and oral medications were completed based on the CGM data review. The CDCES and PharmD ensured patient understanding of glucose target ranges and indications to notify the team if glucose was above or below the target. The PharmD or CDCES provided injection training when necessary. Patients were educated on signs, symptoms, and treatment of hypoglycemic episodes. A professional CGM device was placed at the first or second visit with either the PharmD or CDCES. The CGM device used in this pilot was the Dexcom G6 Pro (San Diego, CA), with results blinded or unblinded to the patient depending on patient preference. All patients who participated in the study used the unblinded mode to view their glycemic data in real time, allowing adjustment and reinforcement in real time of the recommended lifestyle modifications. In addition to the CGM placement, the patient was asked to complete a food, activity, and medication log and to return it in ≥72 hours. At the return visit, the CGM device was removed, data were uploaded, and the patient was given a copy of the ambulatory glucose profile report. The following CGM parameters were recorded: time in range, time above range, time below range, mean glucose, glucose management indicator, and coefficient of variation. The CGM report was sent to the PCP, and therapeutic modifications were generated by the PCP in collaboration with the physician extender. The CDCES or PharmD discussed adjustments to the personalized care plan with the patient. Appropriate billing codes (Table 2) were entered by the CDCES or PharmD and PCP. If patients desired to do so, they were converted to personal CGM. If not, a second professional CGM device was placed by the CDCES or PharmD no sooner than 1 month after the initial professional CGM device was placed. A postintervention $HbA_{1c}$ measurement was obtained ≥3 months after the initial $HbA_{1c}$ measurement. Patients continued to meet with the CDCES or PharmD in between PCP appointments. Follow-up continued with the CDCES or PharmD until patients met the study discharge criteria of $HbA_{1c} \leq 7\%$.



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**Figure 1.** Systematic workflow for CGM implementation in a primary care practice. CDCES: certified diabetes care and education specialist; CGM: continuous glucose monitoring; $HbA_{1c}$: hemoglobin $A_{1c}$; PCP: primary care physician; PharmD: clinical pharmacist; T2DM: type 2 diabetes mellitus.



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**Table .** Billing codes.

| Code | Entered by | Purpose |
|---|---|---|
| 95250 | CDCES[a] or PharmD[b] | Placement, removal, upload of data |
| 95251 | PCP[c] | CGM[d] interpretation |
| 95249 | CDCES or PharmD | Training on personal CGM |
| G0108 | CDCES | Diabetes education |
| 99211 | PharmD | Pharmacist visit |

[a]CDCES: certified diabetes care and education specialist.

[b]PharmD: clinical pharmacist.

[c]PCP: primary care physician.

[d]CGM: continuous glucose monitoring.

### Statistical Analysis

The primary outcomes were time in range, $HbA_{1c}$, and average time from referral to first CGM device placement. Descriptive statistics including the mean (SD) and percentages were used to analyze the age and sex of participants, respectively. Paired 1-tailed *t* tests with 1-sided *P* values were used with 2-sided 95% CIs to determine the differences in initial and postintervention values for mean glucose, glucose management indicator, coefficient of variation, $HbA_{1c}$, time in range, time above range, and time below range. The McNemar test was used to determine the significance of change in patients meeting the goal of ≥70% time in the target range of 70 - 180 mg/dL, according to the International Consensus on Time in Range [15], from the initial compared to postintervention CGM use. A Kaplan–Meier curve was generated to analyze the time to discharge and determine the median number of days participants remaining in the study to meet discharge criteria. Analyses were conducted using JASP 0.18.3 (JASP Team; version 0183, Intel) and the criterion for statistical significance was $P<.05$.

## Results

### Participant Statistics

The mean (SD) age of CGM users (n=46) was 62.39 (14.57) years, and 14 out of 46 participants (30%) were female. A total of 3 individuals were lost to follow-up. The time in range increased significantly by 28.06%, from 43.25% (33.41%) at baseline to 71.31% (25.49%) postintervention ($P<.001$), due to reduced hyperglycemia (Table 3). There was a significant 42.14 mg/dL decrease in the average mean glucose, from 201.71 (51.98) mg/dL to 159.57 (30.68) mg/dL. The percentage of patients meeting the goal time in range (70 - 180 mg/dL) ≥70% [15] increased significantly from 23.81% to 57.14% ($P<.001$). There was no significant change in the time below range (mean 0.12%, SD 0.33% vs mean 0.43%, SD 0.94%; $P=.10$). Postintervention, $HbA_{1c}$ decreased by an average (SD) of 2.37% from 9.68% (1.78%) to 7.31% (1.32%; $P<.001$). Similarly, the glucose management indicator decreased an average (SD) of 0.90% from 8.00% (1.18%) to 7.10% (0.74%).

**Table .** Changes in standardized continuous glucose monitoring metrics.

| Parameters | Baseline mean (SD) | Follow-up mean (SD) | Postintervention change, mean (95% CI) | *P* value |
|---|---|---|---|---|
| Mean glucose (mg/dL) | 201.71 (51.98) | 159.57 (30.68) | −42.14 (−56.92 to −27.36) | <.001 |
| Glucose management indicator (%) | 8.00 (1.18) | 7.10 (0.74) | −0.90 (−1.20 to −0.59) | <.001 |
| Coefficient of variation (%) | 21.15 (6.79) | 21.65 (7.38) | 0.50 (−0.79 to 1.79) | .77 |
| Hemoglobin $A_{1c}$ (%) | 9.68 (1.78) | 7.31 (1.32) | −2.37 (−2.88 to −1.86) | <.001 |
| Percentage time in range (70 - 180 mg/dL) | 43.25 (33.41) | 71.31 (25.49) | 28.06 (18.48 to 37.64) | <.001 |
| Percentage time above range | 56.90 (33.74) | 28.57 (26.27) | −28.33 (−37.90 to −18.75) | <.001 |
| Percentage time below range | 0.12 (0.33) | 0.43 (0.94) | 0.31 (0.94 to 0.53) | .10 |

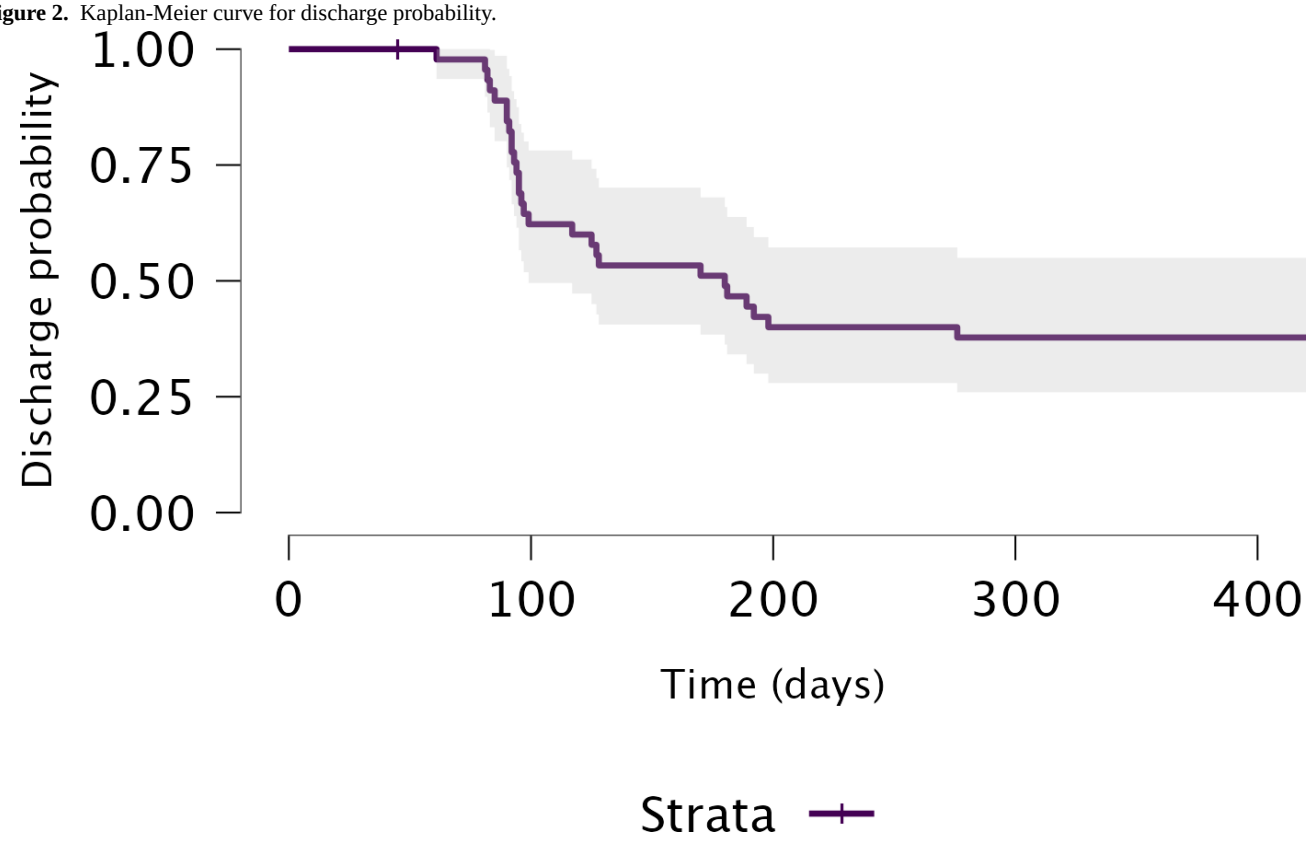
### Systematic Workflow Outcomes

The average time from referral to the first CGM device placement was 21.10 (IQR 6 - 24) days. The average time between the first and second CGM device placement or, if desired, conversion to personal CGM was 66.79 (IQR 43.50 - 78.75) days. Out of 46 people, 21 (46%) people converted to personal CGM devices. Out of 46 people, 28 (61%) patients met the goal of $HbA_{1c}$ ≤7% to be discharged from the pilot program. The median number of days a patient remained in the study from referral to discharge was 180 days (Figure 2).



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**Figure 2.** Kaplan-Meier curve for discharge probability.




## Discussion

### Principal Results

In this pilot study, we demonstrated the feasibility of implementation of a reproducible systematic workflow for the incorporation of CGM into primary care, guided by teaching regarding the systematic interpretation of CGM from endocrinology. Our multidisciplinary approach reduced the burden of implementing CGM into primary care, particularly reducing the workflow of the PCP by using physician extenders to oversee care. Consistent with other studies [7,16], the use of CGM significantly improved glycemic metrics in this pilot program, including an improved time in range and decreased $HbA_{1c}$ without an associated increase in hypoglycemia. The study showed that access to CGM via our systematic workflow occurred in less than 1 month, compared to an average wait time of 227 days [17] to be seen by endocrinology, suggesting that this type of systematic workflow could decrease time to uptake of diabetes technology. Our findings are strengthened by the fact that this systematic workflow, informed by a published stepwise approach to CGM interpretation, could be easily reproduced at other centers. The generalizability of our findings is limited by the fact that our study was a small pilot study limited to two clinical sites. Additionally, the systematic workflow used in the study is limited by the fact that not all primary care clinics have access to physician extenders such as a CDCES or a PharmD.

### Future Directions

Future directions include the expansion of the systematic workflow to additional sites with the goal of expanding generalizability of our findings. Future studies could evaluate whether the conversion of patients to personal CGM will facilitate the long-term use of CGM technology.

### Conclusions

CGM is a powerful tool in modern diabetes management, yet access to endocrinologists with specialized training in use of this technology is curtailed by the limited supply of endocrinologists [18]. PCPs, who see most patients with type 2 diabetes [19], are similarly oversaturated and may lack expertise in CGM interpretation [20]. However, the use of CGM in primary care is increasing as the shortage of endocrinologists continues to present challenges [18,20]. In order to optimize the clinical utility of CGM technology, the prescribing physician must be able to efficiently and accurately interpret CGM data. While educational materials regarding CGM use and CGM data interpretation targeted toward PCPs are expanding [21], this pilot program allowed PCPs to have a structured training experience with an endocrinologist with the goal of increasing familiarity and comfort with the integration of this technology into a primary care practice. Additionally, the program alleviated the burden on PCPs through multidisciplinary collaboration with physician extenders. This collaborative approach not only encourages more efficient diabetes management but also empowers patients with a better understanding of their personalized glycemic trends and the impact of therapeutic adjustments.



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## Acknowledgments

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## Conflicts of Interest

None declared.

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## Abbreviations

**CDCES:** certified diabetes care and education specialist
**CGM:** continuous glucose monitoring
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**PCP:** primary care physician
**PharmD:** clinical pharmacist

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# Insulin Injection Technique Education and Associated Knowledge Factors Among Physicians: Cross-Sectional Survey Study

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## Abstract

**Background:** Insulin therapy is crucial for managing type 2 diabetes mellitus, with its use steadily increasing in Indonesia and its effectiveness well established. However, prescribing insulin poses various challenges that can impact the effectiveness of insulin. Patient education is crucial for the successful implementation of insulin therapy. Proper insulin use remains insufficient in Indonesia.

**Objective:** This study aims to investigate physicians' knowledge and practice in providing education on insulin use to patients with type 2 diabetes mellitus in Indonesia.

**Methods:** This study recruited potential participants (all physicians in Indonesia) through the internet using a convenience sampling method. The participants were asked to fill out a questionnaire. The questionnaire had 32 questions divided into 4 sections: demographics and clinical practice, practice of insulin education, the Indonesian insulin injection technique guideline, and knowledge of insulin injection techniques. The instrument used in this study was developed based on the *Pedoman Teknik Menyuntik Insulin Indonesia*, which was adapted from the international consensus by the Forum for Injection Technique and Therapy Expert Recommendations. The survey lasted from February 2021 to March 2021. Data were analyzed using the Kruskal-Wallis tests.

**Results:** A total of 823 participants were included in the analysis. Out of 823 participants, 680 (82.6%) had given insulin education to patients at least once during the last 30 days. However, out of 823 participants, only 479 (58.2%) used specific guidelines in their practice, with only 280 (34.0%) aware of the Indonesian guidelines. Out of 823 participants, 815 (99.1%) agreed that insulin injection techniques would affect clinical results. The median score of knowledge about insulin injection techniques was 7 (IQR 2) among the study participants, indicating good knowledge. Profession was the only variable significantly associated with knowledge scores, with consultants in endocrinology, metabolism, and diabetes achieving the highest median scores, and other physicians the lowest ($P$<.001).

**Conclusions:** Most physicians in this study reported providing education to their patients. However, there was still a gap between the guidelines and the practice of insulin education, as indicated by the lack of awareness and a fair level of knowledge about the Indonesian guidelines.

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**KEYWORDS**

insulin injection techniques; insulin therapy; diabetes management; health services; patient education; insulin education; outpatient treatment; therapy expert; awareness



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## Introduction

### Background

According to the International Diabetes Federation, Indonesia was ranked as the seventh country with the largest number of adults with type 2 diabetes mellitus in 2019 [1]. Among the 10.7 million individuals with type 2 diabetes mellitus, only 0.7% to 53% achieved their treatment targets, depending on the parameter used (either glycated hemoglobin [$HbA_{1c}$] or fasting plasma glucose) [2-6]. Meanwhile, glycemic stability is needed to reduce the morbidity and mortality associated with type 2 diabetes mellitus [7]. To date, advances in knowledge and science have provided various approaches to achieving glycemic control. In addition to lifestyle modifications, oral and systemic antihyperglycemic agents help patients maintain their blood glucose levels. Insulin, one of the most used agents, is a crucial part of the treatment plan because it is recommended if oral antihyperglycemic agents fail to maintain glycemic stability. The Indonesian guideline on the management and prevention of type 2 diabetes mellitus recommends the use of insulin in cases of persisting $HbA_{1c}$ level ≥7.5% following the use of 1 or 2 oral antihyperglycemic agents, $HbA_{1c}$ level >9%, rapid weight loss, severe hyperglycemia with ketosis, hyperglycemic crisis, severe stress conditions (systemic infections, major surgery, acute myocardial infarct, and stroke), uncontrolled gestational diabetes mellitus, severe kidney or liver function disorders, contraindications and allergies of antihyperglycemic agents, and perioperative conditions as indicated by the clinicians. In Indonesia, insulin is mainly prescribed by internists. However, general practitioners (GPs) may also prescribe insulin for patients with type 2 diabetes mellitus, provided there are no complications [8-10].

With the growing availability and affordability of insulin, as well as improved access to health care services overall in the country, the use of insulin is expected to increase in the coming years [11]. Indonesia has adopted guidelines from the Forum for Injection Technique and Therapy Experts Recommendations for insulin injection techniques, titled *Pedoman Teknik Menyuntik Insulin Indonesia* (PTMII) 2017. The Indonesian guidelines provided recommendations for outpatient and inpatient settings, as well as special populations [12,13]. However, prescribing insulin to patients with type 2 diabetes mellitus is not without its challenges [14,15]. Previous studies showed that lack of access to care and medications, an inadequate health care system, and inadequate education have become obstacles to starting therapy [9,16,17].

In a preliminary cross-sectional study conducted at one of the tertiary hospitals in Jakarta, only 6.1% of 368 patients with type 2 diabetes mellitus received education while receiving outpatient treatment [18]. Similar findings have been reported in other countries. In the United States, type 2 diabetes mellitus education was reported to be received by only 52% of adult patients with type 2 diabetes mellitus. An Iranian qualitative study did not mention the exact number, but the health care professionals reported that most patients have a low level of type 2 diabetes mellitus education. These findings indicate that the patients' education regarding type 2 diabetes mellitus is generally low, although the United States and Iran had better economic status than Indonesia [19,20]. Indonesia's health care system, particularly its infrastructure, has become a significant barrier to type 2 diabetes mellitus management in general. A higher mortality rate is observed in government or military hospitals compared to private hospitals, indicating substantial disparities in health care infrastructures [21]. Education is another vital part because some Asians have skepticism toward Western therapy [9]. It is widely known that patients' awareness and self-management are keys to successful type 2 diabetes mellitus care, especially for those receiving insulin. Thus, patient education and empowerment are essential responsibilities of health care professionals [22,23].

### Objectives

Moreover, there is still a significant gap between insulin injection practice and current guidelines [24]. A study by Chen et al [9] reported that GPs in the Asia Pacific regions, including Indonesia, felt a lack of support and confidence in administering insulin. To improve the outcomes of type 2 diabetes mellitus education, it is vital to examine these issues. To our knowledge, previous studies in Indonesia mostly focused on patients' knowledge of type 2 diabetes mellitus and its impact on their self-management of diabetes. There is still a paucity of studies that have looked at physicians in general. Thus, this study aims to investigate the practice of insulin education and the knowledge of insulin injection techniques among physicians working in Indonesia.

## Methods

### Study Design

This is a cross-sectional web-based open survey in which data collection lasted for 2 weeks, from February 28, 2021, to March 14, 2021. The authors recruited potential participants (the target population consisted of all physicians in Indonesia) through convenience sampling by distributing invitations via WhatsApp groups for seminars, workshops, training sessions, university alumni networks, hospitals, and professional or academic societies. Our study used a targeted recruitment strategy to minimize concern regarding potential self-selection bias in web-based surveys. The survey link (Google Forms) was disseminated specifically to licensed physicians in Indonesia through professional networks, associations, and institutional mailing lists. Eligibility criteria were clearly stated in the informed consent section before accessing the questionnaire. Only physicians who prescribed insulin for patients with type 2 diabetes mellitus in the last 3 months were eligible to participate, as stated in the inclusion criteria. This inclusion criterion was determined to prevent the potential recall bias. Potential participants could then read a detailed explanation about the study on the first page of the survey, that is, study objectives, time needed to complete the questionnaire, and data anonymity, before they consented and proceeded to the questionnaire (Multimedia Appendix 1). In addition, the questionnaire included screening questions to verify eligibility before allowing completion. While anonymous and voluntary, this approach ensured that only qualified physicians participated in the study.



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The questionnaire was developed by the research team at the Fatmawati Central General Hospital Integrated Diabetes Service Center, comprising 2 endocrinologists, 2 internists, and 1 epidemiologist. The questionnaire had 32 questions divided into 4 sections. The first section consisted of 9 questions regarding respondent demographics and clinical practice, covering age, professional background, workplace, years of experience, number of patients with type 2 diabetes mellitus treated, and insulin prescriptions issued in the last 30 days. Section 2 included 7 questions about the practice of insulin education, exploring the frequency of patient education, use of specific guidelines, awareness of national guidelines, and perception of responsibility in delivering insulin injection education. Section 3 consisted of 6 questions based on the adaptation of the Indonesian insulin injection technique guideline, assessed through 20 true or false statements derived directly from the PTMII. Topics included injection site selection, needle length and gauge, skinfold techniques, rotation, timing of injection, and hygiene procedures. The final section consisted of 10 questions about the knowledge of insulin injection technique. The knowledge is considered good if the participant achieves a score of 7 to 8 and very good if the participant achieves a score of 9 to 10. The instrument used in this study was developed based on the PTMII, which was adapted from the international consensus by the Forum for Injection Technique and Therapy Expert Recommendations [12]. This guideline is also endorsed by the Indonesian Society of Endocrinology.

The questionnaire was delivered across 7 online pages: an informed consent page, a screening questions page, and 4 pages covering each section, and a completeness check. The completeness check was to ensure that the participants had completed the questionnaire. If there were questions that had not been filled out, the participants could not submit the data. On the last page, participants were also able to review and change their answers before submitting the results.

The questionnaire was assessed for usability, technical functionality, and reliability before its final version was distributed to the study participants. The questionnaire was pretested on 30 individuals not included in the main study (10 GPs, 8 internal medicine residents, 8 internists, and 4 endocrinologists), which yielded a Kuder-Richardson 20 reliability coefficient of 0.70. The final version of the questionnaire was then distributed among groups.

Data analysis was performed using SPSS (version 20; IBM Corp). The authors did not conduct data imputation or missing data analysis in this study. Numerical data were presented as mean (SD) or median (range), while categorical data were presented as frequency tables or bar graphs. The distribution of numerical data was examined using skewness, kurtosis, and the Kolmogorov-Smirnov test for normality. Bivariate analyses were performed using the Kruskal-Wallis tests.

### Ethical Considerations

Ethics approval for this study was obtained from the ethics committee of Fatmawati Central General Hospital on February 26, 2021 (10/KEP/II/2021). The study was conducted according to the Declaration of Helsinki. Informed consent was obtained before accessing the questionnaire. All data were kept confidential and protected in online files, which can only be accessed by the investigators. The participants did not receive any compensation in the study.

## Results

### Characteristics of Study Participants

A total of 929 physicians participated in the survey. During the preliminary analysis, the authors decided to exclude 100 participants with incomplete answers and 6 participants because of data inconsistency, that is, claiming to prescribe insulin in the last 1 month in 1 question, while there were no patients with type 2 diabetes mellitus under care during the last 30 days. These 6 participants were excluded to prevent the possibility of recall bias or fraud. Thus, 823 participants were included in the final analysis. Table 1 presents the study participants' characteristics.

Out of 823 participants, 362 (44.0%) belonged to the 30 - to 40 years age group, while more than 300 (36.5%) participants were internists. Out of 823 participants, 29 (3.5%) had type 2 diabetes mellitus, while 482 (58.6%) had one or more family members with type 2 diabetes mellitus. Out of 823 participants, 366 (44.5%) worked on Java. Out of 823 participants, 584 (70.9%) have worked less than 10 years in the field.

In Table 1, it is shown that out of 823 participants, 688 (83.6%) worked at hospitals and 290 (35.2%) worked at tertiary care hospitals. Out of 823 participants, 452 (54.9%) had provided diabetes mellitus education services. Out of 823 participants, 387 (47.0%) treated 10 to 50 patients with type 2 diabetes mellitus during the last 30 days and gave 1 to 10 insulin prescriptions to their patients.



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**Table .** Characteristics of study participants (N=823).

| Characteristics | Participants, n (%) |
|---|---|
| Age (years) | |
| <30 | 131 (15.9) |
| 30 - 40 | 362 (44) |
| 40 - 50 | 154 (18.7) |
| 50 - 60 | 119 (14.5) |
| >60 | 57 (6.9) |
| Professional specialty | |
| General practitioner | 206 (25) |
| Internal medicine resident | 210 (25.5) |
| Internist | 300 (36.5) |
| Consultant in endocrinology, metabolism, and diabetes | 72 (8.8) |
| Others | 35 (4.2) |
| Location in Indonesia (island) | |
| Java | 366 (44.5) |
| Sumatra | 128 (15.5) |
| Kalimantan | 46 (5.6) |
| Sulawesi | 208 (25.3) |
| Bali, NTB[a], and NTT[b] | 54 (6.6) |
| Papua | 21 (2.5) |
| Association with individuals with diabetes mellitus | |
| Oneself | 29 (3.5) |
| Friend | 132 (16) |
| Family | 482 (58.6) |
| None | 180 (21.9) |
| Working experience (years) | |
| 1 - 5 | 299 (36.3) |
| 6 - 10 | 285 (34.6) |
| 11 - 15 | 109 (13.2) |
| 16 - 20 | 49 (6) |
| >20 | 81 (9.9) |
| Practice setting | |
| Private primary clinic | 29 (3.5) |
| Private specialist clinic | 11 (1.3) |
| Private practice | 39 (4.8) |
| Primary health care center | 56 (6.8) |
| Primary care hospital | 35 (4.3) |
| Secondary care hospital (limited specialties) | 195 (23.7) |
| Secondary care hospital (limited subspecialties) | 168 (20.4) |
| Tertiary care hospital (top referral hospital) | 290 (35.2) |
| Availability of type 2 diabetes mellitus education service | |
| Yes | 452 (54.9) |
| No | 371 (45.1) |



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| Characteristics | Participants, n (%) |
|---|---|
| Number of patients with type 2 diabetes mellitus treated in the last 30 days | |
| 0 | 22 (2.7) |
| 1 - 10 | 235 (28.5) |
| 10 - 50 | 387 (47) |
| 50 - 100 | 102 (12.4) |
| >100 | 77 (9.4) |
| Number of insulin prescription in the last 30 days | |
| 0 | 100 (12.2) |
| 1 - 10 | 359 (43.6) |
| 10 - 50 | 255 (31) |
| >50 | 109 (13.2) |

[a]NTB: Nusa Tenggara Barat.

[b]NTT: Nusa Tenggara Timur.

## Insulin Education Practice Among Study Participants

Table 2 shows the practice of insulin education among study participants. Out of 823 participants, 680 (82.6%) claimed that they had given insulin education to patients, with 476 (57.8%) participants having given education 1 to 10 times during the last 30 days. Out of 823 participants, 514 (62.5%) said that physicians are responsible for educating patients. Only 4 (0.5%) out of 823 participants said that the responsibility should be given to other professionals. Out of 823 participants, 815 (99.0%) agreed that insulin injection techniques would affect clinical results, with 691 (84.0%) participants recommending the abdomen as the area for insulin injection. Out of 823 participants, 344 (41.8%) did not follow specific guidelines when educating their patients.

Out of 823 participants, 280 (34%) were aware of the Indonesian guidelines for insulin injection techniques. In total, 247 (88.2%) out of the 280 participants used the guideline in their practices. Awareness of the guideline mostly came from societies, such as the Study Society for Diabetes, the Society of Diabetes Educators, and the Society of Endocrinologists (169/280, 60.4%), as well as seminars or symposia (109/280, 38.9%). Out of the 280 participants, 2 (0.7%) learned about the guidelines during their residency.



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**Table .** Insulin education practice (N=823).

| Practice of insulin education | Participants, n (%) |
|---|---|
| Have you ever given insulin education to patients | |
| Never | 143 (17.4) |
| Ever | 680 (82.6) |
| Frequency of insulin education in the last 30 days | |
| 0 | 149 (18.1) |
| 1 - 10 | 476 (57.8) |
| 10 - 50 | 170 (20.7) |
| >50 | 28 (3.4) |
| Use of specific guideline | |
| Yes | 479 (58.2) |
| No | 344 (41.8) |
| Recommended area for injection | |
| Abdomen | 691 (84) |
| Upper arm | 101 (12.3) |
| Thigh | 25 (3.0) |
| All | 5 (0.6) |
| Others | 1 (0.1) |
| Which health care professional should be responsible for educating patients | |
| Pharmacists | 30 (3.6) |
| Physicians | 514 (62.5) |
| Diabetes educators | 229 (27.8) |
| Nurses | 46 (5.6) |
| Other professionals | 4 (0.5) |
| Insulin injection technique would affect clinical results | |
| Agree | 815 (99.0) |
| Disagree | 8 (1.0) |

## Awareness of Important Aspects of Insulin Injections Across Professions

Table 3 shows what participants thought was the most important aspect of the insulin pen injection. Out of 823 participants, 454 (55.2%) regarded the area of injection as the most important, whereas 51 (6.1%) regarded the needle gauge as the most vital aspect of insulin injection.

**Table .** Awareness of important aspects of insulin pen injection across professions (N=823).

| Professional specialty | Needle length, n (%) | Area of injection, n (%) | Disposable needle, n (%) | Skinfold pinching, n (%) | Size of needle gauge, n (%) | Subtotal, n (%) |
|---|---|---|---|---|---|---|
| General practitioner | 14 (18.4) | 106 (23.3) | 38 (30.9) | 36 (30.3) | 12 (23.5) | 206 (25.0) |
| Internal medicine resident | 16 (21.1) | 121 (26.7) | 28 (22.8) | 32 (26.9) | 13 (25.5) | 210 (25.5) |
| Internist | 29 (38.2) | 166 (36.6) | 45 (36.6) | 42 (35.3) | 18 (35.3) | 300 (36.5) |
| Consultant in endocrinology, metabolism, and diabetes | 7 (9.2) | 46 (10.1) | 9 (7.4) | 5 (4.2) | 5 (9.7) | 72 (8.8) |
| Others | 10 (13.1) | 15 (3.3) | 3 (2.4) | 4 (3.4) | 3 (5.9) | 35 (4.2) |



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### Knowledge About Insulin Injection Technique

Table 4 lists the true or false questions on knowledge about insulin injection techniques. Questions in which the majority of participants (737/823, 89.6%) answered correctly were "Insulin absorption is influenced by the correct choice of injection area" and "The angle of insulin injection is usually perpendicular to the area of injection." Meanwhile, the questions with the most incorrect answers were "Before injecting insulin at home, patients must always disinfect with alcohol" (244/823, 29.6%) and "The fastest-absorbing location for insulin injection is the abdominal area" (256/823, 30.6%).

**Table .** Questions regarding knowledge about insulin injection techniques (N=823).

| Questions | True or false | Correct answer, n (%) |
|---|---|---|
| Insulin absorption is influenced by the correct choice of injection area | True | 737 (89.6) |
| The rate of insulin absorption is constant regardless of the injection area | False | 640 (77.8) |
| Injection time of rapid-acting insulin analogs (Aspart, Glulisin, and Lispro) is the same as that of short-acting human insulin (Actrapid and Humulin-R) | False | 594 (72.2) |
| Injecting insulin on intramuscular tissue may relieve the pain better than subcutaneous tissue | False | 577 (70.1) |
| Injecting rapid-acting insulin analogs (Aspart, Glulisine, and Lispro) on thigh areas is good for blood glucose control | False | 475 (57.7) |
| Removing the needle within less than 10 seconds after injecting insulin can reduce the amount of insulin injected | True | 672 (81.6) |
| The fastest-absorbing location for insulin injection is the abdominal area | False | 252 (30.6) |
| The best location for insulin injection is areas with lipohypertrophy | False | 605 (73.5) |
| The angle of insulin injection is usually perpendicular to the area of injection | True | 737 (89.6) |
| Before injecting insulin at home, patients must always disinfect with alcohol | False | 244 (29.6) |

Regarding the participants' scores on knowledge about insulin injection techniques, many participants obtained a total score of 6 and 8, that is, 22% (181/823) and 21% (173/823), respectively. Out of 823 participants, the lowest score of 2 was achieved by 6 (0.7%), while 22 (2.7%) attained a perfect score of 10. The median score was 7 (IQR 2), indicating good knowledge.

Table 5 shows the median knowledge scores about insulin across demographic characteristics. Professional specialty was the only variable significantly associated with knowledge scores, with consultants in endocrinology, metabolism, and diabetes achieving the highest median scores, and other physicians and GPs the lowest.



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**Table .** Knowledge scores across demographic characteristics (N=823).

| Demographic characteristics | Score, median (range) | *P* value |
|---|---|---|
| Age (y) | | .05 |
| <30 | 6 (3-9) | |
| 30 - 40 | 7 (2-10) | |
| 40 - 50 | 7 (2-10) | |
| 50 - 60 | 7 (2-10) | |
| >60 | 7 (2-10) | |
| Professional specialty | | <.001 |
| General practitioner | 6 (2-10) | |
| Internal medicine resident | 7 (3-10) | |
| Internist | 7 (2-10) | |
| Consultant in endocrinology, metabolism, and diabetes | 8 (5-10) | |
| Others | 6 (2-10) | |
| Location in Indonesia (island) | | .12 |
| Java | 7 (2-10) | |
| Sumatra | 7 (2-9) | |
| Kalimantan | 7 (3-10) | |
| Sulawesi | 7 (3-10) | |
| Bali, NTB[a], and NTT[b] | 7 (3-10) | |
| Papua | 6 (3-10) | |
| Close association with individuals with diabetes mellitus | | .94 |
| Oneself | 7 (4-9) | |
| Friend | 7 (2-10) | |
| Family | 7 (2-10) | |
| None | 7 (3-10) | |
| Working experience (y) | | .28 |
| 1 - 5 | 7 (2-10) | |
| 6 - 10 | 7 (3-10) | |
| 11 - 15 | 7 (2-10) | |
| 16 - 20 | 6 (3-10) | |
| >20 | 6 (2-10) | |

[a]NTB: Nusa Tenggara Barat.

[b]NTT: Nusa Tenggara Timur.

## Discussion

### Principal Findings

This study examined the practice of insulin education and knowledge about insulin injection techniques among physicians working in Indonesia. To the authors' best knowledge, the most recent similar study was conducted by a pharmaceutical company in 2012 [6]. Given the numerous challenges surrounding the management of type 2 diabetes mellitus in Indonesia, this study aimed to address the research gap and build on the evidence to improve outcomes for type 2 diabetes mellitus care. More than half of the participants were aged ≤40 years. This was supported by the fact that the majority of them were GPs, internal medicine residents, or internists.

It seemed that participants in this study regarded insulin education as important because almost all of them had given insulin education to patients in the last 30 days. This was supported by another finding that 99% of them agreed that the insulin injection technique would affect clinical results, and more than 80% of the participants thought that the responsibility for patient education lies with physicians and diabetes educators. However, more than 40% of the participants did not use specific



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guidelines in their insulin education practices. This may be due to the finding that 66.98% of the participants were not aware of the Indonesian guideline for insulin injection techniques (PTMII). Participants who were aware of the guidelines mainly received the information through studies or professional societies and seminars or symposia. This finding underscores the importance of further training or education and networking through societies to update knowledge and practices in type 2 diabetes mellitus management. Participants who were not aware of the guideline further stated that they would appreciate it if the study or professional societies could provide webinars or sessions to disseminate the guideline. The distribution of guidelines through social media, such as WhatsApp groups, was also encouraged by many participants.

While participants in this study were generally aware of the importance of the area of insulin injection, knowledge of needle length and size of needle gauge remained low, as only a small proportion of the participants (<10%) regarded them as the most important aspects of insulin injection. The results of this study also showed that the majority of the participants had a good knowledge of insulin injection techniques from the Indonesian guideline PTMII, as evidenced by a median score of 7 (IQR 2). In this study, age, workplace, personal or family history of diabetes mellitus, and years of working experience were not associated with knowledge scores. These findings are notable, as they differ from those reported in other studies.

## Comparison With Prior Work

Examining the geographical distribution of the participants, the pattern matched that of the general population in Indonesia, with a majority concentrated on the island of Java [24]. Thus, it can be assumed that the participants in this study were representative of the population of physicians in Indonesia. While no similar study assessed the compliance of physicians toward insulin injection guidelines, a review emphasizes that there are always barriers between physicians and practice guidelines. These barriers include established personal routines, the complexity of skills required, and physician resistance [14].

Although needle length does not directly affect glycemic control, it is important for correct insulin deposition (subcutaneous vs intramuscular) because there is a greater risk of intramuscular injections with longer needles [25]. Moreover, longer and larger needles would cause more pain and, therefore, make patients uncomfortable during injection [26]. The use of disposable needles must also be encouraged to reduce local complications, such as lipohypertrophy [27,28].

Physicians in Iran also demonstrated fair knowledge of insulin injection techniques (66.29% correct answers), which was higher than in Egypt (where 57% lacked knowledge) but lower than in Singapore (median score 8) [29-31]. However, these findings are not directly comparable due to differences in the knowledge content tested, scoring methods, or cutoff points for categories (poor, fair, and good), and medical curricula across countries. Nonetheless, there is a need to improve Indonesian physicians' knowledge about injection site selection and disinfection procedures, as most participants answered these questions incorrectly.

One finding that was consistent with other studies was that consultants tended to score better than junior physicians [29,31-33]. This may not be surprising as consultants, in general, gain deeper knowledge through further formal training. However, it also indicates that physicians in Indonesia, especially GPs, still need to participate in more continuing medical education programs to increase their knowledge about type 2 diabetes mellitus care, particularly regarding insulin injection techniques.

Age was found to be associated with knowledge among physicians in Iran and Egypt; however, this may be caused by the categorization of age into 2 groups only, with a cutoff age of 40 and 32 years, respectively [29,31]. Meanwhile, in this study, there was no strong association between age and knowledge when age was categorized into 5 groups. Another interesting finding in this study was that only physicians aged <30 years had different ranges of scores; that is, they had lower median scores, better minimum scores, and lower maximum scores. This could be due to physicians aged <30 years being generally not yet in the fellowship (consultant) stage of training and thus lacking the knowledge needed to score well. This finding could also explain why there would be an association between age and knowledge when the cutoff point is set around that number.

Studies in Iran and Egypt found an association between workplace location and knowledge, which differs from the findings of this study [29,31]. This may be due to the different operational definitions used in each study. In this study, working location was defined by the main islands where the physicians practiced, while the Egypt study categorized it as rural versus urban and the Iran study considered whether it was a teaching hospital [29,31]. Looking at the results of this study alone, it is rather commendable that there was no significant difference in knowledge between physicians working in Java and outside Java, considering the common assumption that most of the country's development and growth are concentrated in Java.

Personal and family history of diabetes mellitus was not found to be associated with knowledge in this study, which was in contrast to the studies conducted in Iran and Egypt [29,31]. However, this may be because those factors were combined into a single variable in this study, whereas they were treated as separate variables in the other studies. Working experience was also not associated with knowledge, consistent with the study in Egypt, where years of experience influenced physicians' attitudes in practice but not their knowledge [29].

## Strengths and Limitations

A key strength of this study is that it is one of the few to investigate the knowledge and practice of insulin education among physicians in Indonesia. Thus, the results of this study could provide the basis for future research on similar topics. However, this study has several limitations. First, due to the amount of missing data, the study results must be interpreted accordingly. Second, due to the open and anonymous nature of the online survey and wide dissemination strategy, the exact number of invitations sent could not be determined; therefore, a formal response rate could not be calculated. We acknowledge this as a limitation, common to large-scale online surveys. Due



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to the anonymous nature of the survey, we were unable to identify or contact the participants directly. Hence, we tried to reach as many potential participants as possible to avoid a low sample size. Third, we also acknowledge that the absence of technical constraints on duplicate submissions is a limitation of this convenience sampling approach, common in anonymous online surveys. Due to the anonymous nature of the survey, we could not identify the participants. Hence, future studies should develop strategies to avoid this, such as filtering by IP address or restricting each email address to a single response. Fourth, there might be a recall bias due to the nature of this research. However, we tried to limit the study participants who had been prescribed insulin in the past 3 months and excluded those with inconsistent answers to avoid this. Fifth, as the questionnaire was newly developed, there may be a question about its validity. Usability, technical functionality, and reliability tests were conducted before the final version was distributed to the study participants. This was to ensure its validity and reliability. Sixth, there might be a selection bias due to the eligibility for prescribing insulin. However, we ensured that we reached all different subject groups for this study, including GPs; internists; consultants in endocrinology, metabolism, and diabetes; and other physicians.

### Future Directions

Future research should be conducted to explore the barriers and facilitators to diabetes mellitus or insulin education from the perspectives of both patients and physicians. In response to the demands from participants, it would be helpful if the study and professional societies in Indonesia could increase the promotion and dissemination of the guideline by delivering webinars or sharing the guideline through social media. Seminars should focus on aspects of insulin injection techniques that Indonesian physicians find difficult, such as the areas of injection and sterilization procedures, as well as aspects that physicians were least aware of, that is, needle length and size of needle gauge. Finally, physicians in Indonesia, especially GPs, would benefit from participating in more continuing medical education programs related to type 2 diabetes mellitus care and insulin injection techniques to improve patient outcomes.

### Conclusions

In conclusion, most physicians in this study stated that they had provided education to their patients in the last 30 days. Moreover, there was still a gap between the guidelines and practice of insulin education, as indicated by the lack of awareness and a fair level of knowledge about the Indonesian insulin injection technique guideline.

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## Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

## Authors' Contributions

Conceptualization: IAMK, NM, AAAW, JN, ME, MIM
Data curation: IAMK, NM
Formal analysis: ME, MIM
Funding acquisition: MIM
Investigation: IAMK, NM, AAAW, JN, ME, MIM
Methodology: IAMK, NM, AAAW, JN, ME, MIM
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Validation: AAAW, JN, ME, MIM
Visualization: AAAW, JN, ME, MIM
Writing – original draft: IAMK, MIM
Writing – review & editing: IAMK, MIM

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire.
[PDF File, 190 KB - diabetes_v10i1e65359_app1.pdf ]



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Checklist 1
CHERRIES checklist.
[PDF File, 56 KB - diabetes_v10i1e65359_app2.pdf ]

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## Abbreviations

**GP:** general practitioner
**$HbA_{1c}$:** glycated hemoglobin
**PTMII:** *Pedoman Teknik Menyuntik Insulin Indonesia*


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# DigiBete, a Novel Chatbot to Support Transition to Adult Care of Young People/Young Adults With Type 1 Diabetes Mellitus: Outcomes From a Prospective, Multimethod, Nonrandomized Feasibility and Acceptability Study

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## Abstract

**Background:** Transition to adult health care for young people and young adults (YP/YA) with type 1 diabetes mellitus (T1DM) starts around 11 years of age, but transition services may not meet their needs. A combination of self-management support digital health technologies exists, but no supportive chatbots with components to help YP/YA with T1DM were identified.

**Objective:** The aims of this study were to (1) evaluate the novel DigiBete Chatbot, the first user-led, developmentally appropriate, clinically approved transition chatbot for YP/YA with T1DM from four English diabetes services and (2) assess the feasibility of a future trial of the chatbot.

**Methods:** In a prospective, multimethod, nonrandomized feasibility and acceptability study in the UK National Health Service, YP/YA with T1DM from 4 hospital diabetes clinics (2 pretransition and 2 posttransition) were enrolled in a 6-week study to test the DigiBete Chatbot. During the study, YP/YA completed web-based, validated, and standardized questionnaires at baseline, 2 weeks, and 6 weeks to evaluate quality of life and anxiety and depression, along with chatbot usability and acceptability. Qualitative interviews involving YP/YA, parents, and health care professionals explored their views on the chatbot. Data were analyzed using descriptive statistics and framework analysis.

**Results:** Eighteen YP/YA were enrolled. Qualitative interviews were conducted with 4 parents, 24 health care professionals, and 12 YP/YA. Questionnaire outputs and the emergent qualitative themes (living with T1DM, using the chatbot, and refining the chatbot) indicated that the measures are feasible to use and the chatbot is acceptable and functional. In addition, responses indicated that, with refinements that incorporate the feasibility results, the chatbot could beneficially support YP/YA during transition. Users scored the chatbot as “good” to “excellent” for being engaging, informative, and aesthetically pleasing, and they stated that they would use it again. The results suggest that, with some adaptations based on user feedback, the chatbot was feasible and acceptable among the YP/YA who enjoyed using it. Our reactive conversational agent offers content (messaging and additional multimedia resources) that is relevant for the target population and clinically approved. The DigiBete Chatbot addresses the identified lack of personalized and supported self-management tools available for 11 - 24 year olds with T1DM and other chronic conditions.

**Conclusions:** These results warrant chatbot refinement and further investigation in a full trial to augment it prior to its wider clinical use. Our research design and methodology could also be transferred to using chatbots for other long-term conditions. On



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the premise of this feasibility study, the plan is to rebuild the DigiBete Chatbot to meet identified user needs and preferences and progress to a national cohort study to assess the usability, feasibility, and acceptability of a modified chatbot, with a view to proceeding to rollout for national and international use on the established DigiBete platform.

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**KEYWORDS**

digital health; chatbot; homecare; young people and young adults; feasibility study; multimethods; young people; young adults

## Introduction

### Background

Type 1 diabetes mellitus (T1DM) is a serious chronic condition that affects 1 in 700 children and young people worldwide, with around 29,000 young people in the United Kingdom living with T1DM. Diabetes care is a priority in the UK National Health Service (NHS) Long Term Plan, reinforcing the need to improve the quality of care for children and young people with T1DM through bespoke quality improvement [1,2].

### Self-Management Problems in Young People and Young Adults With T1DM as They Transition

Transition (the purposeful and planned process of supporting young people and young adults [YP/YA] with T1DM to move from child to adult services) is poorly developed in many regions. There is a major gap in knowledge about transition readiness among YP/YA with chronic conditions.

YP/YA with T1DM are expected to learn about and perform multiple clinical self-management tasks while integrating self-management with daily activities. One-third of YP with T1DM show evidence of early diabetes-related complications by the time of transition, and they have a 2.5-fold elevated risk of poor glycemic control by the time of their first adult health service visit. Blood glucose control substantially declines among those aged 18-30 years, with only 14% meeting the required level. Critically, poorly controlled T1DM can cause acute life-threatening complications such as diabetic ketoacidosis and disabling chronic complications, including both microvascular and macrovascular disease [3].

Following transition, YA can experience significant deterioration in diabetes control, increased anxiety levels, and reduced quality of life [4-9], all of which challenge the YP/YA and their families and put a burden on the NHS [10].

### Inadequacy of Existing Support Measures

The highest rates of diabetic ketoacidosis are seen in individuals 15-20 years of age [11] (the age when they are transitioning between NHS pediatric and adult services); this is suggestive of transition support measures not reaching all YP/YA. During standard care, when YP/YA are transitioning, they typically receive support from both pediatric and adult teams to ease the process. However, interim support is often inconsistent, and clear information about the transition remains difficult to access. Clear, accessible resources could improve this process, helping YP/YA navigate the process with confidence and ensuring they receive the support they need at every stage.

A systematic review in 2022 demonstrated that adequate support for YP throughout transition results in improved glycemic control, improved clinic attendance, fewer episodes of hospitalization, lower rates of hypoglycaemia, better self-management, and increased knowledge of T1DM [12]. A more recent scoping review [13] found that a combination of self-management support digital health technologies (DHTs) exists, although no supportive chatbots with components to help YP/YA with T1DM were identified [13].

### Patient and Public Involvement in This Study

Patient and public involvement was central to our study design and delivery. Members of the preexisting DigiBete Expert User Group (EUG) who are YP/YA with T1DM had informed development of the DigiBete platform and app and advised on this study. For example, EUG members guided development of recruitment materials and processes; the content and design of initial chatbot resources; and dissemination. To avoid any conflict of interest, EUG members were not eligible to participate in this study.

The purpose of this paper is to build on our recent scoping review [13] and present the results of a feasibility study that addressed two objectives:

1. To evaluate DigiBete Chatbot, the first user-led, developmentally and age-appropriate, clinically approved transition chatbot for 11- to 24-year-olds with T1DM including underserved, seldom heard, and vulnerable groups.
2. To assess the feasibility and acceptability of a future study of the DigiBete Chatbot in terms of recruitment, retention, data collection procedures, and performance of study measures in this population.

## Methods

### Overview

We conducted a prospective, multimethod, nonrandomized feasibility and acceptability study to enable YP/YA, health care professionals (HCPs), and parents to access the DigiBete Chatbot and associated online materials and to allow researchers to collect feedback from participants through validated questionnaires and qualitative interviews. As this was a feasibility study, a power calculation was not required, and significance was not calculated because of the small sample size [14].

### The DigiBete Chatbot Intervention

This feasibility study forms part of a phased approach to the development and evaluation of the novel DigiBete Chatbot, a



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complex intervention [15] for YP/YA with T1DM. DigiBete, an existing video platform and app, provides support for diabetes management in YP/YA. It was founded and is run by families living with T1DM, and it is a social enterprise funded by NHS England, with all content clinically approved [16].

The DigiBete Chatbot prototype was co-designed and developed in collaboration with YP/YA, parents, and HCPs in 4 NHS hospital diabetes services in England (2 pretransition and 2 posttransition). All content was quality assured by a consultant pediatrician who specializes in type 1 diabetes in YP/YA.

Based on the UK National Institute for Health and Care Excellence Evidence Standards Framework for DHTs, the DigiBete Chatbot is set at National Institute for Health and Care Excellence DHT tier 2 (level 1) and tier 3a (level 2) requirements. To our knowledge, this is the first chatbot to have been rigorously co-designed and evaluated with YP/YA with T1DM. The chatbot content is influenced by self-management theory, the COM-B (capability, opportunity, motivation-behavior change) approach, and the associated behavior change wheel [9,10,17-19]. The DigiBete Chatbot supports users through reactive messaging, providing links to sources of information on T1DM, and including content for peers and HCPs. The chatbot addresses a range of topics that acknowledge barriers and enablers to self-management, offering guidance on how to navigate life while developing physically and emotionally and becoming increasingly independent.

The chatbot used response logic to interpret the user input and generate suitable responses. This involved using natural language processing so that the chatbot could understand the user's intent and provide the relevant information or resources to satisfy the user's queries. In the initial stages of the chatbot build, intents (n=142), which are purposes or goals that are expressed in a user's input, and entities (n=75), which are terms or objects that are relevant to a user's intent and provide context for that intent, as well as questions, which were phrased in a variety of ways, were loaded into the chatbot. When the users inputted a query, based on the question, intent, and entities used, the chatbot would then choose the correct dialog flow, of which 136 were created, and surface the requested answer, which could be in the form of text, film, or a downloadable PDF.

The safety of the users is always a priority, and the language used by the chatbot was of equal importance. With safety in mind, the chatbot was preloaded with clinically approved, pedestrianized responses to questions and queries, which were necessary to ensure the user's safety while using the chatbot. The scope of the chatbot was limited to the resources on the website only [16], to ensure the clinical accuracy and safety of the resources that the chatbot would surface for the user.

Initially, the EUG was tasked with inputting as many questions as they could think of to do with transitioning to adult services, and this served as the baseline for the information that the chatbot would need to present when queried. This immediately highlighted gaps in the resources provided by DigiBete in the transition age category, which resulted in a development sprint to create and adapt resources that could adequately fill the resource gaps. As more testing was carried out with the EUG and HCPs, the need for more content became greater and so more tailored content was created and adapted to cater to these information needs. A flowchart in Multimedia Appendix 1 details user interaction paths, providing an overview of this aspect of the user experience. A more detailed explanation of the DigiBete Chatbot initial development and refinement processes will be reported in a forthcoming publication.

## Recruitment

In the 4 participating NHS diabetes services (2 pediatric and 2 adult centers), those eligible to participate were YP/YA aged 11 - 24 years, parents of participating YP, and all HCPs in the clinical multidisciplinary teams. Clinical teams, under the supervision of local principal investigators, used patient databases to identify eligible patients and requested permission to refer them to the researcher. Thrive by Design (a collective of specialist service designers and researchers who ensure inclusivity in NHS research by engaging underserved, seldom heard, and vulnerable groups) and the YP/YA from the EUG also supported the development of recruitment and data collection processes. In addition, they guided the development and design of initial chatbot resources and dissemination. YPs and YAs were initially approached by HCPs at the site where they were receiving treatment. The HCPs collected the contact details of those who expressed interest in the study. Researchers then followed up with these individuals to provide more detailed information and to obtain their consent and assent.

Researchers emailed the developmentally and age-appropriate study invitation letter and participant information sheet to interested participants and, where appropriate, their parents. These documents explained the purpose of the study, who the investigator was, the timing of the web-based survey, that they would be invited to participate in a semistructured interview at the end of their 6-week chatbot trial, and which data were stored and where and for how long. Where interest was indicated by individuals approached, the researcher then arranged to speak to them via teleconference or by telephone to answer queries and explain the process for providing digital (adult) informed consent (or assent for young people <16 years).

The sample was recruited using a combination of purposive, theoretical, and convenience sampling; we aimed for a total sample of 32 - 40 YP/YA across the 4 study sites, but due to pragmatic constraints, including the prevailing COVID-19 pandemic and associated restrictions, a sample of 18 YP/YA (12 female) was recruited.

By incorporating multiple urban locations with distinct demographic profiles and involving local health care staff in recruitment, the strategy increased the likelihood of obtaining a diverse and representative sample of YPs and YAs across ethnic, socioeconomic, and geographic lines, thereby enhancing the credibility and inclusiveness of the study findings.

Recruitment commenced May 2023 and follow-up ended February 2024.

Before accessing the DigiBete Chatbot, participating YP/YA were contacted by a DigiBete developer (who was not a member of the evaluation team and who monitored DigiBete Chatbot usage) to explain the process of accessing and navigating the chatbot. Participating YP/YA received password-protected



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access to the chatbot for 6 weeks to allow them to ask questions, and they were encouraged to use it as often as they wished. To enable this, at the point of consent/assent, the researchers collected participants' demographic details, including the email address that the YP/YA had previously provided when they initially registered for access to the DigiBete web platform and app. From their secure NHS email addresses, the researchers then forwarded the YP/YAs' emails to the DigiBete team, who confirmed that the email address was consistent with the one held on record by DigiBete and arranged for the participant to have special access to the chatbot that appeared on their own DigiBete app for the duration of the study.

## Data Collection

### *Measures*

At baseline, we collected demographic data from the YP/YA (age, sex, postal code, and ethnicity). The following measures were administered electronically to the participating YP/YA: the user version of the Mobile Application Rating Scale (uMARS) [20], the Hospital Anxiety and Depression Scale (HADS) [21], the 36-Item Short Form Survey Instrument (SF-36) [22], and a modified version of the System Usability Scale (SUS) [23-25]. The measures were administered at 3 time points: before using the chatbot (time zero, T0), 2 weeks later (time 1, T1), and 6 weeks after first using the chatbot (time 2, T2). All questionnaires were imported into Qualtrics$^{XM}$ software, and a secure database was created for data collection and analysis. The usability and technical functionality of the electronic survey had been tested by YP/YA advisors before fielding the questionnaires. The researchers allocated each study participant with a unique, anonymized study number/identifier and YP/YA participants were reminded of this at every communication during the chatbot evaluation. YP/YA also received email messages linking them to the questionnaire database; they accessed the database via their unique identifier, then entered the relevant study time point (T0, T1, T2) and received access to the correct questionnaires for that time point. Noncompleters received 1 reminder after 2 weeks. Multimedia Appendix 2 shows details about the measures used.

### *Qualitative Interviews and Focus Groups*

After T2, YP/YA were invited to participate in a qualitative interview to ascertain their views on the DigiBete Chatbot's design, content, and usability. In addition, parents of participating YP were invited to participate in qualitative interviews to explore their views on the chatbot's potential to enable their child to become autonomous in self-management, and focus groups were conducted with HCPs to determine their views on the chatbot's content and their role in supporting the chatbot if it was later deemed suitable to became part of standard care delivery. During interviews/focus groups with parents and HCPs, the chatbot was demonstrated by the researchers, and participants were invited to suggest questions (which the researcher typed in) and discuss the answers generated. Interviews and focus groups were conducted via teleconference or in person in a quiet room in the hospital by researchers trained in these methods.

## Data Analysis

### *Quantitative Analysis*

Data were analyzed using Qualtrics$^{XM}$ software. Scores on the outcome measures were calculated and missing values on items were handled according to the methods prescribed by the developers. Consistent with the nature of the study and the small sample size, our postintervention analyses should be interpreted conservatively.

### *Qualitative Analysis*

Qualitative data were analyzed using the Framework technique supported by NVivo [26], a recognized, systematic method for handling large amounts of qualitative data. Framework sits in a thematic methodology that is systematic, thorough, and grounded in the data but also flexible and enables easy retrieval of data to show others, thereby providing a clear audit trail. A rigorous, matrix-based method, it allows movement back and forth between levels of abstraction without losing the meaning of the "raw" data. Key quotations were labeled and identified for later retrieval and reporting. In addition, Framework allows both between- and within-case analysis and involves a process of familiarization with the data, identification of themes, indexing, charting, mapping, and interpretation. In line with the inductive nature of qualitative research, themes derived during qualitative data collection and analysis supplemented interview topics with new lines of inquiry [26]. Interview recordings were transcribed by a university-approved transcriber. A sample of anonymized transcripts was independently reviewed by 2 researchers and then discussed until a consensus was reached to assess interrater reliability and strengthen trustworthiness.

## Ethical Considerations

The NHS Research Ethics Committee, the Integrated Research Application System (IRAS reference 292053), the Lead NHS Trust Research and Innovation Department, and the Ethics Committee at the lead/corresponding author's university approved this study. In line with Research Ethics Committee approval, we did not ask those who declined or dropped out for a reason. Data were collected and retained in accordance with the Data Protection Act 2018. Consent/assent forms and investigator site files were electronic. All data were managed in accordance with the data management plan of the lead/corresponding author's university. Encrypted audio recordings and transcripts of qualitative interviews/focus groups and questionnaire data have been stored in password-protected files on a university server and will be retained for 5 years. The raw data were only shared with researchers working on the relevant work packages. Electronic data were transferred using encrypted devices according to standard university data-protection policies. No personally identifiable information was used in the reporting. After study completion, participants received a £25 (USD 34) online shopping voucher to thank them for their time.



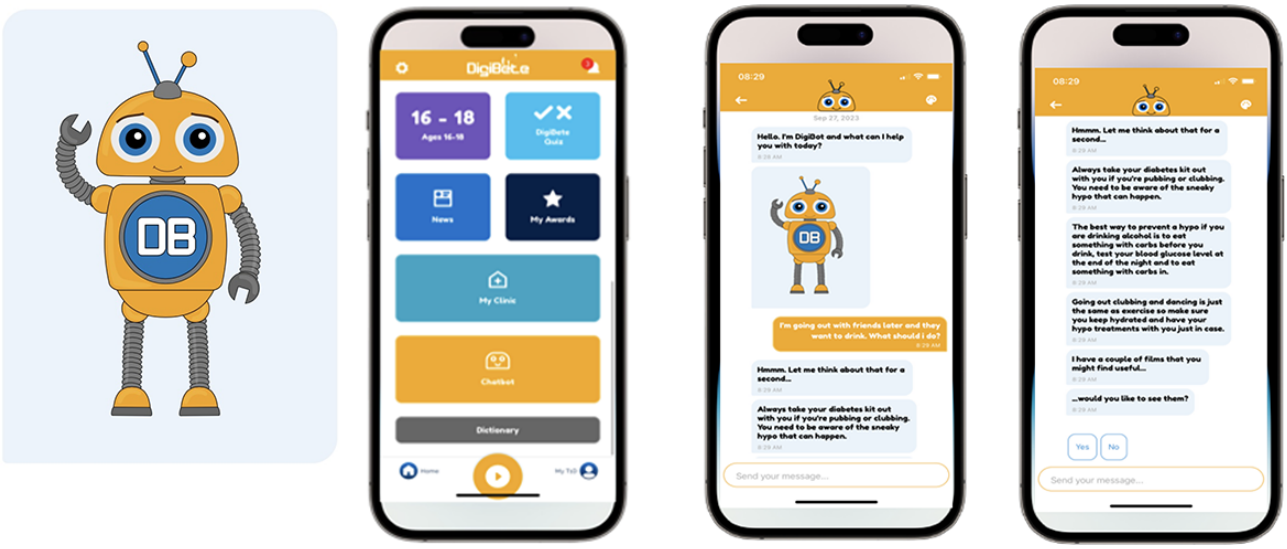
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## Results

### Overview

Figure 1 illustrates screenshot examples from the chatbot as viewed by participants.

**Figure 1.** Screenshots of the DigiBete Chatbot used in the feasibility study. Chatbot image as viewed by users.




Our a priori feasibility criteria rates were partially met. We aimed to recruit 32 - 40 YP/YA but due to pragmatic constraints during the COVID-19 pandemic, we recruited only eighteen 11 - to 24-year-olds with T1DM (12 female; 16 British, 2 White European). Participants' engagement with study procedures varied. The mean age was 17 (SD 4.52) years. The mean number of years since diagnosis was 7.94 (SD 5.57). Three of those who consented/assented did not participate; one completed all questionnaires but not the interview, and another two did not complete questionnaires at the final time point (T2) and did not participate in the interview. Overall, 15 (72% of the participants) fully completed the feasibility study, 11% (n=2) partially completed it, and 17% (n=3) did not engage. Of the 15 who completed measures and interviews, the mean age was 17 (SD 4.52) years, the median age was 16 years, and the mean number of years since diagnosis was 7.94.

Twenty-five HCPs and 4 parents participated in individual or group interviews (Multimedia Appendix 3 for more details about participant characteristics). Semistructured interviews (n=16) were conducted online and focus groups (n=4) were conducted online or in person in a quiet room at the hospital, at times convenient for the participants, by experienced qualitative researchers who facilitated discussions based on topic guides. Discussions were digitally recorded, and transcripts were anonymized and coded by the researchers.

### Quantitative Results

Table 1 shows the 3 time points for administration of questionnaires, and the number of YA/YP who assented/consented and completed the questionnaires.

**Table .** Questionnaire completion time points and number of completions.

| Questionnaires | T0 (baseline) | T1 (2 weeks later) | T2 (6 weeks later) |
|---|---|---|---|
| Hospital Anxiety and Depression Scale | N=15 | N=15 | N=14 |
| 36-Item Short Form Survey Instrument | N=15 | N=15 | N=14 |
| System Usability Scale | N/A[a] | N=15 | N=14 |
| User version of the Mobile Application Rating Scale | N/A | N/A | N=14 |

[a]N/A: not applicable.

In the following subsections, quantitative results are labeled according to the focus of each questionnaire.

### Usability

The SUS was used to evaluate the usability of the chatbot, addressing 3 key aspects of usability: effectiveness, efficiency, and satisfaction.

SUS is a 10-item questionnaire with 5 response options for each item (from Strongly Disagree to Strongly Agree). The scores were calculated using the method recommended by Hägglund and Scandurra (2021) [27].

YPs and YAs were required to answer all SUS items. As reported in Table 2, each item was scored from 0 to 4 (with 4



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being the most positive response). Scoring SUS involved two initial steps:

1. For odd-numbered positive statements: subtract 1 from the user response.
2. For even-numbered negative statements: subtract the user responses from 5.

**Table .** Mean System Usability Scale scores of the DigiBete Chatbot at time points T1 (2 weeks of use) and T2 (6 weeks of use).[a]

| Item | Modified System Usability Scale statement | T1 (15 participants) | T2 (14 participants) |
|---|---|---|---|
| 1 | I think that I would like to use the chatbot frequently | 2.1 | 2.3 |
| 2 | I found the chatbot unnecessarily complex | 3.4 | 3.6 |
| 3 | I thought the chatbot was easy to use | 3.5 | 3.7 |
| 4 | I would need the support of a technical person | 3.9 | 3.9 |
| 5 | I found the various functions in the chatbot were well integrated | 2.6 | 3.1 |
| 6 | I thought there was too much inconsistency in the chatbot | 2.9 | 2.4 |
| 7 | Most people would learn to use this system very quickly | 3.7 | 3.9 |
| 8 | I found the system very cumbersome to use | 3.3 | 3.4 |
| 9 | I felt very confident using the chatbot | 2.9 | 3.5 |
| 10 | I needed to learn a lot of things before I could get going with the chatbot | 3.9 | 3.9 |

[a]In T1, there were 6 items scored above 3.0. In T2, there were 8 items scored above 3.0.

Table 2 shows that two calculations were performed at T1 and T2: (1) mean value of all individual answers and (2) number of items scored above 3.0.

Most items had a mean score above 3.0. At T1, six items scored above the mean of 3.0, whereas at T2, eight items scored above the mean of 3.0.

This shows a positive trend: more items were rated positively at T2 than at T1, suggesting an overall improvement in user-perceived usability, which is consistent with the increase in the overall SUS score (discussed later in this section). However, there was a reduction in the score for item 6 in relation to the consistency of the responses given by the chatbot. This could indicate a specific usability issue; even though overall usability improved, users felt the chatbot became less consistent in its responses.

There was no change in the scores for items 4 and 10. No change implies these aspects (perceived need for support and learning burden) remained stable—neither improved nor worsened.

To calculate the mean and median of all scores, the scores for each item were then added together and multiplied by 2.5 to obtain the final score. The final score ranged from 0 to 100, with higher scores indicating better usability.

At T1, the mean was 80.5 and the median 82.5; at T2, the mean was 85.2 and the median 86.3. The results can be interpreted using Lewis and Sauro's interpretation [23] where:

- An SUS score of 80.5 (at T1) was designated as good or an A– grade.
- An SUS score of 85.2 (at T2) was designated as the best imaginable or an A+ grade.

These high usability scores indicate that the YPs and YAs found the chatbot easy and pleasant to use, and that usability improved from T1 to T2.

## Quality

The uMARS was used to assess the quality of the chatbot. All questions were mandatory for YPs and YAs to answer.

Table 3 provides a detailed breakdown of the number of questions in each category and the highest scores obtained in each category. Based on YP/YAs' responses, the mean score and mean percentage were calculated.



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**Table .** Mobile Application Rating Scale results by category for the DigiBete Chatbot.

| Category | Number of questions | Highest total score that can be obtained | Mean score for each category | Percentage of the mean score |
|---|---|---|---|---|
| Engagement | 5 | 25 | 17.43 | 69.7 |
| Functionality | 4 | 20 | 17.86 | 89.3 |
| Aesthetics | 3 | 15 | 12.93 | 86.2 |
| Information | 4 | 20 | 15.92 | 79.6 |
| App subjective quality | 4 | 20 | 12.79 | 64 |
| Perceived impact | 6 | 30 | 19.79 | 66 |

There are 4 uMARS categories that indicate the quality aspect of the chatbot: Engagement, Functionality, Aesthetics, and Information. Functionality was the highest-rated category (89%), indicating YPs/YAs found the chatbot easy to use, stable, and technically sound. This is a major strength. Aesthetics (86%) was also very high. YP/YAs found the chatbot visually pleasing and well-designed. Combined with high functionality, this suggests good user experience design. The information (80%) category means the chatbot provides trustworthy and relevant content, though there may still be room for refinement. However, the lowest category for quality was Engagement (70%), which could indicate that the chatbot could be more interactive, interesting, or customizable.

Table 4 shows responses (5-point Likert scale plus an N/A response option) for the Engagement, Functionality, Aesthetics, and Information items. Each uMARS item is rated on a 5-point Likert scale from 1 (inadequate) to 5 (excellent). All the quality categories (Engagement, Functionality, Aesthetics, and Information) were mostly rated 4 (good) or 5 (excellent).

**Table .** Mode of participants' responses for the user version of the Mobile Application Rating Scale.

| Categories | 1 (inadequate) | 2 | 3 | 4 | 5 (excellent) | N/A[a] | Total responses |
|---|---|---|---|---|---|---|---|
| Engagement: entertainment, interest, customization, interactivity, target group | 4 | 7 | 19 | 31 | 9 | 0 | 70 |
| Functionality: performance, ease of use, navigation, gestural design | 0 | 1 | 1 | 25 | 29 | 0 | 56 |
| Aesthetics: layout, graphics, visual appeal | 0 | 0 | 4 | 21 | 17 | 0 | 42 |
| Information: quality and quantity of information, visual information, credibility of source | 0 | 3 | 10 | 22 | 19 | 2 | 54 |

[a]N/A: not applicable.

However, 2 respondents selected the N/A response option in the Information category, indicating that they received no information regarding the quality and quantity of the content, availability of visuals, and credibility of the sources contained in the chatbot to answer their questions. These results indicate that although over 50% of YPs and YAs found the DigiBete Chatbot easy to navigate and use, it needs further modifications to make it more accessible for some users.

Table 5 lists the subjective quality item ratings; 86% of the respondents would potentially recommend the chatbot, and 14% would recommend it. However, more than half (64%) would not pay for the DigiBete Chatbot, although over 50% rated it as 4- or 5-star.



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**Table .** Quality of the chatbot (subjective items).

| Subjective chatbot quality items from the user version of the Mobile App Rating Scale | Value (N=14), n (%) |
|---|---|
| **Would you recommend the DigiBete Chatbot to people who might benefit from it?** | |
| 1: Not at all | 0 (0) |
| 2 | 0 (0) |
| 3: Maybe | 6 (43) |
| 4 | 6 (43) |
| 5: Definitely | 2 (14) |
| **How many times do you think you would use DigiBete Chatbot in the next 12 months if it was relevant to you?** | |
| 1: None | 0 (0) |
| 2: 1 - 2 | 0 (0) |
| 3: 3 - 10 | 7 (50) |
| 4: 10 - 50 | 6 (43) |
| 5: >50 | 1 (7) |
| **Would you pay for the DigiBete Chatbot?** | |
| 1: Definitely not | 9 (64) |
| 2: | 2 (14) |
| 3: | 3 (21) |
| 4: | 0 (0) |
| 5: Definitely yes | 0 (0) |
| **What is your overall (star) rating of the DigiBete Chatbot?** | |
| 1: One of the worst apps I have used | 0 (0) |
| 2: | 0 (0) |
| 3: Average | 6 (43) |
| 4: | 6 (43) |
| 5: One of the best apps I have used | 2 (14) |

## Anxiety and Depression

The HADS was used to measure symptoms of anxiety and depression.

The HADS results showed that anxiety subscale values were higher than those of the depression subscale (Table 6). Specifically, some YPs/YAs reported a borderline or abnormal anxiety score (higher mean for anxiety), whereas their depression scores were within the normal range. The anxiety scale also had higher maximum values, which were within the abnormal range. One participant had an anxiety score close to the maximum abnormal range (values of 19 and 20).

**Table .** Proportion of participants with normal, borderline, and abnormal levels of depression and anxiety according to Hospital Anxiety and Depression Scale scores.

| | T0 (N=15) | | T1 (N=15) | | T2 (N=14) | |
|---|---|---|---|---|---|---|
| | Depression | Anxiety | Depression | Anxiety | Depression | Anxiety |
| Normal | 93.33 | 53.33 | 93.33 | 60.00 | 92.86 | 64.29 |
| Borderline | 0.00 | 20.00 | 0.00 | 13.33 | 7.14 | 0.00 |
| Abnormal | 6.67 | 26.67 | 6.67 | 26.67 | 0.00 | 35.71 |

Most reported a normal range of depression scores at all time points. However, between the anxiety and depression subscales, anxiety had a higher percentage at the time points: 26.67% at T0 and T1 and 35.71% at T2. Only 6.67% were classed as “abnormally” depressed at T0 and T1, while no participant was considered “abnormally” depressed at T2. This indicates that anxiety was more prevalent than depression, where more participants had borderline or abnormal anxiety, and extreme anxiety was observed in isolated cases (at least one participant had very high anxiety scores, near the maximum abnormal threshold of 21).



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Depression was largely not a concern because most remained in the normal range for depression at all time points.

## Health Status and Quality of Life

The SF-36 was used to assess overall health status and quality of life across physical, mental, and social domains.

YP/YA were required to answer all 36 questions at all time points. Table 7 shows the average and SD of YP/YA scores across the 3 time points for each health domain. The Physical Functioning domain yielded consistently high mean scores with no significant change observed between the time points. This could indicate that the YPs and YAs can perform basic activities (eg, walking) and instrumental activities of daily living (eg, bathing and dressing). Items in this domain also include participants' perceived ability to perform vigorous activities, such as running and lifting heavy objects, and moderate activities, such as moving a table and bowling.

**Table .** Quality of life results from the 36-Item Short Form Survey Instrument at 3 time points.

| Domain | T0 (N=15), mean (SD) | T1 (N=15), mean (SD) | T2 (N=14), mean (SD) |
|---|---|---|---|
| Physical Functioning | 92.33 (9.42) | 92 (8.62) | 91.43 (12.16) |
| Role limitations due to Physical health | 80.00 (30.18) | 88.33 (20.85) | 83.93 (33.41) |
| Role limitations due to Emotional health | 77.78 (32.53) | 80.00 (37.37) | 80.95 (33.88) |
| Energy/Fatigue | 61.67 (24.03) | 62.00 (19.71) | 56.79 (23.66) |
| Emotional Well-being | 69.07 (19.85) | 70.13 (20.50) | 68.86 (23.70) |
| Social Functioning | 85.00 (23.24) | 82.50 (24.91) | 86.61 (24.25) |
| Bodily Pain | 83 (15.12) | 83.50 (15.26) | 83.93 (16.60) |
| General Health | 59.33 (15.91) | 63.00 (13.73) | 65.36 (16.69) |

The domain Energy/Fatigue, however, has 2 mean values, which are the lowest in comparison to the mean values in other domains. In this domain, questions related to emotional well-being (feeling energetic, lively, and enthusiastic) and physical well-being (feeling worn out and tired). Low scores in this domain could indicate that they are feeling drained and demotivated.

Overall, there was no significant change across the 3 time points for all domains.

## Qualitative Findings

### *Overview*

A total of 41 participants (6 YP aged 11 - 15 y, 6 YA aged 16 - 24 y, 4 parents, and 25 HCPs) participated in an individual or focus group interview. Using framework analysis, themes derived during qualitative data collection and analysis (living with T1DM, using the DigiBete Chatbot, and refining the DigiBete Chatbot) supplemented interview topics with new lines of inquiry [26,28]. The full framework of themes/subthemes derived from qualitative data analysis is available in Multimedia Appendix 4. Below, we present summary narratives juxtaposed with verbatim quotations to illustrate the derived themes.

### *Living With T1DM*

YP and YA spoke of the shock of diagnosis and the overwhelming information related to it, as one YA described:

> *I think my parents took it harder than I did, and no one really knew about it. Dad struggled …. Lockdown [Covid] difficult straight after diagnosis.*

Also, her parents thought the diagnosis was wrong at first, so when it was confirmed correct:

> *…that was quite sad. But after that, once I'd accepted it, found it quite insightful. It was hard, get used to it, [but] becomes second nature.* [YA aged 22 y, diagnosed aged 19 y]

YP/YA acted as peer supporters and educators for those around them and were aware that learning more about their condition may be stressful for others; they generally accepted living with T1DM and could not remember a time before diagnosis, although some indicated frustration about the inconvenience of self-management.

Parents showed an awareness of future needs as their child moved toward independence, and they were pleased with how their child coped:

> *He's done very well to adapt to it.* [Parent of 13 year old, diagnosed at 9 y]

### *Using the DigiBete Chatbot*

The participants were positive about the chatbot and its benefits to users and those around them. It provides reassurance, generally offers accurate advice, and has potential as an educational tool for others. A short, easy-to-read format was preferred, and all found it straightforward to use. A strong preference was indicated by YPs/YAs and HCPs for short text messages and videos over links to websites and PDFs. Some participants indicated that the chatbot was not their only source of T1DM information and reassurance and that they may not rely on it in an emergency.

One YP thought the chatbot might be useful when he is out with friends, and while he seemed confident about managing his T1DM, he thought he may in future need further advice from the chatbot with self-management, for example to calculate alcohol units in a specific drink:



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> *Yeah because, like drinking alcohol maybe?* [11-year-old boy, diagnosed at 2 y of age]

Without exception, YP, YA, and parents would recommend the DigiBete Chatbot to others because they liked its accessibility, together with the reassurance and knowledge it provides. Generally, HCPs received the chatbot positively and thought it might fill a gap by addressing questions typically not asked in the clinic by YP/YA. As one HCP said, patients may ask, for example:

> *'What happens if I give too much insulin?' or 'Can I lose weight by not taking insulin?'. It's those unsaid things [often] not asked in clinic.* [Clinical psychologist]

However, some HCPs were more reserved about recommending it in its current stage of development, citing safety and accuracy concerns. For example, some were concerned about the accuracy of some information provided, given the wide age range of prospective users. Some HCPs were also worried that some terminology used by the YP/YA when asking questions of the chatbot may be interpreted incorrectly. One HCP said they would:

> *…like to see safety mechanisms built in before recommending its use…* [Consultant pediatrician]

### *Refining the DigiBete Chatbot*

The appearance of the chatbot was well received by participants, although options for customization of the avatar were suggested (this finding corresponds with results from the uMARS). Participants recommended further refinement of the accuracy of chatbot responses, with options to tailor or streamline responses by age, comprehension abilities, language preference, and voice activation. These recommendations are consistent with the results of the uMARS, which also indicate that the chatbot needs further modification, with improvements to enable users to customize it and make it more entertaining. See Multimedia Appendix 5 for participants' (YP/YA, parents, and HCPs) specific qualitative suggestions for DigiBete Chatbot improvements and the developers' responses regarding the feasibility of integrating these suggestions in a future version.

The complexity of the chatbot's responses could be reduced to encourage engagement with the information provided. For example, some highlighted a need for the chatbot to supply short, text-based answers first, rather than what they sometimes received in response to their questions (ie, lengthy and complicated information documents). Participants suggested that safety issues around mental health and emotional support should be enhanced by referencing correct and appropriate support in a timely manner. Suggestions for expanding chatbot content focused on the provision of reassurance and accurate contemporary information while recognizing users' developmental stages and the potential for experimentation alongside peers. For instance, one diabetes nurse was concerned that those with "English as a second language may struggle" and that YP/YA may think they are talking directly with their clinical team via the chatbot; this respondent also highlighted a need to be clear that the diabetes team are not available 24/7, so they:

> *…may need DigiBete Chatbot to remind them in [a] bold, big message flashing up and give contact numbers.*

This diabetes nurse also said it would be helpful if information about meals and carbohydrates in food outlet chains was linked to the chatbot, as YP/YA may be embarrassed to request this information when eating out.

The chatbot could encourage compliance with medications, clinic attendance, and/or engagement with specialist teams. The difficulty of deciding what information to include in the chatbot was acknowledged, along with the extensive age range of potential users.

### DigiBete Chatbot Engagement Metrics

Over the course of the feasibility study, 65 conversations of varying lengths were recorded, with an average of 3.3 interactions per conversation. The user conversations were captured and exported from the chatbot to analyze how it was performing. The trial data were anonymized, so we are unable to identify who the users were. Within IBM Watson x Assistant, we collected the conversations and determined how many interactions in each conversation involved the chatbot; sometimes only one question was needed for the user to find something out quickly, but in most conversations, multiple questions were asked.

## Discussion

### Principal Findings

To our knowledge, this is the first national (United Kingdom/NHS) or international self-management chatbot to be co-designed, developed, and evaluated by patients living with T1DM during their transition journey, as well as by their parents and HCPs [1,3-13,29]. The results reported here will inform the design and delivery of a future large-scale cohort study to assess the acceptability, functionality, and usability of the DigiBete Chatbot when assessed by 11 - 24 year olds with T1DM. Even with the small sample size of this nonrandomized feasibility and acceptability study and no other transition chatbots to compare DigiBete with, the results suggest that with some adaptations based on user feedback, the chatbot is feasible and acceptable among the YP/YA who enjoyed using it. This and the proposed cohort study will pave the way for the development of a national and fully functional NHS-approved, developmentally and age-appropriate, online and app-based chatbot to "go live" after the end of the cohort study.

The DigiBete Chatbot addresses the identified lack of personalized and supported self-management tools available for 11 - 24 year olds with T1DM and other chronic conditions [9,13,30,31]. Our reactive conversational agent offers content (messaging and additional multimedia resources) that is relevant for the target population and clinically approved. The chatbot was co-designed and co-developed with and for YP/YA with T1DM as they transition from child to adult health services, providing them with informational support to enhance their knowledge, skills, and confidence (as they transition toward adulthood and independent self-management) in navigating their T1DM self-management journey [9,18]. Scores from the



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SUS, designed to measure users' perception of the usability of a system, indicated improvement from baseline to the second time point, with improvements in perceived ease of use, functionality, and confidence. This demonstrates that participants viewed the chatbot as highly usable. Having used the chatbot for 6 weeks, YA/YP who were more likely to use it in the future found that its functions were well integrated, became more confident in using it, and perceived the chatbot to operate in a consistent way. This aligns with the consolidated star rating from the uMARS showing that more than 50% of participants allocated the DigiBete Chatbot 4 or 5 stars out of 5, with no respondents rating the app below 3 out of 5 stars.

After using the chatbot, participants scored it highly in the domains of engagement, functionality, aesthetics, and the information provided, with lower overall scores in subjective quality and perceived impact. Functionality scored highly, suggesting that the chatbot met the intended needs of users in relation to performance, ease of use, navigation, and gestural design. Despite this, feedback from the HADS questionnaire demonstrates that the chatbot is unlikely to have a significant impact on depression and anxiety over the short time scale applied to this feasibility study. This aligns with the lower score for the perceived impact in the uMARS questionnaire. Similarly, from the SF-36 results, the chatbot did not impact physical or emotional well-being and did not improve social functioning, although there was a trend toward an improvement in general health.

Qualitative data demonstrate that participants were positive about the chatbot and its benefits to users and those around them. In the qualitative assessment, users recognized that the chatbot could identify issues around mental health and emotional well-being and suggested that "safety-netting" within the chatbot could support timely referral and so was required. Responses in uMARS also demonstrated that the chatbot was aesthetically pleasing to users, although in future developments, participants would like the ability to customize the chatbot based upon their personal preferences. Reassuringly, all participants would recommend the chatbot and would use it again during the following 12 months.

The DigiBete Chatbot provides reassurance and gives accurate advice, and all participating YP/YA and parents would recommend it to others. HCPs also received the chatbot positively; however, more work was suggested by some HCPs to develop it further. Quantitative analysis also demonstrated that the chatbot was usable; over time, YP/YA gained confidence in its use. Users particularly liked the functionality and information provided. However, the areas of improvement cited include the need for more technical information and support when using the chatbot.

Before proceeding further, and based on qualitative comments from YP/YA, parents and HCPs recommended improving the usability of the DigiBete Chatbot by, for example, enabling it to remember each user at return visits, recording details relating to user characteristics to assist the persuasive conversational capacity of the intervention, accommodating user language choices in their conversational dialogue, and supporting customization and personalization (see Multimedia Appendix 5 for additional qualitative suggestions). Given the increasingly ubiquitous use of smartphones and popularity of chatbots in daily life for YP/YA, chatbots such as DigiBete may also be an increasingly popular and scalable solution to promote confident and competent self-management during transition by YP/YA living with other chronic conditions [8]. For example, YP/YA with juvenile arthritis or chronic kidney disease [32,33] also often experience high levels of self-management support needs before, during, and after transition to adult health care; these needs could be addressed by tailored, disease-specific chatbots such as the DigiBete Chatbot.

In the next phase of the DigiBete Chatbot development and evaluation, user safety will continue to be of the utmost importance. The current version is designed to meet the transition needs of YP/YA aged 11 - 24 years. The next phase will open the chatbot up to other age groups so the language used by the DigiBete Chatbot will have more complexities due to this wider age and developmental differences; the vocabulary used by the different ages will vary as they query the chatbot. The resources within the revised DigiBete Chatbot will need to reflect the age and developmental stage of the person making the query, so again, language matters. The resources will all be housed on the DigiBete website, which will ensure clinical safety and accuracy. Although the resources will be clinically accurate and safe, the language used by the chatbot will be pedestrianized so that users do not feel that they are in a clinical environment. If a user's query indicates signs of distress or suggests they are in crisis or an emergency, then the chatbot will respond by signposting other agencies that can help, along with advice to contact their local diabetes team for help and support.

### Strengths and Limitations

A nonrandomized preliminary feasibility study (as opposed to a pilot randomized controlled trial, which resembles an intended randomized controlled trial in aspects such as having a control group, randomization, and determining efficacy and effectiveness) effectively met our aims, which included an intention to determine access to participants (eg, willingness of clinicians to introduce eligible patients/parents to the study, participant responses to invitations, barriers to participation, and the feasibility and suitability of assessment procedures and outcome measures). Therefore, we regard this as a strength of our study design as it helped us to achieve these aims.

The study design was strengthened by basing it on the Template for Intervention Description and Replication (TIDieR) checklist (Checklist 1 details this as a guide) and using a multimethod design in which qualitative data helped to foster new insights into factors underpinning quantitative data.

The feasibility and acceptability testing enabled us to refine and put study procedures in place and incorporate inclusion and exclusion criteria and processes for tracking enrollment and data collection. The research design also enabled us to evaluate the performance of the measures used in combination with the qualitative findings to determine if the intervention was acceptable. These procedures were tested in a sample drawn from the target population for a future full-scale study. We were also able to train research staff in administering study



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procedures—including participant identification and referral, recruitment, enrollment, and data collection—and chatbot development staff in teaching participants how to use the chatbot.

The DigiBete Chatbot has the potential to beneficially affect patients' self-reported self-management outcomes, and a full-scale study of its usability and acceptability following iterative changes to the chatbot based on the reported findings was found to be feasible. Most data were collected remotely, which was convenient for participants during the COVID-19 pandemic.

The study had some limitations; for example, while the primary source of participant identification and recruitment was clinical appointments, this process could be further strengthened in the future by clinicians inviting existing DigiBete users via the app. In addition, due to the prevailing COVID-19 restrictions at the point of recruitment, there was a relatively small sample size and limited diversity regarding digital exclusion and ethnic diversity. We did not analyze the characteristics of participants who engaged more versus less, which could have yielded valuable additional insights into acceptability and usability, and we did not collect exploratory data on clinical outcomes such as glycated hemoglobin to detect significance, as this was outside the scope of this study. There are also limitations to the reactive chatbot's content/functionality and content recommendations; some of these recommendations cannot yet be achieved owing to the current technological capabilities of the chatbot. A future chatbot evaluation would be strengthened by addressing these limitations.

Although questionnaire completion rates were less than optimal, the measures could be used in a future full study with small amendments. For example, the respondent burden for the SF-36 was high as it involves 8 domains across 36 items, but this could be reduced to 17 items by selecting only the 3 most relevant domains: physical function (10 items), social function (2 items), and mental health (5 items).

The chatbot was only available to each user for a 6-week period; it is likely that this period was too short to demonstrate a significant impact on the overall physical, emotional, and social health of YP/YA. For instance, the study period may have been insufficient to produce significant changes in anxiety and depression, as meaningful improvements in mental health often require extended support, structured interventions, and time for individuals to process information and adapt to their new circumstances. Mental health progress is influenced by multiple factors, including the severity of symptoms, engagement with therapeutic techniques, and additional support systems. Although chatbots can provide immediate coping strategies, emotional validation, and psychoeducation, sustained improvements in mood and anxiety levels typically develop over months rather than weeks. Furthermore, given that this was a feasibility study, the small number of responses may have been insufficient to demonstrate an impact on emotional and physical well-being. In future studies of the DigiBete Chatbot, a longer trial period with more participants in more centers to assess impact in the domains of the HADS and SF-36 may provide a more realistic view of its impact.

Our participating YP/YA were predominantly female and experienced in the use of smartphones and chatbots. Geographic sample limitations included recruitment only from urban areas but no specific representation from rural areas where internet access may be less reliable. Because of the small sample size, the chatbot may have been trained on biased data, potentially leading to inadequate responses. The chatbot is designed to have a gradual or cumulative effect on users' health behaviors and many health outcomes take time to manifest so such a short study may not have been able to capture this progression, especially because chatbots can sometimes feel cold and robotic to users, lacking the empathy and nuance of human interactions [34].

Potential biases may have affected the study outcomes. For example, although we worked with a collective of specialist service designers and researchers who aim to ensure inclusivity in NHS research by engaging underserved, seldom heard, and vulnerable groups and who supported recruitment and data collection, differences may exist between patients who volunteered and those who refused participation (self-selection bias). In addition, although we made every effort to accommodate participants' commitments when scheduling qualitative interviews or focus groups, some may have been inadvertently excluded because of personal time constraints (participation bias). Finally, some YP/YA participants may have had difficulty recalling their thoughts about the chatbot when completing outcome measures at 2 weeks and 6 weeks and qualitative interviews at 6 weeks (recall bias). Despite controlling for these and other types of bias, unidentified limitations may still exist.

Because of the study limitations, the results should be interpreted with caution and will require validation in a larger study with a more representative sample and potential generalizability of results. Future research needs to determine whether our findings extend to a more heterogeneous sample.

## Conclusions

The impact of chatbots in T1DM care remains unclear. Prior to examining the DigiBete Chatbot's effectiveness in the future, its usability, acceptability, and impact on users' psychological well-being in the target YP/YA population were examined. The DigiBete Chatbot was deemed usable, acceptable, and feasible for delivery. Our results warrant some refinement of the chatbot content based on the recommendations reported here and further investigation prior to its wider use in clinical practice. Our research design and methodology could also be transferred to the development and evaluation of chatbots for YA/YP living with other chronic conditions before and after transition.

On the premise of this feasibility study, the plan is to rebuild the DigiBete Chatbot to meet identified user needs and preferences and progress to a national cohort study to assess the usability, feasibility, and acceptability of a modified chatbot, with a view to proceeding to roll it out for national/international use on the established DigiBete platform.



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## Data Availability

All relevant data are within the manuscript and its Multimedia Appendix files.

## Authors' Contributions

PD conceived and planned the study with input from VS, MJ, RJ, FC, AS, RZ, SD and AR. JH and EM distributed the questionnaires and analysed the data. JH, EM, VS, HM, JB and JMK conducted and analysed the interviews/focus groups. VS, PD, JB, JH, HM and EM drafted the manuscript; PD, JH, EM, JB, AR, FC, HM, AS, RZ, MJ, RJ and JMK provided feedback on the manuscript. All authors approved the final version of the manuscript for submission.VS, PD, JB, JH, HM, and EM drafted the manuscript. PD, JH, EM, JB, AR, FC, HM, AS, RZ, MJ, and JMK provided feedback on the manuscript. All authors approved the final version of the manuscript for submission.

## Conflicts of Interest

A potential conflict of interest is that coauthors MJ and RJ are also DigiBete developers; however, they were not involved in participant recruitment, data collection, or data analysis and did not view any data until they were anonymized. The remaining authors declare no conflicts of interest.

Multimedia Appendix 1
User interaction flowchart.
[PNG File, 1257 KB - diabetes_v10i1e74032_app1.png ]

Multimedia Appendix 2
Details on measures used.
[DOCX File, 23 KB - diabetes_v10i1e74032_app2.docx ]

Multimedia Appendix 3
Participant characteristics.
[DOCX File, 17 KB - diabetes_v10i1e74032_app3.docx ]

Multimedia Appendix 4
Framework of derived themes from qualitative data.
[DOCX File, 15 KB - diabetes_v10i1e74032_app4.docx ]



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Multimedia Appendix 5
Participants' qualitative suggestions.
[DOCX File, 19 KB - diabetes_v10i1e74032_app5.docx ]

Checklist 1
TIDieR checklist.
[DOCX File, 32 KB - diabetes_v10i1e74032_app6.docx ]

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## Abbreviations

**DHT:** digital health technologies
**EUG:** Expert User Group
**HADS:** Hospital Anxiety and Depression Scale
**HCPs:** health care professionals
**NHS:** National Health Service
**SF-36:** 36-Item Short Form Survey Instrument
**SUS:** System Usability Scale
**T0:** baseline
**T1:** time 1 (2 weeks)
**T1DM:** type 1 diabetes mellitus
**T2:** time 2 (6 weeks)
**TIDieR:** Template for Intervention Description and Replication
**uMARS:** user version of the Mobile Application Rating Scale
**YP/YA:** young people and young adults



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# “Digital Clinicians” Performing Obesity Medication Self-Injection Education: Feasibility Randomized Controlled Trial

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## Abstract

**Background:** Artificial intelligence (AI) chatbots have shown competency in a range of areas, including clinical note taking, diagnosis, research, and emotional support. An obesity epidemic, alongside a growth in novel injectable pharmacological solutions, has put a strain on limited resources.

**Objective:** This study aimed to investigate the use of a chatbot integrated with a digital avatar to create a “digital clinician.” This was used to provide mandatory patient education for those beginning semaglutide once-weekly self-administered injections for the treatment of overweight and obesity at a national center.

**Methods:** A “digital clinician” with facial and vocal recognition technology was generated with a bespoke 10- to 15-minute clinician-validated tutorial. A feasibility randomized controlled noninferiority trial compared knowledge test scores, self-efficacy, consultation satisfaction, and trust levels between those using the AI-powered clinician avatar onsite and those receiving conventional semaglutide education from nursing staff. Attitudes were recorded immediately after the intervention and again at 2 weeks after the education session.

**Results:** A total of 43 participants were recruited, 27 to the intervention group and 16 to the control group. Patients in the “digital clinician” group were significantly more knowledgeable postconsultation (median 10, IQR 10 - 11 vs median 8, IQR 7 - 9.3; *P*<.001). Patients in the control group were more satisfied with their consultation (median 7, IQR 6 - 7 vs median 7, IQR 7 - 7; *P*<.001) and had more trust in their education provider (median 7, IQR 4.8 - 7 vs median 7, IQR 7 - 7; *P*<.001). There was no significant difference in reported levels of self-efficacy (*P*=.57). 81% (22/27) participants in the intervention group said they would use the resource in their own time.

**Conclusions:** Bespoke AI chatbots integrated with digital avatars to create a “digital clinician” may perform health care education in a clinical environment. They can ensure higher levels of knowledge transfer yet are not as trusted as their human counterparts. “Digital clinicians” may have the potential to aid the redistribution of resources, alleviating pressure on bariatric services and health care systems, the extent to which remains to be determined in future studies.

**Trial Registration:** ISRCTN ISRCTN12382879; https://www.isrctn.com/ISRCTN12382879

***(JMIR Diabetes 2025;10:e63503)*** doi:10.2196/63503

**KEYWORDS**

automation; automate; machine-human interface; clinical education; digital clinician; virtual human; trust; chatGPT; chatbots; machine learning; ML; artificial intelligence; AI; large language models; natural language processing; NLP; deep learning; randomized controlled trials; RCTs; feasibility studies; obesity; medication

## Introduction

Obesity, an “abnormal or excessive accumulation of fat that poses a health risk” [1], is a primary contributor to global health challenges [2]. Reports suggest its involvement in up to 80% of cases of type 2 diabetes and 43% of cardiovascular incidents [3] while significantly contributing to depression and anxiety [4].



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Recent breakthroughs in bariatric medicine have elevated the role of injectable therapy, namely glucagon-like peptide-1 agonist agents such as semaglutide. New injectable agents are showing weight loss surpassing 20% and 25% [5]. With over half of adults in the World Health Organization (WHO) European Region [2] potentially eligible, use is hindered by scalability of clinical services and supply. Generative AI has been identified to have the potential to offset the clinical and administrative demands associated with the management of patients on these medication types [6]

Patient education is a critical component of the clinical care pathway and a prerequisite at many clinics for the prescription of pharmacotherapy. Even in resource-rich countries, the necessary services are not always available. Studies have predicted the United States needs careful restructuring of health service expenditure to meet demand for the costs of overweight and obesity services [7].

Health care systems are underresourced and understaffed, particularly in rural areas [8]. This impacts productivity, sustainability [9], and the health of both patient and health care professionals [10]. Health care worker shortages, propelled by aging populations [11] and the COVID-19 pandemic [12], are exacerbated in areas such as the Global South, increasing health care inequities [13]. Tasks that health care workers perform are often repetitive and administrative. Redistribution of such tasks has been shown to potentially improve health outcomes such as blood pressure, $HbA_{1c}$, and mental health [14].

Artificial Intelligence (AI) chatbots have the potential to be used for a variety of medical tasks, including note taking [15] and personalized medicine [16]. Anonymized AI chatbots have been judged to provide better, more concise, empathetic answers to general health queries than verified physicians [17]. ChatGPT-3 is known to be accurate with common chief complaints [18] and GPT-4 recently outscored 99.98% of simulated human readers when diagnosing complex clinical cases [19]. Automated personalized messaging systems are being researched to enhance behavioral change in a hope to enhance health outcomes [20].

However, there are concerns about trust, usability, and efficacy [21]. Hallucinating models can spread misinformation and private medical data may be misused [16]. Trust is fundamental to the physician-patient relationship shown to affect health behaviors, compliance, and quality of life [22]. Willingness to use supportive technologies has been shown to be influenced by complex factors, such as perceived usefulness, health threat, and resistance to change [23]. Chatbots are text-based and have rarely been integrated with physical form, for example, avatars or "virtual humans." Adding form to a faceless chatbot to create a "digital clinician" may increase trust, engagement, and usability [24].

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Automation may offer benefits in standardization, efficiency, effectiveness, cost, confidentiality, and access. Social desirability response bias is associated with higher levels of treatment nonadherence [25] and reduces the accuracy of clinical history taking [26] in human-human interactions. In educational settings, certain interactions, such as quizzing, enhance information retention but may be more socially appropriate from a "digital clinician" than from a health care professional.

Virtual humans have been shown to be efficacious in nonclinical patient-facing scenarios [27]. There has been a paradigm shift since the advent of ChatGPT, bringing automated communicators into a new light, mandating research focus. The aim of this study is to investigate the use of a medically approved task-specific "digital clinician" to provide patient education in a clinical environment, comparing it with a human counterpart.

## Methods

### Research Design

All patients at Galway University Hospitals must attend an education session with a Clinical Nurse Specialist before starting semaglutide injectable therapy. This session covers basic semaglutide pharmacotherapy and the safe self-administration of injections using a semaglutide pen. During the study period, allocated, eligible participants received their mandatory education from a "digital clinician" with human oversight. The control group received current standard-of-care, human, nurse-led education.

Once a clinical decision was made that treatment of overweight or obesity with semaglutide injections would be commenced, eligibility was assessed. Overweight and obesity were classified as a BMI greater than 25 $kg/m^2$. Eligibility criteria included being aged 18 years or older, without an intellectual or physical disability, which would interfere with a participant's ability to self-administer semaglutide injections. All eligible patients were invited to participate in the study. Given the nature of the intervention ("digital clinician"), blinding was not feasible.

Eligibility criteria included patients aged older than 18 years, without an intellectual or physical disability, which would interfere with a participant's ability to self-administer semaglutide injections. All eligible patients were invited to participate in the study. Given the nature of the intervention ("digital clinician"), blinding was not feasible.

### The "Digital Clinician"

To inform design, clinicians were observed educating patients. Their mannerisms, behavior, and conversations were recorded. Transcripts of educational sessions given by the local obesity nurse specialist were generated.

A 10- to 15-minute educational script was generated with multiple conversation streams. Information on medication name, dosages, mechanism of action, pen preparation, administration, side effects, and storage was included. User questioning was used to maximize engagement and knowledge retention.

Akin to natural clinical education, the "digital clinician" led the primary section of the tutorial, offering information and asking the patient questions throughout to test retention and assess



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understanding. The question types used by the "digital clinician" varied. Some were open, while others were multiple choice, true or false, yes or no, or numerical. After the clinician-led portion of the tutorial had ended, patients were invited to type or voice any question they wished. The option to see and hear the answers to some frequently asked questions was also offered by way of onscreen prompts.

Unclear or ambiguous responses were identified by the digital clinician as such, and this was communicated to the user who was then kindly asked to repeat themselves. If not understanding the user twice in a row, the "digital clinician" would simply offer the correct answer and continue. This prevented the possibility of an infinite loop. When offered the chance to ask general queries, the user may query infinitely if they wish, although a comprehensive list of frequently asked question prompts on screen, and an onscreen button to end the tutorial, were in place to reduce this need.

A careful selection of trigger words and combinations of "IF," "AND," "OR," and "NOT" statements was used to design the conversational flow. Rigorous internal testing, including over 100 iterations of the conversational flow, was tested by the research team to ensure a fluent, cohesive, usable digital clinician with little risk of misinterpreting the user's intent.

This "digital clinician" could be accessed with native web browsers on the participants' phone, tablet, or laptop. In this case, the participants accessed the session under supervision on an iPad (Apple) device.

Two multiscene videos were recorded by the team and integrated into the tutorial using screen-in-screen projection. The videos offered human views and instructions of what preparing and using the injection pen entailed. The videos, while being demonstrated by members of the research team, were narrated by the "digital clinician."

The software IBM Watson Assistant was used to generate conversation streams. Microsoft ClipChamp Video Editor was used to edit videos, then uploaded to Imgur, accessed via source code written on IBM Watson. The IBM Watson conversation code file was integrated with an animated avatar on the SoulMachines Creator Website. The "digital clinician" uses natural language processing and an evolving bank of AI-driven animation responses that monitor vocal tone and facial expression to regulate behavior. The "digital clinician" has a programmed personality, name, voice, and identity and is being used in a role traditionally considered to require human intelligence.

Logos of affiliated educational and health care institutions were included on the user interface screen to increase trust. Cinematic screening offered different angles of the avatar's face to make for a more interesting experience. Multiple avatars of different genders, races, and names were used to promote inclusivity. All possible conversation streams had been verified against official pharmaceutical literature. The individual scripts were not recorded, but each participant-AI interaction was supervised to monitor for technical issues or hallucinations. Multiple avatars of different genders, races, and names were used to promote inclusivity. All possible conversation streams had been verified against official pharmaceutical literature. The individual scripts were not recorded, but each participant-AI interaction was supervised to monitor for technical issues or hallucinations. A short video of the "digital clinician" in use is included in Multimedia Appendix 1

### Randomization: Minimization

Minimization is a method used in clinical trials and experimental research to allocate participants [4,28]. Participants were allocated in order of enrollment to the study arm that minimized the difference across 4 selected numerical baseline variables, namely, age, BMI, pretutorial knowledge of semaglutide score, and pretutorial injection self-efficacy score. Order of enrollment in the study was determined by check-in time at the clinic. Allocation by minimization is deterministic and hence precludes traditional concealment.

The first participant was assigned at random using a coin toss. The second participant was subsequently assigned to the alternative group. Allocation was verified using Microsoft Excel by an independent assessor with access to study data in real-time at a separate location via a secure web-based suppository. The assessor then communicated the allocation to the research team on site.

Allocation was verified using Microsoft Excel by an independent assessor with access to study data in real-time at a separate location via a secure online suppository. The assessor then communicated the allocation to the research team on site.

### Self-Efficacy

Self-efficacy was measured using the 2-part validated Self Injection Assessment Questionnaire (SIAQ) [29]. The preinjection SIAQ was used as baseline data. The postinjection SIAQ was scored across 5 domains considering 2-week postintervention feelings about injections, self-image, self-confidence, pain and skin reactions, ease of use, and satisfaction. The SIAQ has been shown to be a valid, robust tool with sufficient validity, reliability, consistency, and sensitivity. Cronbach $\alpha$ and the test-retest coefficient were >0.70 for all domains [30].

### Knowledge Attainment

Unvalidated knowledge assessments were designed specifically for the purpose of this research. The pre-educational assessment tool consisted of 4 questions. The posteducational assessment tool contained the same initial 4 questions and a further 8 questions. Questions were multiple choice and covered topics, such as drug name, drug class, mechanism of action, side effects, injection technique, and storage requirements.

### Consultation Satisfaction

The validated Patients' Overall Satisfaction with Primary Care Physicians Scale (CPSS) [31] has criterion-related validity coefficients mostly in the 0.80s and 0.90s when considering empathy, physician recommendation, and general satisfaction. Cronbach coefficient $\alpha$ for the patient satisfaction scale is 0.98. The 7-point Likert scale was used in the study.



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### Trust

The "Trust between People and Automation Scale" (TPA) has undergone validation [32] and been in use for more than 20 years. It was adapted and integrated with the consultation satisfaction measure for this study.

### Technology Usability and Future Use

The validated Technology Usability Questionnaire (TUQ) [33] was adapted. The questionnaire has high reliability with Cronbach Coefficient α more than 0.8 across all domains, and high validity expressed through its multiple native questionnaires [34]. A shortened version including questions from 4 of 5 domains was used. The domains were "Ease of use and Learnability," "Interface Quality," "Interaction Quality," and "Satisfaction and future use." Open-ended questions were used to record general themes and attitudes toward the "digital clinician." The outcome measure tools are included as Multimedia Appendix 2.

### Sample Size Calculations

When calculating sample size, a similar study using the validated SIAQ to measure self-efficacy was used [29]. It showed a mean 7.09 (SD of 1.5), on a 10-point Likert scale. A significant difference of two-thirds the SD was proposed to boundary noninferiority, with 80% power and α=.05; this would require 28 participants to be recruited into each arm of the study.

### Ethical Considerations

A randomized controlled noninferiority trial of "digital clinician"-led patient education was designed with ethical approval from Galway University Hospitals, Clinical Research Ethics Committee (Ref: CA 2920). The trial and trial protocol were guided by SPIRIT-AI (Standard Protocol Items: Recommendations for Interventional Trials involving Artificial Intelligence) [35] and CONSORT-AI (Consolidated Standards of Reporting Trials- Artificial Intelligence) [34] extensions. Further information on the study protocol can be found in Multimedia Appendix 3. It was ensured that all patients were offered at least the current standard of care. After data collection, all patients were seen by the clinical nurse specialist. The nurse assessed the patients who had received safety-net instructions before being discharged with a medication information leaflet. Contact with the nurse minimized disruption of the patient-clinician relationship. This established human oversight and accountability. Informed written consent was obtained from all participants before enrollment and randomization, after provision of a patient information leaflet and discussion with the research team. All patient data was anonymized. No patient identifiable information was included in data analysis and confidentiality was maintained. Data was stored on password-protected encrypted devices. No compensation was offered to participants.

### Statistical Analysis and Missing Data

Data were analyzed using Jamovi version 2.4.14 developed by Love, Droppman, and Selker [36,37] and R Studio, developed by Posit PBC [37]. All Likert scale data were appropriately aggregated in treatment and control arms and recalibrated to scales from 1 to 10 for self-efficacy, and 1-7 for trust, satisfaction, and usability.

The Mann-Whitney U test was used to assess differences in primary and secondary outcome variables. This nonparametric test is robust to the distribution of the outcome data. The Mann-Whitney *U* test compares the ranks of all the data points in 2 groups. *P* values below .05 were deemed statistically significant. Conventional content analysis was used to interpret qualitative data. Missing outcome data were omitted from analysis. Observed outcome data were analyzed as if representative of the entire cohort.

Knowledge, satisfaction, trust, and usability were measured immediately posttutorial. Subsequent loss to follow-up at 2 weeks did not affect the handling of this data.

Those lost to follow-up were unavailable for self-efficacy analysis. The profile of those with complete data and those with missing data were explored in Multimedia Appendix 4.

## Results

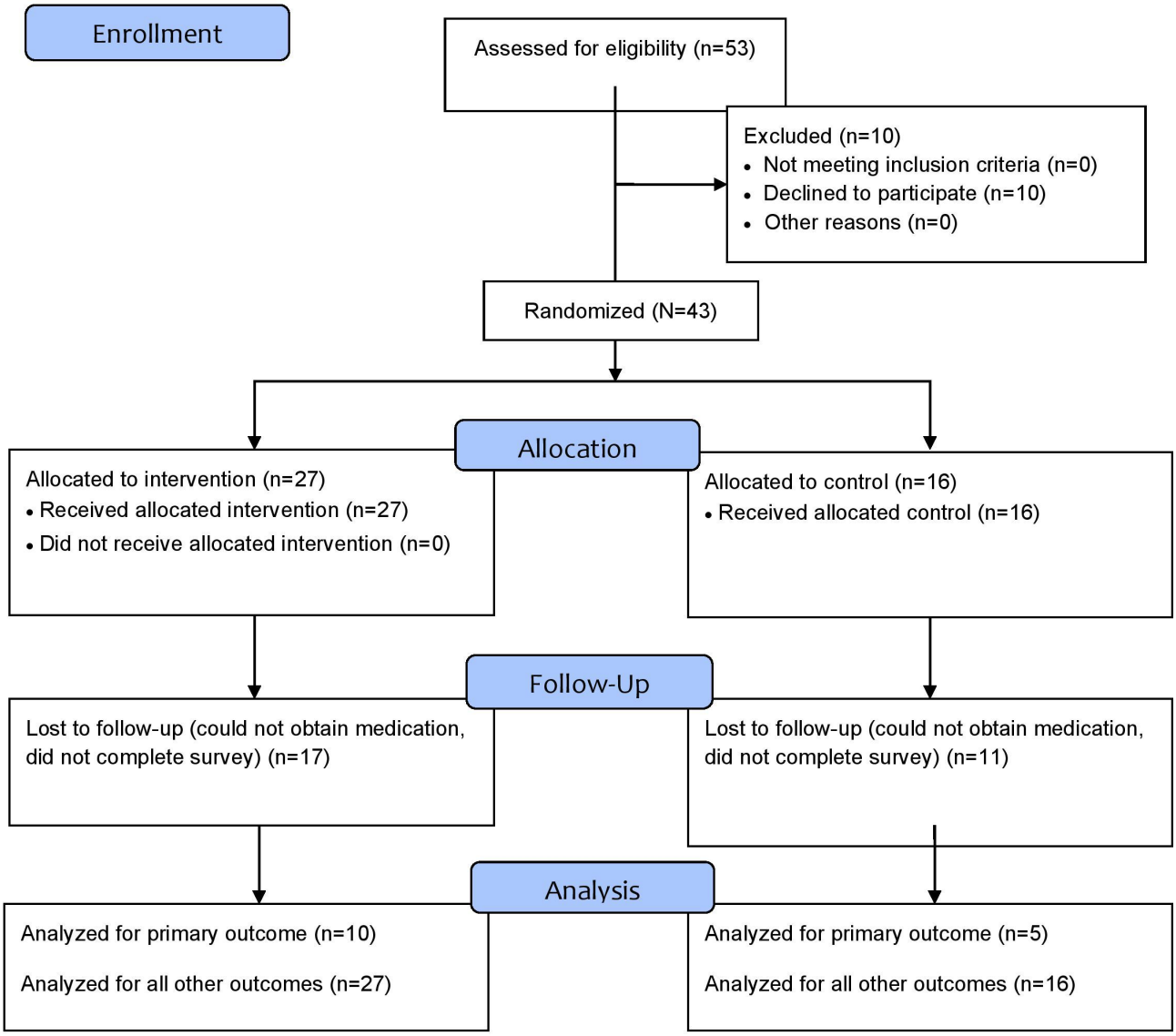
### Baseline Characteristics

During the 7-week study period in the bariatric clinic, 53 patients were prescribed semaglutide self-administered injections for the treatment of overweight or obesity (see Figure 1). Of this cohort, 43 agreed to participate in the study. Of those enrolled, 100% (43/43) completed the pretutorial questionnaire, their assigned education session, and their posttutorial questionnaire. Only 41.9% (18) participants completed the 2-week follow-up self-efficacy questionnaire (Table 1).



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**Figure 1.** A flowchart of enrollment, allocation, and attrition details.






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**Table .** A summary of participants' baseline characteristics.

| Characteristic | Total (n=43) | Digital clinician (n=27) | Control (n=16) | *P* value |
|---|---|---|---|---|
| Age, mean (SD) | 47.41 (13) | 46.4 (13) | 49.2 (13) | — |
| BMI, mean (SD) | 43.6 (8) | 42.9 (6.8) | 44.8 (10) | — |
| Sex, n (%) | | | | |
| Male | 9 (21) | 3 (11) | 6 (38) | — |
| Female | 34 (79) | 24 (89) | 10 (63) | — |
| Ethnicity, n (%) | | | | |
| Irish | 30 (70) | 19 (70) | 11 (69) | — |
| Other | 4 (9) | 3 (11) | 1 (6) | — |
| Missing | 9 (21) | 5 (19) | 4 (25) | — |
| Education level, n (%) | | | | |
| None | 1 (2) | 1 (4) | 0 (0) | — |
| Primary | 2 (5) | 1 (4) | 1 (6) | — |
| Secondary | 19 (44) | 12 (44) | 7 (44) | — |
| Third level | 21 (49) | 13 (48) | 8 (50) | — |
| Pretutorial Knowledge, median (IQR) | 2 (1 - 2) | 2 (1 - 3) | 2 (1 - 2) | .41 |
| Pretutorial Self Efficacy, median (IQR) | 27 (31 - 33) | 32 (27 - 33) | 31 (27.8 - 33.3) | 1.00 |

## Self Efficacy

Both groups had a median self-efficacy level of 10/10, with the “digital clinician” group having a marginally lower first quartile of 8, compared with the control group (8.2; Figure 2). This difference was not statistically significant (Table 2; *P*=.52).

Responses recording “Pain and Skin reactions” from the control group had a favorable, nonsignificantly higher mean rank.



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**Figure 2.** Self-Efficacy scores across control and digital clinician groups. SIAQ: Self-Injection Assessment Questionnaire.

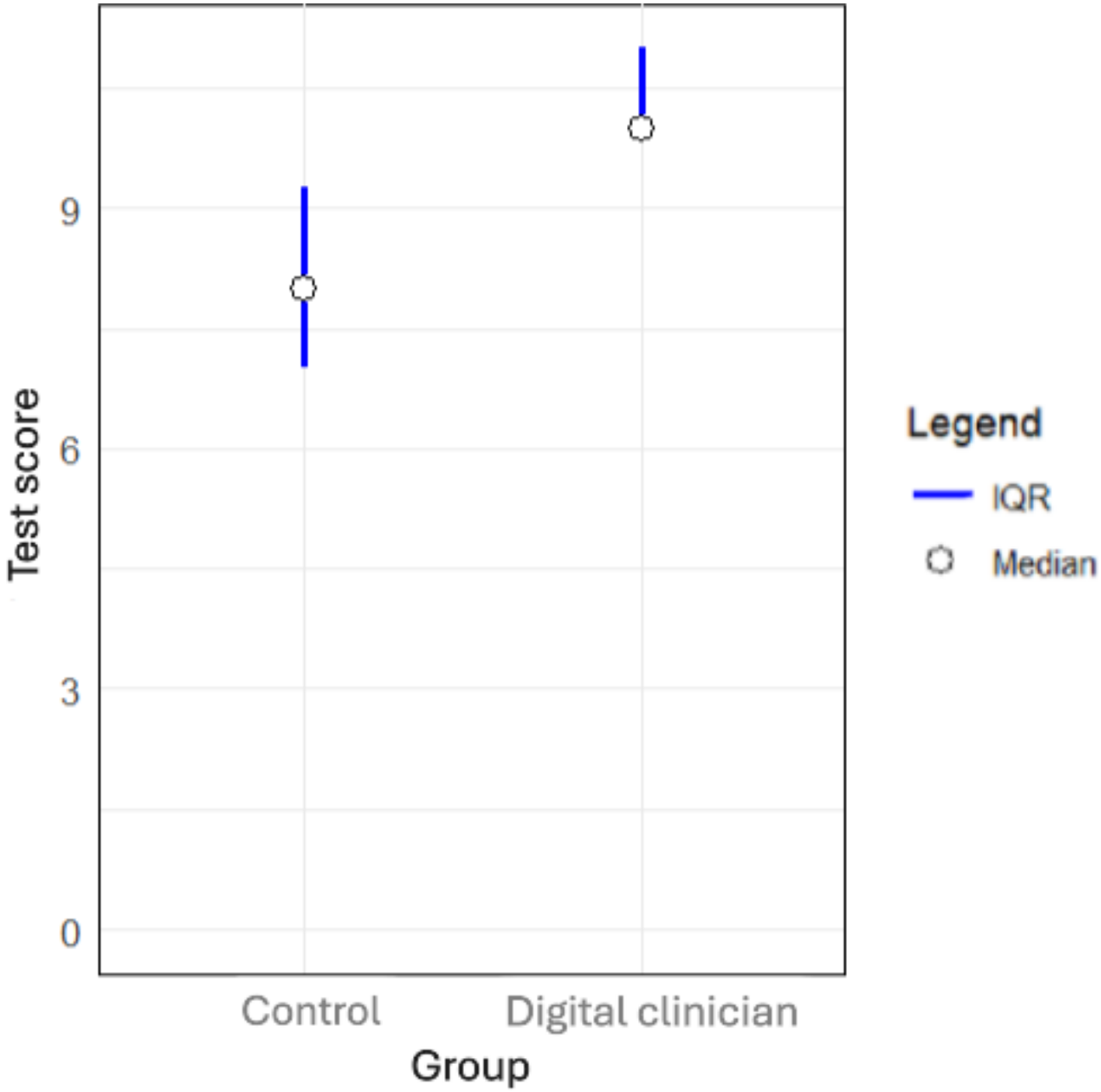



**Table .** Self-injection self-efficacy assessment results at 2 weeks post intervention.

| Domain | Digital clinician (n=10), median (IQR) | Control (n=5), median (IQR) | *P* value |
|---|---|---|---|
| Feelings about injections | 5.0 (5.0-5.0) | 5.0 (4.0-5.0) | .08 |
| Self-image | 5.0 (4.0-5.0) | 5.0 (5.0-5.0) | .66 |
| Self-confidence | 4.5 (4.0-5.0) | 5.0 (4.0-5.0) | .45 |
| Pain and skin reactions | 5.0 (5.0-5.0) | 5.0 (5.0-5.0) | .08 |
| Ease of use | 6.0 (5.0-6.0) | 5.0 (5.0-6.0) | .22 |
| Satisfaction | 5.0 (4.0-5.0) | 5.0 (4.0-5.0) | .61 |
| Overall self-efficacy | 10.0 (8.0-10.0) | 10.0 (8.2-0.0) | .52 |

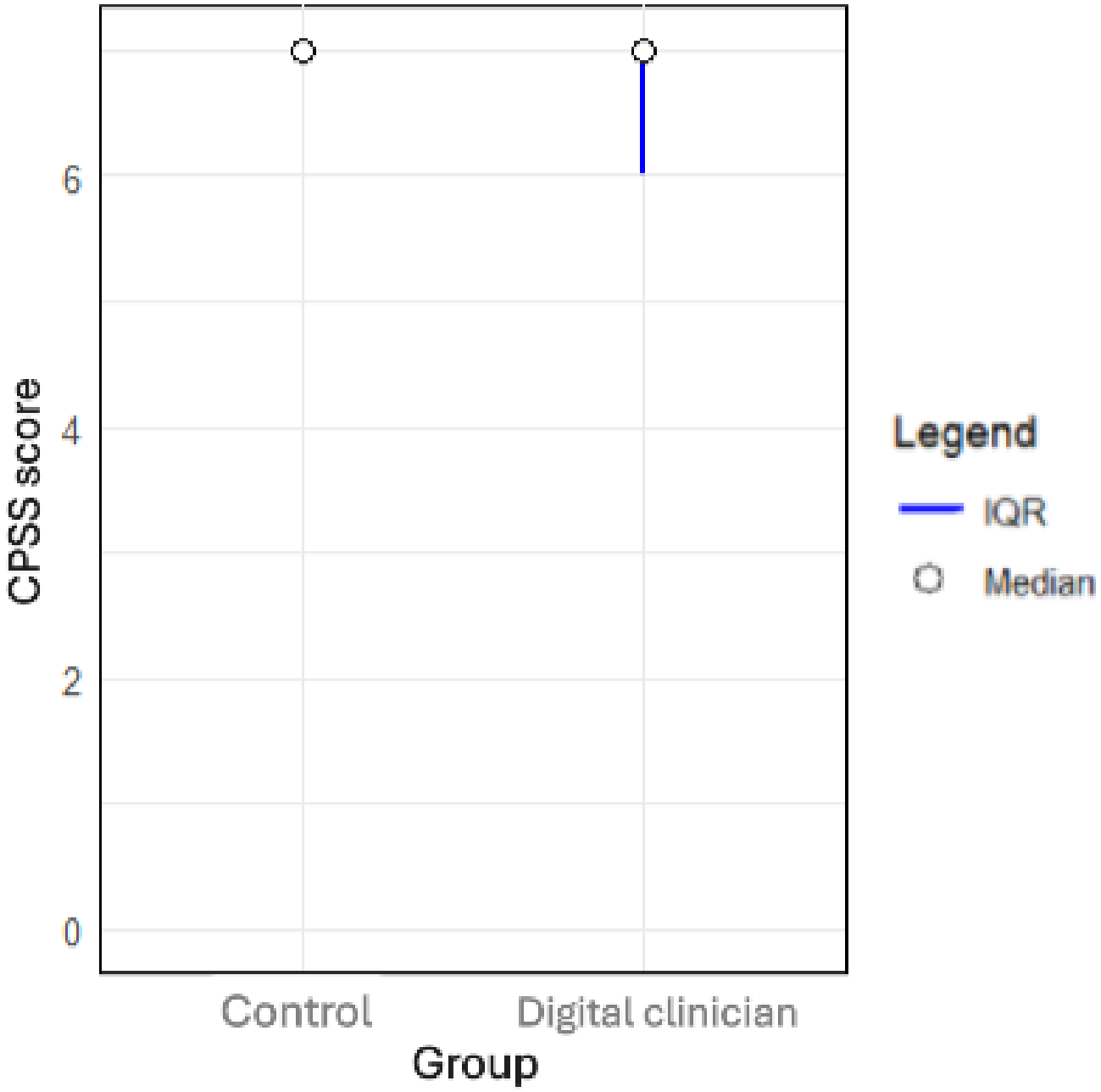


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### Knowledge (Test Score)

Overall, the median test score of participants postconsultation in the "digital clinician" group was 10/12 (84%; IQR 10-11), while the median score in the control group was 8/12 (69%; IQR 7-9*; P*<.001; Figure 3, Table 3).

**Figure 3.** Knowledge scores across control and digital clinician groups. SIAQ: Self Injection Assessment Questionnaire.






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**Table .** Knowledge, trust, and satisfaction levels were assessed in participants that received their education from both the "digital clinician" and the clinical nurse specialist (controls).

| Secondary Outcome | Digital clinician (n=27), median (IQR) | Control (n=16), median (IQR) | *P* value |
|---|---|---|---|
| Knowledge | 10.0 (10.0-11.0) | 8.0 (7.0-9.3) | <.001 |
| Trust-Distrust Scale Domain | | | |
| I am confident of the nurse's knowledge and skills | 7.0 (7.0-7.0) | 7.0 (7.0-7.0) | .18 |
| The nurse cares about you as a person | 6.0 (4.0-7.0) | 7.0 (7.0-7.0) | .003 |
| I am (not) suspicious of the nurse's intentions and actions | 5.0 (1.5-7.0) | 7.0 (6.0-7.0) | .002 |
| Overall Trust | 7.0 (4.8-7.0) | 7.0 (7.0-7.0) | <.001 |
| Consultation Satisfaction | | | |
| Overall Satisfaction | 7.0 (6.0-7.0) | 7.0 (7.0-7.0) | <.001 |

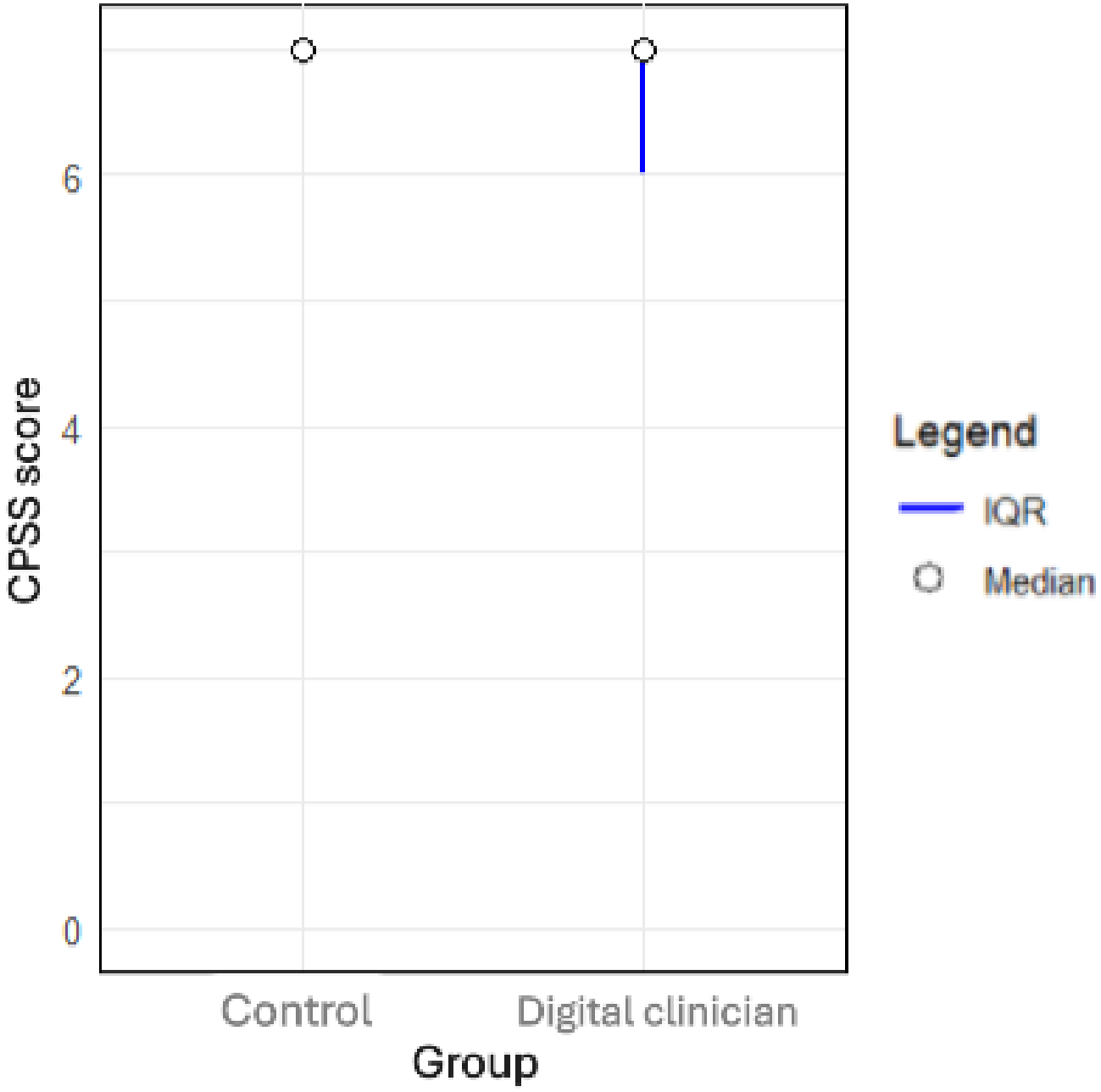
## Consultation Satisfaction

In total, 44% (12/27) respondents in the "digital clinician" group were more than 90% satisfied. The lowest score was 63%. In the control group, 94% (15/16) respondents were more than 90% satisfied with their consultation. The lowest score was 86%. The IQR of the "digital clinician group" was 6-7 (median 7), whereas it was 7-7 (median 7) in the control group (Mann-Whitney *P*<.001). This is shown in Figure 4 and Table 3 on a Likert scale between 1 and 7.



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**Figure 4.** Satisfaction scores across control and digital clinician groups. CPSS: Overall Satisfaction with Primary Care Physicians Scale




### Trust

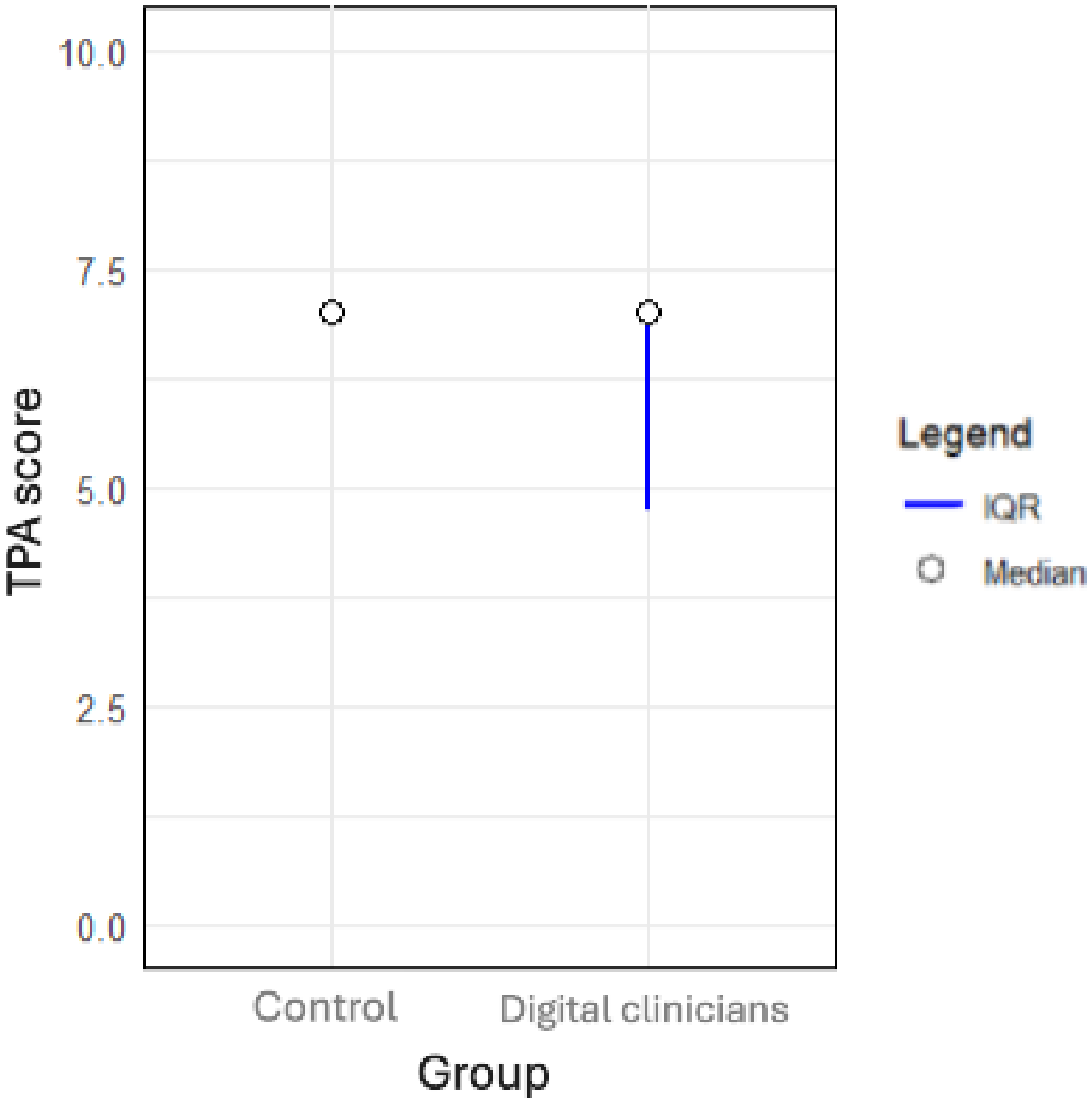
Figure 5 shows that participants in the "digital clinician" group scored their education provider lower for empathy ($P$=.003), clear intentions ($P$=.002), and overall trust ($P$<.001).

While Figures 4 and 5 show that the medians of the ordinal data are the same, the Mann Whitney U test is nonparametric and is not dependent on central tendency. As nonparametric data can be asymmetrical by nature, central tendency can be misleading. While the medians are the same, the IQR and ranks of the groups are shown to be significantly different with a $P$ value <.05.



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**Figure 5.** Trust scores across control and digital clinician groups. TPA: Trust between People and Automation Scale.




### Resource Quality

On a scale of 100, the "digital clinician" was found to be 86.667 usable (Table 4), scoring lowest for interface quality and highest for interaction quality.

Of the 27 participants in the intervention group, 22 (81%) of participants affirmed they would use the "digital clinician" for educational purposes in their own time, while 2 (7%) of participants recorded that "maybe" they would. A total of 3 (11%) said they would not.



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**Table .** The Usability of the "digital clinician" was rated by the user across three domains, scoring highest for interaction quality and ease of use, with 82% of users reporting they would use the resource in their own time.

| Usability Domain | Values, mean (SD) |
|---|---|
| Interaction quality | 89.6 (15.1) |
| Interface quality | 81.5 (17.4) |
| Ease of use | 88.9 (16.0) |
| Overall | 86.7 (16.4) |
| Would you use this resource in your own time? n (%) | |
| Yes | 22 (82) |
| No | 3 (11) |
| Maybe | 2 (7) |

### Analysis of Open-Ended Feedback

Below are the described questions about the analysis of open-ended feedback.

> *Question: "What do you think about using avatars with automated conversation in a healthcare environment?"*

Four responses made reference to a great invention or great possibility for future use. Seven said the idea was good, or very good. Four described it as "okay." One respondent felt the avatar was "not ideal," and another stated they would "prefer a human." Two responses were of mixed sentiment:

> *"I don't think the real nurse can be replaced but it is great tool for people who live far away to refer to"… "They are helpful but. They are not as good as having a human explaining things to you.*"

> *Question: "What concerns would you have about using avatars with automated conversation like this in the future?"*

Twelve responded that they would have no issues using the resource. Two expressed concerns over technical issues, such as freezing and audio quality. One expressed concern over language barriers. Four expressed concerns regarding the lack of empathy or possible loss of personal touch. One expressed concern over the ability of the avatar to answer the questions required. In total, 20% - 25% expressed some form of apprehension. The prevalence of triggering the wrong conversational stream was not formally measured in the study; however, users did not remark on it when providing open-ended feedback on usability.

> *Question: "Any other comments?"*

Two responses:

> *good to use at home*

> *Needle testing could have been shown twice*

### Missing Data

Those with complete data had higher levels of education, female sex, were less trusting of (*P*=.04) and less satisfied (*P*=.03) with their health care professional than those lost to follow-up (Multimedia Appendix 3). However, the response rates of those in "digital clinician" and the "control" groups at follow-up were similar, as were measures of knowledge, self-efficacy, and usability.

## Discussion

### Principal Findings

Those who received education from the digital clinician were significantly more knowledgeable about their medication and its administration. They tended to have less stress and anxiety associated with using their injections, though this was not significant. Paradoxically, they had less confidence administering injections. They also trusted that their education provider was significantly less than those in the control group and were significantly less satisfied with their consultation. This suggests that from a health care psychology standpoint, participants' injection-related confidence was more related to who they received their information from, rather than how well informed they were.

While being less satisfied than those in the control group, the intervention group still reported very high levels of trust and satisfaction at levels, with median levels of 7/7 in both measures. Participants were extremely positive about the intervention, with more than 80% of participants expressing that they would use the resource in their own time. If not used clinically, distribution of a "digital clinician" for home use could also add value. The study did not recruit adequate numbers to test noninferiority at the predetermined level of self-efficacy due to global semaglutide shortages hindering patient access. However, there were significant differences in a range of secondary outcomes.

Human clinician-patient interactions are not scripted. They are shaped by human factors, including rapport and variability. Consultations with the "digital clinician" are more uniform and consistent. This may explain why a human was more successful at ensuring trust and satisfaction, while the "digital clinician" was more effective at ensuring information was provided, tested, and retained.

Certain studies have compared physicians versus chatbots, in educational settings, by assessing accuracy. No study has been uncovered showing that patients themselves were better educated by a chatbot or an LLM than by a specialist clinician. It is one thing to assess what information the chatbot is providing; it is



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another thing to assess if a patient is receiving, retaining, and trusting that information. Moving forward, only the true benefit of "digital clinicians" can be judged when research examines the risks and benefits of integration on a systemic level.

Standards for new technologies should be established to enable regulation, safety, and trust. Bespoke task-specific conversation streams such as this, which mimic large language models, may be easier to control and regulate while taking advantage of growing trust and recognition in the public domain.

Automation may incorporate tradeoffs in patient satisfaction and health care system trust, but may offer benefits in comprehensiveness, efficacy, and uniformity. Tradeoffs could potentially be minimized through research, human oversight, and clear physician accountability. The opportunity cost of using these technologies or not should be considered in terms of productivity, finance, access, and workforce and patient health.

### Limitations

Limitations of the study include the loss of participants to follow-up questioning due to a global shortage of semaglutide, possibly contributing to some of the nonsignificant results in the study. There were significant missing data at the 2-week follow-up, which were omitted from analysis. Table S1 in Multimedia Appendix 4 shows the different profile of responders at the 2-week follow-up. Responders tended to have stronger views and were not a reliable representation of the initial cohort, making the conclusions regarding self-efficacy less applicable to the general population.

Nonvalidated measures of knowledge and adapted measures of usability, trust, and consultation satisfaction were used. While the trial design focuses on intergroup analyses, nonvalidated measures preclude direct comparison of the study cohort with the study population, as existing data for the latter does not exist using the same parameters. As a result, nonvalidated and adapted measures may not correlate well with other health outcomes such as compliance or the incidence of side effects as established measures.

This feasibility trial, while not measuring traditional health outcomes, would have been strengthened by prospective trial registration, a prerequisite for all interventional AI trials from January 01, 2025 [38]. Trial registration was initially omitted from the design process. Contributing factors included the novelty of the intervention and the relative sparsity of an established industry proforma at the time. During the trial and data analysis period, further recognition of AI use as a significant health care intervention led to the emergence of industry directives, prompting reflection and retrospective trial registration. While not included in this study, further longitudinal research could focus on clinical outcomes such as adherence to therapy or weight loss over longer periods (eg, 1 year).

### Conclusion

There is a worsening shortage of health care workers globally. Systems are not adapting to keep up with demand in areas such as bariatric medicine. "Digital clinicians,"chatbots integrated with digital avatar and emotional intelligence technology, may be part of scalable AI solutions.

"Digital clinicians" may ensure higher levels of information retention among patients compared with humans. However, users have significantly lower levels of trust and satisfaction in their information provider. Despite not being as satisfied, users are still overwhelmingly positive about their consultation, with over 80% saying they would use the resource in their own time.

Offering a degree of automation feasibly allows existing health care workers to focus on more demanding tasks, reduce stress, and improve health care system performance. It may offer more patients and systems access to medication and resources, provided they have the necessary internet connection and operability.

Safety should be established through regulation and research to improve trust and satisfaction. Ethical principles such as human oversight and accountability should build on this. Rigorous policy analysis should be performed to assess the potential tradeoffs in using these technologies as AI becomes more widespread across resource-rich and resource-poor contexts.

## Conflicts of Interest

Kate Loveys is a former employee of and contractor to Soul Machines. Elizabeth Broadbent is a former contractor to Soul Machines. Francis Finucane is an investigator (unpaid) on the REDEFINE 2 and REDEFINE 3 randomized controlled trials, run by Novo Nordisk. He is a paid member of the Data Safety and Monitoring Board for the LEGEND and LEAP randomised controlled trials, run by the University of Michigan. He was a paid reviewer for the Danish Diabetes Academy until 2024.

Multimedia Appendix 1
Video of digital clinician in use.
[MP4 File, 204026 KB - diabetes_v10i1e63503_app1.mp4 ]

Multimedia Appendix 2
Outcome measures.
[DOCX File, 66 KB - diabetes_v10i1e63503_app2.docx ]



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Multimedia Appendix 3
Trial protocol.
[PDF File, 136 KB - diabetes_v10i1e63503_app3.pdf ]

Multimedia Appendix 4
Self-efficacy scores across control and digital clinician groups.
[PDF File, 175 KB - diabetes_v10i1e63503_app4.pdf ]

Checklist 1
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File, 12518 KB - diabetes_v10i1e63503_app5.pdf ]

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## Abbreviations

**AI:** artificial intelligence
**CONSORT-AI:** Consolidated Standards of Reporting Trials- Artificial Intelligence
**SIAQ:** Self-Injection Assessment Questionnaire
**SPIRIT-AI:** S
**SPIRIT-AI :** Standard Protocol Items: Recommendations for Interventional Trials involving Artificial Intelligence
**TUQ:** Technology Usability Questionnaire
**WHO:** World Health Organization



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# eHealth Literacy and Its Association With Demographic Factors, Disease-Specific Factors, and Well-Being Among Adults With Type 1 Diabetes: Cross-Sectional Survey Study

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## Abstract

**Background:** The use of digital health technology in diabetes self-care is increasing, making eHealth literacy an important factor to consider among people with type 1 diabetes. There are very few studies investigating eHealth literacy among adults with type 1 diabetes, highlighting the need to explore this area further.

**Objective:** The aim of this study was to explore associations between eHealth literacy and demographic factors, disease-specific factors, and well-being among adults with type 1 diabetes.

**Methods:** The study used data from a larger cross-sectional survey conducted among adults with type 1 diabetes in Sweden (N=301). Participants were recruited using a convenience sampling method primarily through advertisements on social media. Data were collected between September and November 2022 primarily through a web-based survey, although participants could opt to answer a paper-based survey. Screening questions at the beginning of the survey determined eligibility to participate. In this study, eHealth literacy was assessed using the Swedish version of the eHealth Literacy Scale (Sw-eHEALS). The predictor variables, well-being was assessed using the World Health Organization-5 Well-Being Index and psychosocial self-efficacy using the Swedish version of the Diabetes Empowerment Scale. The survey also included research group–developed questions on demographic and disease-specific variables as well as digital health technology use. Data were analyzed using multiple linear regression presented as nested models. A sample size of 270 participants was required in order to detect an association between the dependent and predictor variables using a regression model based on an *F* test. The final sample size included in the nested regression model was 285.

**Results:** The mean Sw-eHEALS score was 33.42 (SD 5.32; range 8 - 40). The model involving both demographic and disease-specific variables explained 31.5% of the total variation in eHealth literacy and was deemed the best-fitting model. Younger age (*P*=.01; B=–0.07, SE=0.03;95% CI –0.12 to –0.02), lower self-reported glycated hemoglobin levels (*P*=.04; B=–0.06, SE=0.03; 95% CI –0.12 to 0.00), and higher psychosocial self-efficacy (*P*<.001; B=3.72, SE=0.53; 95% CI 2.68-4.75) were found associated with higher Sw-eHEALS scores when adjusted for demographic and disease-specific variables in this model. Well-being was not associated with eHealth literacy in this study.

**Conclusions:** The demographic and disease-specific factors explained the variation in eHealth literacy in this sample. Further studies in this area using newer eHealth literacy tools are important to validate our findings. The study highlights the importance of development and testing of interventions to improve eHealth literacy in this population for better glucose control. These eHealth literacy interventions should be tailored to meet the needs of people in varying age groups and with differing levels of psychosocial self-efficacy.

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**KEYWORDS**

cross-sectional studies; diabetes mellitus, type 1; digital technology; eHealth literacy; health literacy



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## Introduction

Self-care in type 1 diabetes imposes considerable challenges on the individual due to the complexities of insulin therapy and the lifestyle management it requires [1]. It is described as a constraining disease that is manageable through various approaches and support [2]. Advancements in digital devices and software applications designed to aid in diabetes self-care—digital health technology (DHT)—have helped ease these self-care challenges and people's management of diabetes in their daily lives [1,3]. DHT includes devices and applications that support lifestyle modifications, monitor glucose levels, and adjust therapy. They include blood glucose meters, continuous glucose monitoring (CGM), continuous subcutaneous insulin infusion (CSII) pumps, automated insulin dosing (AID) or hybrid closed loop systems, smart insulin pens, and associated mobile health (mHealth) apps [3]. These have been found to improve glucose outcomes in people with diabetes [3-5]. Research shows an increase in the use of CGM [4], CSII [5], and AID [4] in recent years. As per the data available in the Swedish National Diabetes Register, 93.5% of adults with type 1 diabetes use CGM, and 33.1% use insulin pumps, including AID [6]. However, each DHT's features and functionalities may pose challenges, such as learning to use a new device and the time required to get it to work, fatigue induced by frequent alarms, calibration requirements, the need to manage multiple devices, and possible signal loss. These factors can impact DHT uptake and use [7]. Additionally, negative attitudes toward DHTs have been associated with poor glucose control [8]. Education and awareness play an important role in fostering understanding and the effective use of advanced DHTs for diabetes [9]. Studies have found higher levels of health literacy being associated with better understanding and comfort in using CGM [10]. Therefore, when introducing various DHTs for diabetes, it is important to consider people's readiness for health technology, which includes their level of eHealth literacy [11].

eHealth literacy encompasses the ability to search, find, understand, and evaluate health-related information through electronic platforms to address or solve health issues. eHealth literacy is influenced by 6 core skills, namely, traditional literacy, health literacy, information literacy, scientific literacy, media literacy, and computer literacy. It is also influenced by people's current health conditions, educational background, health status during the time of the eHealth encounter, reason for seeking information, and the digital technologies used. This skill set evolves over time alongside the introduction of new technologies and changes in personal, social, and environmental contexts [12]. An awareness of a DHT user's eHealth literacy is important for reducing health inequalities stemming from modifiable social factors [13]. Previous studies have found that eHealth literacy is significantly associated with age [14], education [15,16], gender [14,16], income [16], employment status [17], well-being, living alone [17], psychological distress [14], quality of life, self-efficacy [18], using the internet for health-related purposes, technology readiness [15], and mHealth use [19]. High eHealth literacy has been linked to smart device use [20] and less stress while using computers [21]. Among people with diabetes, higher eHealth literacy is associated with better self-care behaviors [22,23], moderated through digital diabetes information seeking [23]. Among this population, eHealth literacy scores are significantly higher among those who are women [23], younger than 65 years, with a university education [22,23], are employed, living with others [22], and using mHealth apps [24].

The management of type 1 diabetes is complex, and DHT use for self-care and disease management is on the rise. Despite the positive impact of DHT on people's glucose outcomes [3], the changing features and functionalities related to various DHTs may pose challenges in their use. Therefore, eHealth literacy may play an important role in mastering the effective use of DHT for type 1 diabetes self-care. Studies have found that higher eHealth literacy is associated with improved digital device use. However, there are limited studies examining eHealth literacy among adults with type 1 diabetes. Exploring the associations between eHealth literacy and various predictors may help us understand the eHealth literacy needs of this population and the factors influencing it. This knowledge may help health care practitioners to develop targeted interventions to improve eHealth literacy among vulnerable groups and thereby promote effective DHT use for self-care. This is also important in promoting equity in DHT use in type 1 diabetes, which is a social responsibility [9]. Therefore, the aim of this study was to explore the associations between eHealth literacy and demographic factors, disease-specific factors, and well-being among adults with type 1 diabetes.

## Methods

This paper is part of a larger cross-sectional survey study conducted in autumn 2022 and is reported here in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [25].

### Population

The study used a convenience sampling method and included adults (≥18 years) with type 1 diabetes who could understand Swedish. Women with type 1 diabetes were excluded if pregnant due to changes in maternal insulin sensitivity during pregnancy, as this may require alterations in their treatment plan [26]. This could indirectly influence other predictor variables like well-being and psychosocial self-efficacy [27,28].

### Recruitment

Participants were recruited primarily through advertisements on social media, particularly Facebook (using the marketing feature as well as posting in private groups for people with diabetes in Sweden). In addition, advertisements were placed on the websites of various associations for people with diabetes in Sweden and at a diabetes center in a regional hospital. More details on recruitment methods are available in a previously published paper [29].

### Sample Size Calculation

The sample size was calculated using SPSS (version 28; IBM Corp). A sample size of 270 participants was required in order to detect an association between the dependent and predictor variables using a regression model. This calculation was based



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on an *F* test with 20% predictability using 25 predictors in the full model and 15% predictability with 10 predictors in the nested model at 80% power and a .05 level of significance. To account for potential missing values, we decided to include 300 participants in the study.

### Data Collection

Data were collected between September and November 2022 (approximately 2 months) until the desired sample size was reached, primarily through a web-based survey (Survey&Report platform by Artisans Media). The survey could be accessed via a website link or QR code provided in the advertisement flyer. Three screening questions (age, diabetes type, and pregnancy status) at the beginning of the survey helped determine eligibility to participate. The survey closed automatically if any of the exclusion criteria were met. Alternatively, participants could opt to answer a paper-based survey, which was sent to the address they provided (n=6). The survey was in Swedish and was part of a larger study. It had 64 questions in total, and data from 55 questions have been included in this paper. Certain questions were marked as mandatory, requiring participants to answer them before proceeding to the next page. Additionally, questions that were not applicable were hidden based on the participant's responses to the preceding question. Thus, the number of questions each participant answered varied from 53 to 64. Participants had the option to partially complete the survey and save their progress to finish it at a later time. Therefore, the duration taken to answer the web-based survey varied highly from 5 minutes to 1.5 days. The majority (273/295, 92.5%) answered the web-based survey in 60 minutes, with 15.2% (45/295) answering it in less than 8 minutes.

### Ethical Considerations

This study was conducted in accordance with the World Medical Association's Helsinki Declaration. The study plan was reviewed by the Swedish Ethical Review Authority, and ethics approval (Dnr: 2021-05337-01 and Dnr: 2022-04079-02) was received for this paper before the commencement of data collection. Participation in the survey was voluntary, and informed consent was obtained from all participants either via the survey tool or in written form. The participants did not receive any remuneration or compensation for their participation in the study. To deidentify the data and protect participant privacy, the raw data were pseudonymized either using the web survey tool or using codes and keys (for paper surveys). In addition, the survey tool, cloud storage (Sunet Drive), laptops, and software used in the analysis were procured by Karlstad University, ensuring the European Union's General Data Protection Regulation.

### Variables and Measurement Tools

#### *Outcome Variable*

eHealth literacy was measured using the 8-item Swedish version of the eHealth Literacy Scale (Sw-eHEALS). No additional contextual questions were used. Each item is rated on a 5-point Likert scale, ranging from 1=strongly disagree to 5=strongly agree, with a higher score indicating higher eHealth literacy. The scale has a good internal consistency (Cronbach $\alpha$=0.94). The total Sw-eHEALS score is obtained by calculating the sum of the scores of each item, with possible scores ranging from 8 to 40 [30,31]. In this paper, the eHealth literacy score was treated as a continuous variable.

#### *Predictor Variables*

The predictor variables included in this study were identified from previous research in eHealth literacy as well as diabetes self-care. Psychosocial self-efficacy, which is a measure of psychosocial adjustment to diabetes, was measured using the 23-item Swedish version of the Diabetes Empowerment Scale (Swe-DES-23). A higher Swe-DES-23 score indicates greater psychosocial self-efficacy [32,33]. The total Swe-DES-23 score (ranging from 1 to 5) was calculated by adding the scores of individual items together and dividing by the number of items. Well-being was assessed using the World Health Organization-5 Well-Being Index [34]. The total World Health Organization-5 Well-Being Index score ranges from 0 to 100, with higher scores indicating higher levels of well-being [35].

The survey also contained questions related to demographic variables, disease-specific variables, and DHT use. These questions were developed by the research group and were pilot-tested among adults with type 1 diabetes (n=9) and diabetes nurses (n=4) to validate the content. The suggestions received from the pilot test were incorporated into the main survey questionnaire. See Multimedia Appendix 1 for outline of questionnaire.

### Data Analysis

Data analysis was conducted using SPSS (version 28; IBM Corp). Mean and SD or frequency and percentages were used to describe the characteristics of the included participants. In these data, residuals were found to be normally distributed, homoscedastic, and free from multicollinearity. Nested linear regression models were used to identify the best-fitting model. Predictor variables were grouped into 3 blocks. Block 1 consisted of demographic variables, block 2 comprised disease-specific variables, and block 3 involved well-being. Model 1 included variables from block 1, model 2 included variables from block 1 and block 2, and model 3 encompassed variables from all 3 blocks. Multiple linear regression was run using the enter method to identify the best-fitting model. A *P* value of <.05 was considered to be statistically significant. No imputations were performed for missing values.

## Results

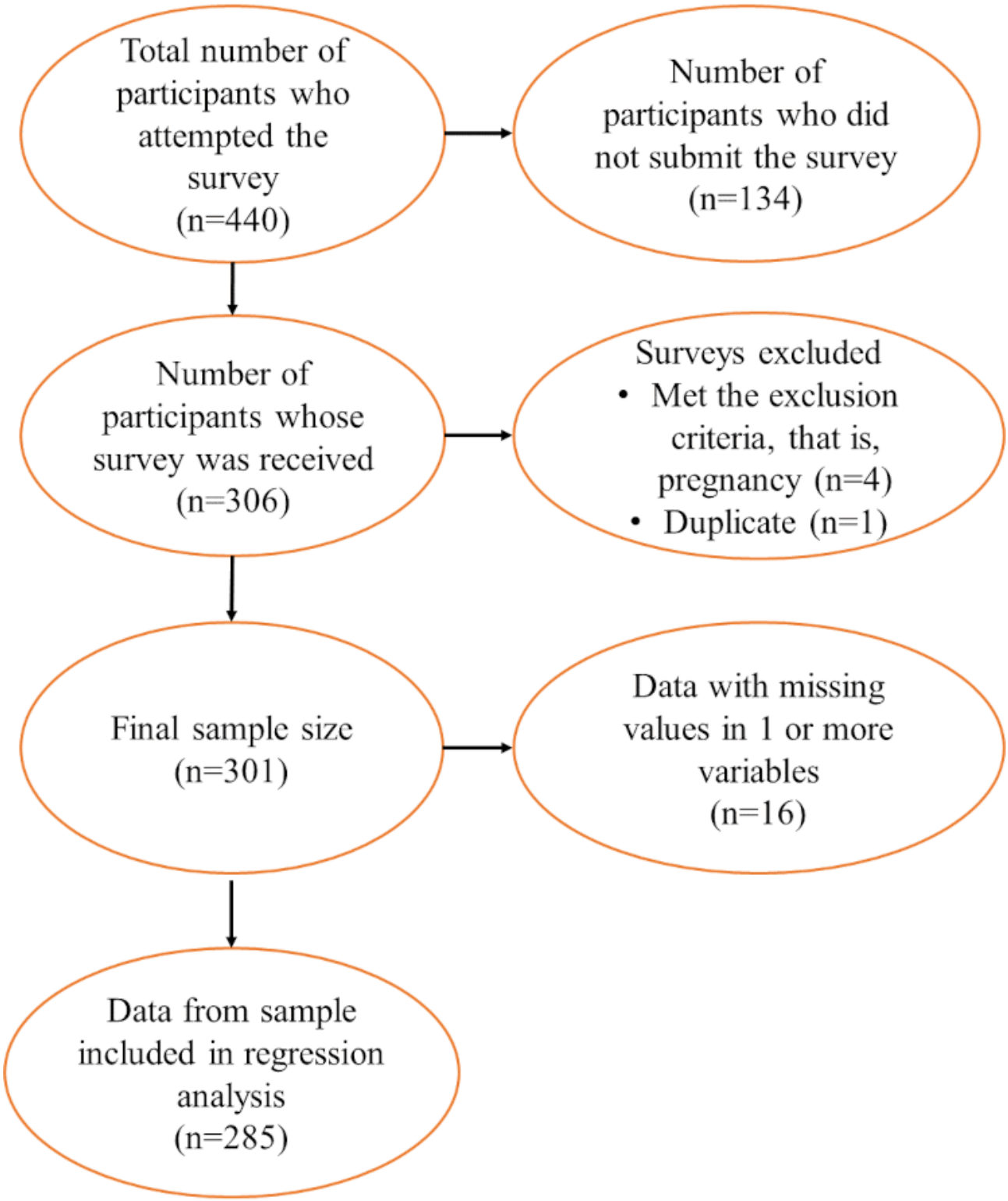
### Characteristics of the Study Sample

The final sample size achieved was 301. Data from participants with missing values in 1 or more of the predictor variables were excluded from the regression analysis (n=16), resulting in a sample size of 285 participants for analysis. A survey completion rate of 68.4% (301/440) was achieved for the web-based survey. This was calculated by dividing the number of participants who completed the survey and was included in the final sample by the total number of participants who initiated answering the survey (see Figure 1 for more details).



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**Figure 1.** Flowchart of participants included in the study and in regression analysis.

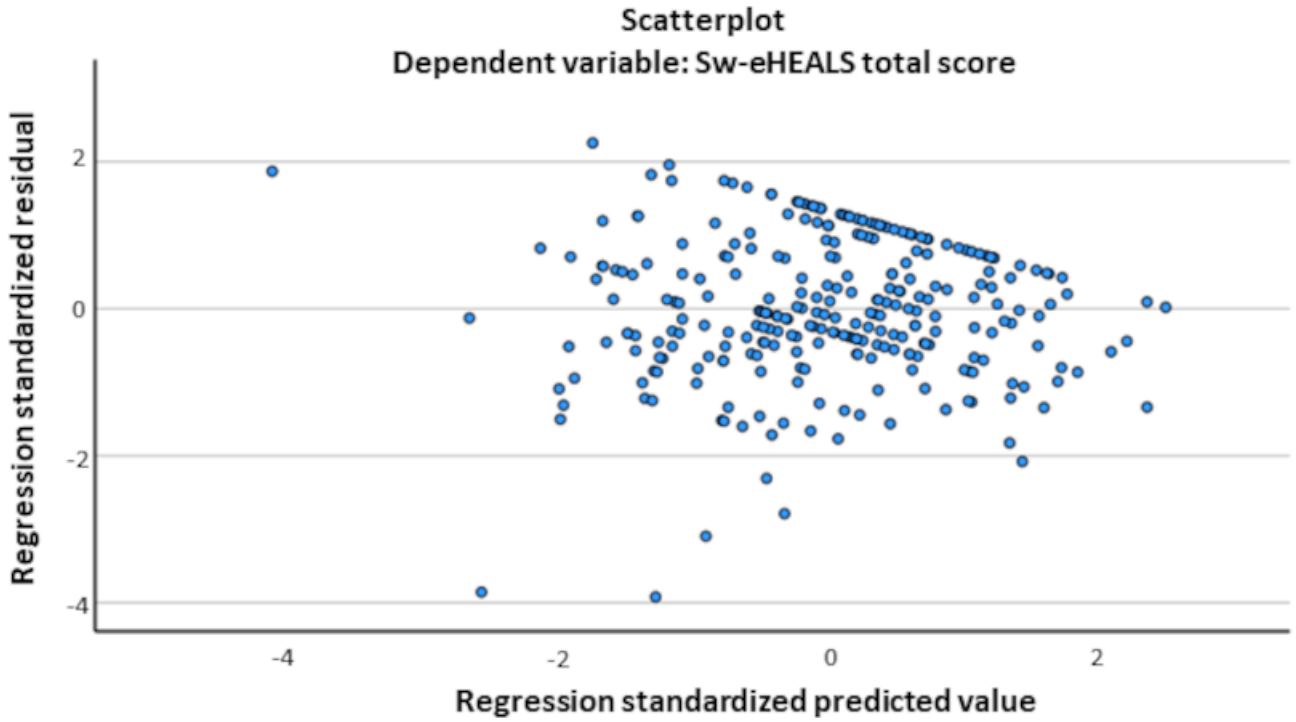



The mean Sw-eHEALS score among this sample was 33.42 (SD 5.32; range 8 - 40). A ceiling effect in the Sw-eHEALS score (with the maximum score of 40 achieved by 56/301, 18.6% of participants) was found in this sample (see Figure 2 for more details). The majority of participants completed the survey digitally (295/301, 98%). Participants had a mean age of 43 (SD 16) years, with the majority being women (215/301, 71.4%). See Table 1 for descriptive statistics on variables included in the regression analysis. All participants (301/301, 100%) reported using 1 or more forms of digital device for their diabetes self-care. Digital device use by participants consisted of blood glucose meters (146/301, 48.5%), intermittent scanning CGM (119/301, 39.5%), real-time CGM (156/301, 51.8%), CSII (102/301, 33.9%) pumps, AID (71/301, 23.6%), and smart insulin pens (28/301, 9.3%). See Table 2 for details on the Sw-eHEALS score in relation to DHTs used by the participants.



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**Figure 2.** Scatter plot depicting ceiling effect in Sw-eHEALS total score. Sw-eHEALS: Swedish version of the eHealth Literacy Scale.






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**Table .** Descriptive statistics of variables included in the regression analysis.

| Predictor variables | Values |
|---|---|
| Demographic variables | |
| Age (years) (N=301) | |
| Mean (SD) | 42.7 (15.8) |
| Range | 18 - 86 |
| Gender (N=301), n (%) | |
| Women | 215 (71.4) |
| Men | 86 (28.6) |
| Education level (n=299)[a], n (%) | |
| University level education | 167 (55.9) |
| Primary or secondary school | 132 (44.1) |
| Employment status (N=301), n (%) | |
| Studying | 47 (15.6) |
| Employed full or part time | 191 (63.5) |
| Unemployed or sick or retired | 63 (20.9) |
| Living condition (N=301), n (%) | |
| Living alone | 73 (24.3) |
| Living with a spouse or partner or another adult | 131 (43.5) |
| Living with a spouse or partner or another adult or with children | 97 (32.2) |
| Income level[b] (SEK[c]) (n=300)[a], n (%) | |
| ≤24,999 | 114 (38) |
| 25,000 - 34,999 | 76 (25.4) |
| 35,000 - 44,999 | 64 (21.3) |
| ≥45,000 | 46 (15.3) |
| Disease-specific variables | |
| Chronic diabetes complications (N=301), n (%) | |
| No chronic complication | 214 (71.1) |
| 1 chronic complication | 56 (18.6) |
| 2 or more chronic complications | 31 (10.3) |
| Multimorbidity (n=300)[a], n (%) | |
| No other illness | 166 (55.3) |
| 1 other illness | 78 (26) |
| ≥2 other illness | 56 (18.7) |
| Duration of diabetes (years) (N=301) | |
| Mean (SD) | 21.7 (16.8) |
| Range | <1 - 75 |
| $HbA_{1c}$[d] (mmol/mol) (n=290)[a] | |
| Mean (SD) | 51.4 (11) |
| Range | 30 - 107 |
| Swe-DES-23[e] total (N=301) | |
| Mean (SD) | 3.8 (0.6) |
| Range | 2.0 - 5.0 |



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| Predictor variables | Values |
|---|---|
| BMI (kg/m$^2$) (n=300)[a] | |
| Mean (SD) | 26.7 (5.1) |
| Range | 16.8 - 46.3 |
| Well-being | |
| WHO-5[f] total (n=300)[a] | |
| Mean (SD) | 56 (19.9) |
| Range | 4.0 - 100 |

[a]Total number of cases is not 301 for all variables due to missing values.

[b]Income level refers to monthly income before tax deductions.

[c]SEK: Swedish Kronor. A currency exchange rate of 1 SEK=US $0.10 is applicable.

[d]$HbA_{1c}$: glycated hemoglobin.

[e]Swe-DES-23: Swedish version of Diabetes Empowerment Scale.

[f]WHO-5: World Health Organization-5 Well-Being Index.



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**Table .** Swedish version of the eHealth Literacy Scale (Sw-eHEALS) score in relation to digital health technology (DHT) used by the participants.

| DHT used | Values, n (%) | Sw-eHEALS score, mean (SD) |
|---|---|---|
| Digital device use (n=300) | | |
| 3 or more digital device | 73 (24.3) | 34.2 (4.9) |
| 2 digital device | 160 (53.4) | 33.2 (5.8) |
| 1 digital device | 67 (22.3) | 33.1 (4.4) |
| mHealth[a] app use (n=301) | | |
| Users | 241 (80.1) | 33.6 (5.3) |
| Nonusers | 60 (19.9) | 32.7 (5.5) |
| mHealth app feature type (n=241) | | |
| Automatic data transfer from devices to mHealth app | | |
| Users | 224 (92.9) | 33.8 (5.2) |
| Nonusers | 17 (7.1) | 31.4 (5.9) |
| Glucose entry | | |
| Users | 220 (91.3) | 33.7 (5.3) |
| Nonusers | 21 (8.7) | 32.9 (4.6) |
| Warning alarm for high or low glucose levels | | |
| Users | 203 (84.2) | 33.7 (5.4) |
| Nonusers | 38 (15.8) | 32.8 (4.6) |
| Graphical features | | |
| Users | 162 (67.2) | 34.3 (4.5) |
| Nonusers | 79 (32.8) | 32.1 (6.4) |
| Insulin dose registration | | |
| Users | 116 (48.1) | 34.1 (4.9) |
| Nonusers | 125 (51.9) | 33.1 (5.5) |
| Reminder | | |
| Users | 105 (43.6) | 34.4 (4.9) |
| Nonusers | 136 (56.4) | 33.0 (5.5) |
| Carbohydrate calculator | | |
| Users | 86 (35.7) | 34.0 (4.9) |
| Nonusers | 155 (64.3) | 33.4 (5.5) |
| Physical activity monitoring | | |
| Users | 78 (32.4) | 34.1 (4.9) |
| Nonusers | 163 (67.6) | 33.4 (5.4) |
| Diet monitoring | | |
| Users | 68 (28.2) | 34.6 (4.9) |
| Nonusers | 173 (71.8) | 33.2 (5.3) |
| Contacting or data sharing with health care personnel or relatives | | |
| Users | 56 (23.2) | 34.5 (4.3) |
| Nonusers | 185 (76.8) | 33.3 (5.5) |
| Insulin bolus calculator | | |
| Users | 46 (19.1) | 33.9 (5.4) |
| Nonusers | 195 (80.9) | 33.5 (5.2) |



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[a]mHealth: mobile health.

### Predictors of eHealth Literacy

Nested linear regression models were used to explore the associations between the outcome variable, eHealth literacy, and predictor variables. Model 1, comprising demographic variables alone, accounted for 12.9% of the total variation in eHealth literacy, with age, education level, and income level showing associations with the Sw-eHEALS score. Model 2, involving both demographic and disease-specific variables, explained 31.5% of the total variation in eHealth literacy and was deemed the best-fitting model. In model 2, the predictors' age, glycated hemoglobin ($HbA_{1c}$), and psychosocial self-efficacy showed associations with the Sw-eHEALS score after adjusting for demographic and disease-specific variables. Model 3, involving all predictors (ie, demographic and disease-specific variables and well-being), explained 31.6% of the variance in eHealth literacy. However, the *F* change for this model was not significant and therefore is not presented here. See Table 3 for detailed results of the regression analyses.



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**Table .** Nested multiple linear regression models on the association between eHealth literacy (Swedish version of the eHealth Literacy Scale) and potential predictive variables (n=285).

| Potential predictive variables | Model 1: demographic variables[a] | | | Model 2: demographic and disease-specific variables[b] | | |
|---|---|---|---|---|---|---|
| | B[c] (SE) | 95% CI | *P* value | B[c] (SE) | 95% CI | *P* value |
| Constant | 30.24 (2.18) | 25.94 to 34.53 | <.001 | 18.50 (3.69) | 11.24 to 25.76 | <.001 |
| Age (years) | –0.06 (0.03) | –0.11 to 0.00 | .04 | –0.07 (0.03) | –0.12 to –0.02 | .01 |
| Gender (reference=men) | | | | | | |
| Women | 0.25 (0.71) | –1.15 to 1.66 | .72 | 0.74 (0.65) | –0.54 to 2.02 | .26 |
| Living condition (reference=living alone) | | | | | | |
| Living with a spouse or partner or another adult | 0.67 (0.78) | –0.87 to 2.21 | .39 | 0.22 (0.71) | –1.18 to 1.62 | .76 |
| Living with a spouse or partner or another adult or with children | 0.62 (0.85) | –1.06 to 2.30 | .47 | 0.31 (0.78) | –1.23 to 1.85 | .69 |
| Education level (reference=primary or secondary school) | | | | | | |
| University level education | 1.91 (0.66) | 0.61 to 3.22 | .004 | 1.19 (0.61) | –0.01 to 2.40 | .053 |
| Employment status (reference=employed full or half time) | | | | | | |
| Unemployed or sick or retired | 0.18 (1.06) | –1.91 to 2.27 | .87 | –0.24 (1.03) | –2.27 to 1.80 | .82 |
| Studying | 1.41 (1.19) | –0.93 to 3.75 | .24 | 0.62 (1.10) | –1.55 to 2.78 | .58 |
| Income level[d] (SEK[e]) (reference is ≤24,999) | | | | | | |
| 25,000 - 34,999 | 1.71 (1.02) | –0.30 to 3.71 | .09 | 1.03 (0.95) | –0.85 to 2.91 | .28 |
| 35,000 - 44,999 | 2.65 (1.11) | 0.47 to 4.83 | .02 | 1.53 (1.03) | –0.50 to 3.57 | .14 |
| ≥45,000 | 2.91 (1.23)[d] | 0.49 to 5.33 | .02 | 1.67 (1.13) | –0.55 to 3.89 | .14 |
| Diabetes complication (reference=no complication) | | | | | | |
| 1 complication | —[f] | — | — | 1.10 (0.75) | –0.39 to 2.58 | .15 |
| 2 or more complications | — | — | — | 1.34 (1.08) | –0.80 to 3.47 | .22 |
| Multimorbidity (reference=no other illness) | | | | | | |
| 1 other illness | — | — | — | –0.33 (0.66) | –1.62 to 0.97 | .62 |
| 2 or more other illness | — | — | — | –1.02 (0.78) | –2.56 to 0.51 | .19 |
| BMI (kg/m$^2$) | — | — | — | 0.08 (0.06) | –0.03 to 0.19 | .15 |
| $HbA_{1c}$[g] (mmol/mol) | — | — | — | –0.06 (0.03) | –0.12 to 0.00 | .04 |
| Duration of diabetes (in years) | — | — | — | 0.00 (0.02) | –0.04 to 0.04 | .93 |
| Swe-DES-23[h] total score | — | — | — | 3.72 (0.53) | 2.68 to 4.75 | <.001 |

[a]Multiple $R^2$=0.129; $R^2$ change=0.129; $F_{10}$ change=4.07; significance of *F* change <.001 (statistically significant at *P*<.05).

[b]Multiple $R^2$=0.31; $R^2$ change=0.19; $F_8$ change=9.04; significance of *F* change <.001 (statistically significant at *P*<.05).

[c]Unstandardized β value.

[d]Income level refers to monthly income before tax deductions.

[e]SEK: Swedish Kronor. A currency exchange rate of 1 SEK=US $0.10 is applicable.



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[f]Not applicable.

[g]$HbA_{1c}$: glycated hemoglobin.

[h]Swedish version of Diabetes Empowerment Scale.

## Discussion

### Principal Findings and Comparison to Prior Work

This study explored associations between eHealth literacy and demographic factors, disease-specific factors, and well-being among adults with type 1 diabetes. The sample in this study was slightly younger, predominantly women, and had a shorter duration of diabetes compared to the statistics on adults with type 1 diabetes published by the Swedish National Diabetes Register [6]. The majority of the participants in this study had a university-level education, which is not in line with studies reporting on type 1 diabetes population from Sweden [36] or other countries [37]. The mean Sw-eHEALS score among this sample was higher than that found in other studies among people with type 2 diabetes [38], the general population [30], and older adults [14] in Sweden and in other cultural and language settings [39]. Comparable empirical studies on eHealth literacy among adults with type 1 diabetes were not found. The mean Sw-eHEALS score is slightly higher among participants who use 3 or more digital devices, mHealth app users, and users of various features. However, this difference is too minor to draw a conclusion.

Similar to our results, other studies have found that younger age [14,22] and self-efficacy [18,40] are associated with higher eHealth literacy scores. However, in contrast to our findings, some studies found no association between eHealth literacy scores and age [17,39]. Additionally, some studies did not find any association between eHealth literacy and gender [15,17], education, or income [17], which aligns with this study's findings when adjusted for disease-specific factors. Conversely, some studies found significant associations of eHealth literacy with gender [14], education level [15], employment status, well-being, and living status [17]. In this study, higher eHealth literacy was associated with lower $HbA_{1c}$ levels, but similar studies to compare our results were not found. Similar to our findings, studies have found a relationship between $HbA_{1c}$ levels and health literacy [41,42] or functional health literacy [43]. In contrast, other studies found no association between $HbA_{1c}$ levels and mobile eHealth literacy [44] or functional health literacy [45]. However, the finding on the association between higher eHealth literacy and lower $HbA_{1c}$ levels needs to be read with caution, considering the near normal range mean $HbA_{1c}$ levels, self-reported $HbA_{1c}$, ceiling effect in Sw-eHEALS, and various other uncontrolled factors that could influence $HbA_{1c}$ levels in this sample. Therefore, further studies are needed to determine the clinical relevance of this finding.

### Strengths and Limitations

eHealth literacy and its association with various factors among people with type 1 diabetes is a less studied area. This study utilized widely used and validated questionnaires to measure eHealth literacy [30,31], psychosocial self-efficacy [32,33], and well-being [46]. Other questions in the survey were pilot-tested to validate their content among the targeted population and health professionals. We achieved a sufficient sample size to perform regression analysis with adequate power. The study also had higher than average completion rates for a web-based survey [47]. The total survey response time of less than 8 minutes, which may indicate insufficient effort responding, was seen in 15.2% (45/295) of the sample who answered the web-based survey, reducing the risk of inflated correlations [48]. However, we have not done an in-depth analysis to detect and eliminate insufficient effort responding. The majority of participants were recruited via social media, allowing for recruitment from all over Sweden, which strengthens the study's transferability. Additionally, the higher rate of digital survey responses compared to paper format responses may imply that participants with higher eHealth literacy were more likely to volunteer, potentially leading to selection bias. We may also have missed participants who do not use social media. The sample in this study consisted entirely of DHT users, which is not surprising, given that CGM and CSII use is high in Sweden [6], as it is financed through a publicly funded high-cost protection scheme [49].

The outcome variable, the eHealth Literacy Scale (eHEALS) score, is a valid and reliable measure of self-reported eHealth literacy among people with chronic diseases [50]. This instrument has been widely tested, used in diverse populations, and has sufficient moderate quality evidence for comprehensibility [51]. However, the eHEALS instrument has its weaknesses. The original eHEALS measures people's perceived skills with eHealth and is an indirect measure of eHealth literacy [31]. It is a single-factor scale, which was developed before the time of social media and mHealth, prioritizing ease of administration [52]. Therefore, it is not updated to account for the current dynamicity, interactivity, and multifaceted nature of the internet, social media, and mobile web [51-53]. This has led to the development of newer, more relevant instruments to measure eHealth literacy [53-55]. Findings from this study, therefore, call for further research in this field using newer measures that account for the dynamicity and evolving nature of eHealth literacy.

The ceiling effect in the eHEALS score seen in this study (Figure 2) may have led to an inability to capture true differences between participants achieving the highest possible score, thus reducing the reliability of the results [56]. It may also point toward the outdated content validity of this instrument [56] in the current digital era. However, this ceiling effect has not been previously reported in other studies using the same instrument [30,38,39]. The results of this study, therefore, should be generalized with caution, considering the advanced DHTs currently used by people with type 1 diabetes.

### Conclusions

In this study, associations were found between eHealth literacy and age, psychosocial self-efficacy, and $HbA_{1c}$ levels. People with lower $HbA_{1c}$ levels had higher eHealth literacy scores,



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which may indicate their ability to effectively use electronic information and DHT to manage their glucose levels. Interventions to improve eHealth literacy in this population are therefore important for better glucose control. Therefore, further studies focusing on the development and testing of eHealth literacy interventions are recommended. Our results highlight the importance of considering people's age and psychosocial self-efficacy in acquiring appropriate eHealth literacy. Therefore, eHealth literacy interventions should be tailored to meet the needs of people in varying age groups and with different levels of psychosocial self-efficacy. Further studies in this area are therefore recommended.

The use of nested regression models is a strength of this study, improving data generalizability. However, the results of this paper are to be interpreted with caution, especially due to the ceiling effect observed in the eHealth literacy scores. Further studies in this area using newer eHealth literacy tools are important to validate our findings.

## Acknowledgments

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## Data Availability

The datasets generated or analyzed during this study are available from the authors on reasonable request.

## Authors' Contributions

DAS, AN, UBJ, and JN were involved in designing the study and the questionnaire. Data were collected by DAS. Additionally, DAS performed the data analysis with support from the statistician, which was critically reviewed by AN, UBJ, and JN and amended as needed. DAS drafted the first version of the manuscript, and along with AN, UBJ, and JN, critically reviewed and modified it. All 4 authors approved the final manuscript.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire outline.
[DOCX File, 117 KB - diabetes_v10i1e66117_app1.docx ]

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## Abbreviations

**AID:** automated insulin dosing
**CGM:** continuous glucose monitoring
**CSII:** continuous subcutaneous insulin infusion
**DHT:** digital health technology
**eHEALS:** eHealth Literacy Scale
**$HbA_{1c}$:** glycated hemoglobin
**mHealth:** mobile health
**STROBE:** Strengthening the Reporting of Observational Studies in Epidemiology
**Sw-eHEALS:** Swedish version of eHealth Literacy Scale
**Swe-DES-23:** Swedish version of the Diabetes Empowerment Scale

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Original Paper

# An Exergames Program for Adolescents With Type 1 Diabetes: Qualitative Study of Acceptability

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## Abstract

**Background:** Numerous barriers to moderate to vigorous physical activity exist for youths with type 1 diabetes (T1D). The virtual exercise games for youth with T1D (ExerT1D) intervention implement synchronous support of moderate to vigorous physical activity including T1D peers and role models.

**Objective:** This study aims to understand the acceptability of this intervention to participants.

**Methods:** We conducted postprogram, semistructured, televideo interviews with participating youths to elicit perspectives on the acceptability of the intervention and experience with the program. Two coders independently reviewed and analyzed each transcript using a coding scheme developed inductively by senior researchers. Discrepancies were resolved by team discussion, and multiple codes were grouped together to produce 4 main thematic areas.

**Results:** All 15 participants provided interviews (aged 14-19 years; 2 nonbinary, 6 females; median hemoglobin $A_{1c}$ level of 7.8% (IQR 7.4%-11.2%), 5 with a hemoglobin $A_{1c}$ level of ≥10%). Qualitative data revealed four themes: (1) motivation to engage in physical activity (PA)—improving their physical capabilities and stabilizing glucose levels were cited as motivation for PA and challenges of living with T1D were cited as PA barriers; (2) experience with and motivation to manage diabetes while engaging in PA—participants provided details of accommodating the inherent uncertainty or limitations of PA with diabetes and sometimes preparing for PA involved psychological and motivational adjustments while some relayed feelings of avoidance; (3) peer support encouraged engagement with the intervention—participants appreciated the peer aspects of components of ExerT1D and participants' reflections of the facilitated group experience highlight many benefits of a small-group virtual program; and (4) improvements in PA and diabetes self-management efficacy—all participants credited the program with improving or at least raising awareness of T1D management skills.



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**Conclusions:** Our virtual PA intervention using an active video game and discussion component provided adolescents with T1D the confidence and peer support to engage in PA, improved awareness of diabetes-specific tasks to prepare for exercise, and improved understanding of the effect of PA on glucose levels. Engaging youths with a virtual video game intervention is a viable approach to overcome barriers to PA for adolescents with T1D.

**Trial Registration:** ClinicalTrials.gov NCT05163912; https://clinicaltrials.gov/ct2/show/NCT05163912

***(JMIR Diabetes 2025;10:e65665)*** doi:10.2196/65665

**KEYWORDS**

diabetes education; exercise; lifestyle modification; pediatrics; psychosocial-behavioral modification; diabetes mellitus, type 1; adolescent; self-management; exergames; qualitative study; acceptability; physical activity; youths; children; interviews; physical activity intervention; virtual intervention; video game; awareness

## Introduction

Numerous changes that occur during the adolescent years present unique challenges to youths with type 1 diabetes (T1D). During this time, youths experience multiple psychosocial obstacles, including depression, anxiety, diabetes-specific emotional distress, and diabetes stigma [1]. Furthermore, adolescents have the highest glucose levels of any age group with T1D [2], which put them at greater risk of developing long-term diabetes complications (blindness, kidney failure, and cardiovascular disease). Navigating this transitional time is difficult, underscoring a vital need for interventions to provide psychosocial and educational support for adolescents with T1D.

While physical activity (PA) is well known to improve cardiovascular and mental health [3], it brings unpredictable blood glucose changes. Numerous hormones that affect glucose levels are released in response to different types of physical activity, including catecholamines, growth hormone, cortisol, and glucagon [4]; likewise, insulin sensitivity during exercise can be impacted by stress and overall energy stores [5], and incorporating all of these factors makes diabetes-specific management decisions difficult [6]. The resultant fear of hypoglycemia and diabetes distress also impedes PA [7], as does stigma, especially in group settings due to the visibility of T1D devices during PA, making them feel isolated and exposed [8,9]. Moreover, adolescents report teachers and coaches have limited T1D knowledge [10], and parents may discourage PA [7]. In summary, there are underexplored bidirectional relationships among psychosocial concerns, glycemia, and low PA among teens with T1D. Thus, it is no surprise that adolescents with T1D engage in even less PA than the general adolescent population [11]. Further, few studies have provided exercise self-management education and guided goal-setting for adolescents with T1D [12-17].

A less explored area of equal relevance is the impact of peer support [18]. Peer support involves engaging others with a shared experience and can be emotional (eg, empathy about glucose destabilization from PA), informational (eg, sharing strategies for glucose management), or instrumental (eg, testing glucose together before PA) [19]. Notably, adolescents with T1D see support from peers and peer mentors as important for general well-being [20-22].

Peer interactions among adolescents in the 21st century occur primarily over digital media. Leveraging this affinity, at least a dozen studies have tested digital, mostly asynchronous peer support interventions for adolescents with T1D to discuss diabetes self-management [23]. We sought to build upon them with the virtual exercise games for youth with T1D (ExerT1D) intervention, where participants are focused on performing movements engaging large muscles (ie, exergaming) and experiencing aspects of PA that include not only diabetes management education but also realized PA achievements, in a synchronous virtual room with peers.

Assessing acceptability is an important consideration when designing interventions. Adopting the definition of acceptability from the taxonomy of Proctor et al [18] of implementation outcomes, acceptability is defined as “the perception among implementation stakeholders that a given treatment, service, practice of innovation is agreeable, palatable, or satisfactory.” Studies to assess acceptability enable researchers to identify potential facilitators and barriers to an intervention by eliciting participant feedback. Findings can inform modifications to an existing protocol to further improve the intervention prior to attempting large-scale clinical trial or scaling up the intervention. To understand the acceptability of ExerT1D, we conducted semistructured interviews with all enrollees to complement quantitative evaluations reported elsewhere, in which participant acceptability of this intervention was demonstrated with results from survey data [19]. This paper will focus on the findings from a qualitative evaluation by eliciting participant perspectives on the acceptability of various aspects of the intervention as well as implications for their self-management practices to provide insight into the acceptability of ExerT1D.

## Methods

### Participants and Recruitment

The study was approved by the Yale University institutional review board (2000030105) and registered on ClinicalTrials.gov (NCT05163912). Eligibility for the intervention (see the Intervention Overview section) included youths aged 14-19 years with a T1D diagnosis for at least 6 months, meeting 60 minutes of moderate to vigorous PA (MVPA) fewer than 50% of days, and participants needed to be able to read and speak English. Participants needed to be seen regularly by a clinician specializing in diabetes who could be contacted for safety concerns or insulin dose adjustments. Recruitment occurred at the Yale Children’s Diabetes Center and through an internet posting circulated on Facebook by the nonprofit Children with



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Diabetes (T1-Today, Inc) which provides education and support to youths with T1D and their families.

### Ethical Considerations

This study was approved by the Institutional Review Board of the Yale Human Investigation Committee (#2000030105). Informed consent or parental permission and assent (younger than 18 years), including the option to be audiotaped for interviews (all participants accepted), were completed prior to any study activities. Participants were required to complete an institutional review board–approved assent form in English, while their parents completed a parental permission form (consent) in English or Spanish. Participants were excluded if they had a medical condition that would limit MVPA participation. Consent was performed in either English or Spanish by our study team. Spanish-speaking families were included as long as the participant met the criteria of reading and speaking English. The research team included a speaker fluent in Spanish (JM).

Each participant was given a unique study identifier to protect their privacy. Interviews were transcribed, the transcript was checked against the recording for transcription errors, identifying information from the interview transcripts was redacted, and then the recording was deleted.

Completion of both glucose safety checks each week (start of Saturday session, start of Wednesday session) was compensated by US $10 for week 1 and then US $5 for consecutive weeks (US $15 for week 2, US $20 for week 3, and so on) with a reset to US $10 if missing a week. There was also US $50 compensation for completing the follow-up visit. The total possible compensation was US $185.

### Intervention Overview

Briefly, the first study of ExerT1D [19] (from December 23, 2021, to July 27, 2022) was a pilot feasibility and acceptability study where 4 cohorts of 3-5 teens with T1D completed the 6-week ExerT1D program, led by a young adult role model with T1D, a T1D clinician, and an exercise physiologist. The intervention included an MVPA video game with a customizable player avatar (Nintendo Ring Fit Adventure), continuous glucose monitoring (CGM) by Dexcom G6 or Freestyle Libre 2, physician-led education regarding managing T1D around MVPA, habitual MVPA goal-setting with a Fitbit Inspire 2 device, and role-playing skits that involve educational points related to T1D management. All activities were done synchronously with the other participants digitally. The curriculum content was iteratively refined after each cohort. The final curriculum content, metrics of feasibility, fidelity, safety, glycemic changes both acutely with exercise and as biweekly summary metrics over time, and exit surveys about acceptability will be reported separately [19]. This paper reports on semistructured exit interviews that accompanied the surveys.

### Interviews

Interviews were conducted by a graduate student (JM) external to the intervention, who was trained in qualitative methodology and interviewing, and mentored by senior members of the research team. The interviewer is female and has a bachelor's degree while pursuing a master's degree in exercise physiology. She wrote a field notes summary after each interview and a weekly reflective journal and discussed both with the principal investigator (GIA) on a weekly basis in the first month and biweekly thereafter. A semistructured interview guide [20] was developed by the research team to elicit participant perspectives about the acceptability of the intervention, including their experiences with the intervention components and how these experiences affected their attitudes and perceptions of diabetes self-management practices. Questions also addressed psychosocial experiences with the program and suggested improvements for the program. The first draft of the interview guide was developed collaboratively among the senior investigators (GIA, LMN, and SN) based on questions from previous interventions. This draft was discussed and revised after the first cohort had completed the intervention to incorporate questions about the implementation of the intervention. The interview guide was piloted by the interviewer (JM) in 2 mock interviews with another team member. A senior researcher (GIA) reviewed the recordings of both mock interviews and offered feedback to the interviewer. Recordings of the first 4 participant interviews were subsequently reviewed by senior researchers (GIA and SSM) to iteratively coach the interviewer to improve on open-ended probes. The list of probes was added to the final guide (Multimedia Appendix 1).

Interviews were conducted no more than 7 days after the end of the program using Zoom (Zoom Video Communications), a HIPAA (Health Insurance Portability and Accountability Act)-compliant videoconferencing platform. The interviews were recorded by audio only and transcribed by a professional transcriptionist, and the transcripts were reviewed prior to analysis and updated for accuracy by a study team member.

### Positionality Statement

The interview and coding team reflected on their personal experiences and biases. The team acknowledged their positions of privilege and the fact that some team members live with T1D, which may influence the conducting of interviews and interpreting the data. The multidisciplinary team included a broad range of expertise, including endocrinology, public health, qualitative methodology, and exercise science, as well as social and cultural factors that impact health. This was a collaborative team project that ensured the study was sensitive and appropriate to the context in which it was conducted.

### Data Analysis

Data management and analysis were supported by NVivo 12 (Lumivero). Two senior members of the study team (GIA and SSM) developed a coding scheme [21] based on a literature review for relevant themes and adapted social cognitive theory to guide the analysis. Social cognitive theory predicts that individual health behavior, such as MVPA, is influenced by individual experiences, environmental factors, and the actions of others [22]. The initial coding scheme was piloted with 3 transcripts. Revisions were made after comparing codes, reviewed by another team member (LMN), and discrepancies resolved. The codebook was revised by grouping multiple codes together to produce four main thematic areas: (1) motivation to engage in physical activity, (2) experience with and motivation



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to manage blood glucose while engaging in physical activity, (3) peer support encouraged engagement with the intervention, and (4) improvements in physical activity self-efficacy and diabetes self-management efficacy. Two members (JM and RM) piloted the revised coding scheme by reviewing 3 other transcripts independently. Codes were compared and discussed, and a codebook was finalized. The coders (JM and RM) used the codebook to code all remaining transcripts independently and met biweekly to resolve discrepancies to maintain rigor in the analytic process. Trustworthiness was ensured by having the same team members involved in the analysis, and the team returned to the interview data to check themes with each participant's interview and original quotations as needed.

The purpose of the qualitative descriptive analysis is to describe the acceptability and overall impact of the intervention from the perspectives of adolescent participants. A descriptive approach [24] was used to understand participants' experience with the program, in which there was a heavy reliance on the participants' words, except when abstracting meaning or intent that fit well-established biomedical or psychosocial aspects of T1D care. The themes are presented with representative quotes and participant descriptors. Adolescents' ages are described as either "younger" (aged 14-15 years) or "older" (aged 16-19 years) to protect participant anonymity. We applied the COREQ (Consolidated Criteria for Reporting in Qualitative Research) in the reporting of our qualitative study (Multimedia Appendix 2) [25].

## Results

### Demographic Characteristics

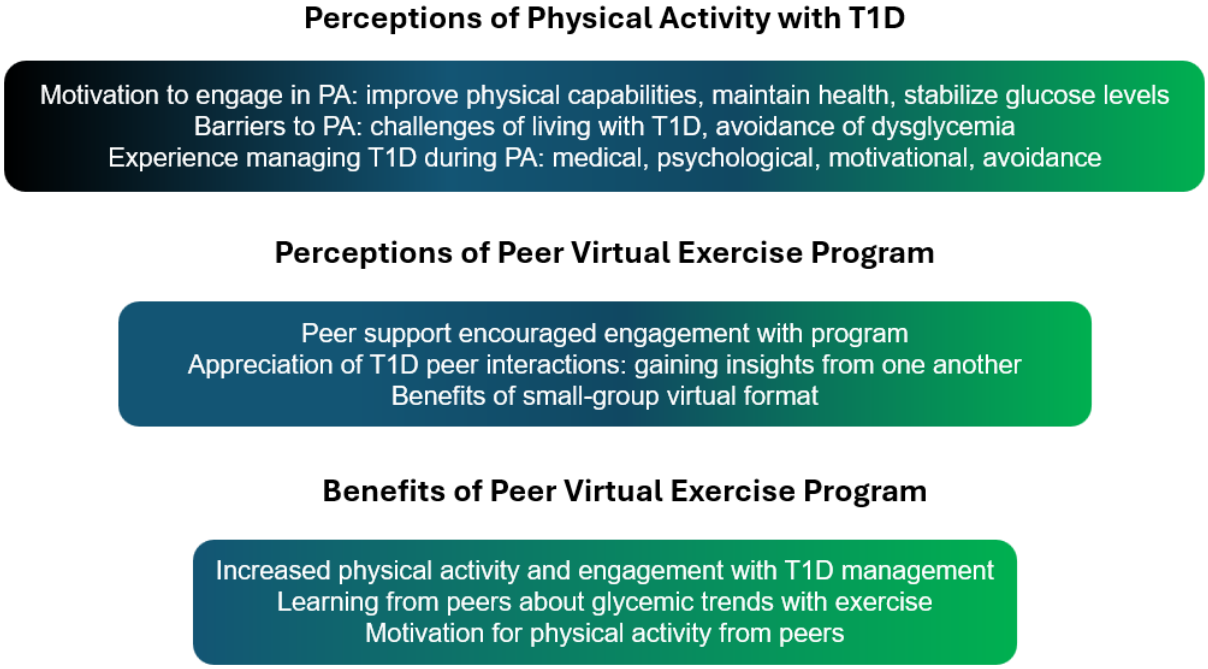
A total of 15 adolescents enrolled in the program: median age 15.4 (IQR 14.5-16.4; range 14.1-19.7) years, mixed-sex (2 nonbinary, 6 females, and 7 males), median hemoglobin $A_{1c}$ level of 7.8% (IQR 7.4%-11.2%; range 6.2%-12.5%), average T1D diagnosis duration 8.2 (SD 3.8; range 2.6-14.6) years, and used automated insulin delivery (AID, n=3), a sensor-augmented pump (SAP, n=11), or multiple daily injections (MDIs) on a basal-bolus regimen (n=1). At baseline, they had an average of 1.5 (SD 1.1, range 0-3) days per week with 60 minutes and more MVPA. Baseline PA included school physical education (n=2), formal extracurricular activities (n=3), both (n=1), informal group activities (n=1), or informal individual activities (n=4, of which 1 was exempt from school physical education). During the intervention, they set individual and group goals related to daily steps, sports participation, or playing the active video game on their own time with approximately 40% success [19]. None of the participants experienced diabetic ketoacidosis, severe hypoglycemia, or physical injuries during the study. The protocol was published elsewhere [19]. All 15 adolescents participated in a semistructured exit interview. Interviews lasted between 18 and 48 minutes.

### Interview Themes

#### *Overview*

We begin by outlining the participants' perceptions and experiences with PA and diabetes self-management to offer context for how adolescents with T1D view their biopsychosocial experiences related to the condition. This is followed by participants' perceptions of and experiences with ExerT1D and how their participation in the program might have affected their views on PA and diabetes self-management (Figure 1).

**Figure 1.** The interview themes related to perceptions of PA with T1D and perceptions of the ExerT1D peer virtual exercise program. PA: physical activity; T1D: type 1 diabetes.






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### *Motivation to Engage in PA*

Participants were asked to reflect on their goals, motivation, and barriers to PA to better understand what motivates them to engage in PA. Almost all participants mentioned that they had participated in some form of organized PA before this research study. Activities included running, going to the gym, soccer, volleyball, dance, gymnastics, and flag football. When asked about goals related to PA, many participants shared their desire to improve their current physical capabilities. Specifically, a few of the participants' main motivation to remain physically active was to maintain good health or to stabilize glucose levels, or both.

> *I just wanna be, you know, the healthiest I can...the healthiest in terms of like blood sugar especially, and that could be helped a lot by, being physically active, so I think...having good blood sugar is, is what motivates me.* [Male, older, MDI]

> *I feel like when I exercise my blood sugars are more stable throughout the day, so exercise usually is a part of my daily routine.* [Male, older, MDI]

Almost all participants said that an external barrier to being physically active was having other priorities like work, school, extracurricular activities, and other obligations like taking care of younger siblings or house chores. Many of the participants mentioned having unstable glucose levels and other medical conditions (such as asthma) as internal barriers to PA.

> *Sometimes, if I'm having like a bad blood-sugar day, which isn't too often, but if do then I'm just like really wiped out, and then I don't feel comfortable exercising that day, so that'll stop me from exercising sometimes, or if I'm having like, frequent low episodes throughout the day that's like a big reason not to, since exercise can make it lower, for me at least.* [Male, older, MDI]

A few participants mentioned they currently do not make time to exercise and expressed that they wished to devote more time and consistency to exercise.

Further, participants shared how they felt when they engaged in PA. One participant mentioned that this study was "the first time [she] ever truly exercised." Another participant mentioned that diabetes affected their relationship with PA but "as long as I have, like all the things I need, and make sure I'm on good settings with my pump and all that, then it's not really that much of a problem." One participant was adamant about their distaste for PA due to the feelings it invokes.

> *My whole life, I have hated exercising...[it's not] even like, the fact that I'm lazy, like I could exercise if I wanted to, but it's just [the] feeling, that like during it and afterwards I'm like 'eww, no.'* [Nonbinary, younger, SAP]

We see that the participants are busy adolescents living full lives filled with family obligations, school, and extracurricular activities. Most participants acknowledged the importance of engaging in PA, but the additional challenges of living with T1D can be a barrier to engaging in PA for some. Several mentioned avoiding PA to prevent hypoglycemia and having to ingest carbohydrates before engaging in PA. Others mentioned following standard recommendations by keeping food with them in case their glucose level got too low. We discuss in more detail how participants manage diabetes in the next section.

### *Experience With and Motivation for Diabetes Management While Engaging in PA*

Participants shared personal experiences related to living with T1D and how this influenced their interactions with peers and feelings about themselves. Some avoided discussing diabetes, while others felt managing diabetes was difficult to explain.

> *I barely even talk about my diabetes to anybody...like I will go months knowing somebody they won't know I'm diabetic and I'll avoid it at all costs.* [Nonbinary, younger, SAP]

> *[There were] times where I'm like, at dance, or, maybe like in school doing gym and stuff I've been low, and it's, kind of, hard to explain to people why I'll stop and I'll have a juice or something.* [Female, younger, SAP]

Others shared how they had felt abnormal and burdened by diabetes-specific tasks.

> *I remember like being younger, I was like, 'Oh my god, I wished I was just like a normal kid that didn't have to do all this extra stuff.* [Nonbinary, younger, SAP]

Participants also described how they medically managed diabetes and what they did to stabilize their glucose levels during exercise. Some described using diabetes technology (ie, CGM) to help them track and manage their glucose levels. They also described how they are using diabetes technology, adjusting carbohydrate intake, and using routines to help them manage diabetes.

> *I'll usually just have gummies with me and I'll check my blood sugar before [exercising].* [Male, older, SAP]

> *[The CGM] kinda helps regulate [my blood sugar], I feel fine. Like if I do go low, I'm not like scared or anything so, I'm pretty good about exercising.* [Male, older, SAP]

They also described moments where they experienced low or high glucose levels and actions they took to stabilize glucose levels before engaging in PA.

> *Depending on...my numbers, I'll either drink a little juice before...and depending on the exercise I'll get...a little bit of insulin, but...for exercising, I like [my glucose levels] to be a little higher.* [Female, younger, SAP]

> *I think, a couple times, I did, in the morning sessions...when I woke up, I was a little bit low or like going low so I'd set a temp basal to counteract that, but other times I would eat before it so...that would also, stabilize my blood sugar.* [Male, older, SAP]



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One participant explained how she used her CGM to help her figure out diet and insulin adjustments during and after exercise.

> *I also have a Dexcom that [monitors] my blood sugar so I can give corrections...if I'm...above 70 it'll give me an alarm saying like 'hey, you're 70, eat something.'...So it, tells me when I need to do something about my blood sugar. But, if I'm really high and doing exercise, I might give myself insulin but, it would be,...half of the normal [dose] and, see if it does anything...After the exercise, I might just [give the rest] later, like after it to see if it...is making a big difference.* [Male, younger, SAP]

While participants expressed some understanding of managing glucose levels during PA, they provided details of having to accommodate the uncertainty or limitations related to diabetes.

> *Sometimes, during soccer games, I would have to go to the sideline to [treat a low], and I wouldn't be able to play during that game until...my blood sugar got up, and sometimes it's annoying or difficult because you can't play while you have to watch your friends...* [Male, younger, AID]

> *Not all days are the same, so, it makes it harder to manage, because you never know what to expect, [you] just have to wake up and see what happens...it's hard seeing the ups and downs.* [Female, older, AID]

Sometimes preparing for exercise involves psychological and motivational adjustments. One participant mentioned that if they were experiencing hypoglycemia, it could prevent them from exercising. Another participant talked about pushing through with hyperglycemia.

> *[If my] blood sugar's too low, I [wouldn't] participate really because I don't want it to go any lower. Or if it's too high, and I have ketones then I normally don't do it, but if it's high and I don't have ketones I [can], just, [push through]. I'll become a little bit more sluggish, and it's, not my best effort...But that's really all it affects.* [Male, younger, SAP]

### *Peer Support Encouraged Engagement With the Intervention*

One of the main objectives of the group program was to integrate skillful competence (ie, managing T1D around exercise) with relatedness, as per self-determination theory. The components of the program were carefully designed to facilitate and promote interactions between the instructor and participants and between the participants themselves. We asked about the adolescents' perceptions of the virtual peer experience and how the class format affected their experience.

A little more than half of the participants noted that the instructors of the program were "nice," "respectful," and "very supportive." One participant said.

> *If the instructors weren't nice...I may not have stayed with it.* [Male, younger, SAP]

One participant said the instructor's demeanor eased his anxiety about meeting new people.

> *It was just the way they came in with such a high spirit, well the...instructors at least, I know, as I was coming in [you] would probably be a little bit nervous just because you've never seen anyone before...* [Female, younger, SAP]

Another shared that they felt it was easy to communicate with the instructor because knowing the instructor also had T1D.

> *Pretty comfortable for me to go and tell them things that were happening.* [Female, older, AID]

Participants also felt the instructors were knowledgeable about living with diabetes and were helpful when glucose-related issues came up. One participant also mentioned her positive experience with the physician.

> *I knew she had a lot of knowledge in [diabetes], so I, felt like I could trust her and what, what she had to say, in what, what changes she wanted to make.* [Female, younger, SAP]

It was evident from the interviews that participants appreciated gathering as a group for discussion and gameplay. Although we are unable to compare the experience of adolescents who joined this program and adolescents who play the game by themselves, our participants' reflections on the group experience highlighted many benefits of having set up the virtual program in a group setting as opposed to providing the game to adolescents to play on their own. Many of the participants expressed that the inclusion of peers around their age with T1D enhanced the acceptability of the program.

> *I liked that it was other like, teenagers doing it, so I didn't feel like obviously they were like, older than me, but I didn't feel like it was, like young young kids that I couldn't really relate to at all or [it] was like, older people that I was like, "okay, why am I exercising with a bunch of adults?* [Nonbinary, younger, SAP]

> *I don't think I, would've enjoyed it as much if it was, just the adults...but, with other kids my age, it was a little more like, relatable and, easier to, talk to.* [Male, younger, SAP]

> *I haven't met many [people with diabetes] my age.* [Male, younger, AID]

The small-group setting provided a forum for adolescents and instructors to share experiences, provide peer support, and set personal goals. These features are in line with the information-motivation-behavioral skills model, as the program provided information feedback to reinforce motivation for PA. One teen thought the group setting helped him feel more comfortable exercising.

> *...having someone, there, not, that's not just me, felt like it, it probably divided a little bit of the attention, which I think is good, because too much attention can be bad, sometimes.* [Male, younger, SAP]

Another participant explained that group activities helped them cope with social anxiety.

> *I have like bad social anxiety, so it's like nice, getting to know people.* [Male, older, AID]



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The peer modeling aspect of the program provided motivation for some participants.

> *[The other participants gave] me like a sense of progression...it was interesting to see how far they were, compared to me.* [Male, younger, SAP]

> *...we would be asked like certain questions every single day, and so we would actually hear like what [the other participants] were saying and how they felt about the whole exercise.* [Male, older, SAP]

Goal-setting was another important component of the program. By sharing personal goals with each other as well as agreeing on a group goal, the adolescents established intrinsic and extrinsic accountability as motivation to achieve their own goals and the group goal.

> *I know someone made a goal to run, I think it was run a mile in...six minutes and forty-five seconds...and another one was to get to...twelve thousand steps, I believe, and the other one was to get...A1C down. I felt like that was another one I could've done, because I know with the, study, it brought my...A1c down a lot, and I know one other guy did beat his goal.* [Female, younger, SAP]

> *In the program you have a group goal, so, our group goal was to get like, ten or fifteen miles a week, and I think that's one of the things that motivated me because I wanted to get the group goal...so, that motivated me to go outside [and] walk around [with] my sister or, play with the dog, run around more with the dog, and things like that.* [Female, older, AID]

Participants expressed an interest in peer responses to living with diabetes and PA. In an effort to normalize the practice of regularly checking and sharing glucose levels, participants were asked to share their glucose levels before and after the game. There were mixed feelings about having to share their glucose levels in the group.

> *I literally avoid that, at, if I can avoid it, I will. If there's something else I could do than other show my numbers, I will do that, because I, that's something very personal to me, like, like for the other kids I feel like it was so much easier,...it just felt so much more, it felt, effortless, it looked effortless for the other kids.* [Nonbinary, younger, SAP]

> *I think this game was fine to help the barrier like showing people my blood sugars, I never ever ever do that, that's something I never do, I hate people seeing my numbers, I hate people seeing when I check my blood sugar seeing my sensors or anything...it makes me so uncomfortable.* [Nonbinary, younger, SAP]

They not only found it beneficial to learn exercise skills but also learn about how others' glucose levels responded to exercise and how others managed it.

> *I thought it'd be fun and I thought it'd be like a different way to do exercise and it would kinda distract me from the fact that it's exercise, and then...it would be super helpful to see how like diabetic people react, like how their bodies react to exercising...* [Nonbinary, younger, SAP]

> *[The blood sugar is] like really usually like a huge issue for me, so I kinda got to learn even just from what other people's goals were like, I got to be able to like, learn more tips and tricks for myself and for my diabetes.* [Female, younger, SAP]

Several participants indicated an interest in building community:

> *I wanted to meet more kids my age [with type 1 diabetes] so I wasn't really sure how to do that.* [Female, older, SAP]

Having all participants on Zoom during and after the game allowed flexibility in making connections with other participants. Some enjoyed being able to interact through Zoom during the game, facilitated by the Zoom-Ring Fit hybrid delivery (the Ring Fit game itself is not networked).

> *[the program was] super cool, having, a, team type of thing, and I feel like you would also be able to get closer with the other person.* [Female, younger, SAP]

Others found the postgame virtual discussions valuable.

> *When we were actually in the game we didn't really interact that much, just because we were focused on our own game, but afterwards, you could like hear everyone's blood sugars, and how they came down I guess, and you could see everyone else's goals and, [who had beat] their goals and how, how they got to, beating that goal.* [Female, younger, SAP]

Some mentioned they did not have much interaction in the program and outside of it because either they chose not to or the platform for the game made it difficult for them to interact with one another.

> *It was nice. I feel like we didn't interact as much as we could have...but, for the few interactions we did have, it was nice. Again, everybody was really nice and, sweet and kind.* [Female, younger, SAP]

### *Improvements in PA Self-Efficacy and Diabetes Self-Management Efficacy*

All the participants credited the program with improving or raising awareness of T1D management skills. As a result of the program, participants were more conscious of checking and testing their glucose levels so they could adjust therapy plans and mitigate hypoglycemia and hyperglycemia. They reported having developed pre-exercise planning skills for T1D, such as monitoring their glucose levels more actively and having snacks nearby while exercising as a result of the program. Several participants relayed improved hemoglobin $A_{1c}$ and more success with stabilizing their glucose levels before and after exercising. A few noted that exercising is beneficial for their health since it keeps their glucose levels stable. Their comments demonstrated improved self-efficacy.

> *I'm trying to be more aware of it now, and, like, consciously checking...* [Female, younger, SAP]

> *I know what my blood sugar is, just, being more on top of it.* [Female, younger, SAP]



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> *I noticed that [in] the program I was testing my blood sugars a lot more, or looking at the Dexcom a lot more, [just] to see what was happening.* [Female, younger, SAP]
>
> *...keeping myself in check because they would ask, what your blood sugar was every morning, [and I thought], "Well I should do something about this [on my own].* [Female, younger, SAP]
>
> *[I now can] exercise for a long period of time, and not be like too worried about my blood sugar.* [Male, older, SAP]

Even for someone who felt knowledgeable about managing her own diabetes, this participant acknowledged the benefits of participating in a group.

> *I've been doing that for a long time, it just gave me some insight onto, how other people do it, so I can compare what I'm doing with other people.* [Male, younger, AID]

Participants had high praise for the overall program structure. As previously discussed, participants enjoyed the small-group format with other adolescents living with T1D and developed a rapport with instructors who also had diabetes. Having the game component as well as a discussion or class component gave participants different ways to connect with each other and practice the skills modeled in the program.

Participants were also asked to reflect on their experience with the game. They appreciated learning new exercises through playing the game, as the game's feedback helped participants know if they were doing the exercise correctly. Some participants credited the game for helping them improve their endurance. One person mentioned the ability to set the intensity level of the exercises allowed participants to match the intensity to how they were feeling. The storyline of the game allowed them to take their mind off the fact that they were exercising; because they liked the competition, it was more enjoyable. They were focused on beating the game rather than performing the exercises.

> *I don't really like [exercising], but...because there was a game and everything that just kind of, took my mind away from the fact that it is exercise.* [Nonbinary, younger, SAP]

One participant said that their favorite part of the program was performing the exercises because of how fun they were. The participants enjoyed the different types of exercises and the feature that allows player to unlock more levels. While the game caused one participant to feel tired because of the intensity level, they expressed excitement about how the game helped them increase their fitness levels.

Some participants talked about how much they enjoy exercising more because of the program. For example, the program was "fun," and it motivated them to exercise more by having a more consistent workout structure.

> *It [gave me] a bit, more of a schedule for doing exercises, and, diabetes, I think [you need a bit] more discipline.* [Male, younger, SAP]

The program gave them the confidence to safely engage in PA and gain a better understanding of the effect of PA on blood glucose levels.

> *[I was] able to like track my blood sugar and understand the effects of being low or being high.* [Male, older, SAP]
>
> *...that was really helpful with the [Ring]Fit, I kind of got a better understanding of like how far I can push myself without having to...eat a snack.* [Male, older, MDI]
>
> *It helped me like realize that...I can exercise for a long period of time, and not be...too worried about my blood sugar, because I realize that...my blood sugar might even be stable if I eat before [exercise] so it was nice to see that...it made me realize that I can do these more...vigorous exercises and not be that worried about my blood sugar.* [Male, older, SAP]

## Discussion

### Principal Findings

Through the ExerT1D intervention, we present a novel approach to promote PA while providing psychosocial support for adolescents with T1D utilizing both exergaming and virtual reality. The positive participant responses to the program demonstrated the acceptability of hosting a fully virtual program, as participants enjoyed the small-group format and appreciated the convenience of meeting digitally from their homes. Highly rated components of the intervention included the instructors with lived T1D experience and perceived group cohesion. Using exergames and virtual reality, we provided a fun and interactive environment for participants to interact and engage in PA in our study. Pairing a video game or virtual reality with group activities in a virtual setting proved to be a viable approach to addressing some of the psychosocial challenges that adolescents with T1D experience.

Participants attributed the ExerT1D program to enhancing their diabetes knowledge and management skills, both overall and during PA. The program gave them the confidence to safely engage in PA, and they gained a better understanding of the impact of PA on glucose levels. The combination of increased self-efficacy and peer support can create a positive feedback loop; as youths create supportive peer networks, these supportive relationships can further enhance their confidence in managing diabetes effectively. Other key benefits of the program were the structured nature of the sessions that started by addressing diabetes management prior to PA, as well as real-time feedback about how to manage diabetes during PA. Further, after PA sessions, participants had the opportunity to reflect on how their glucose levels changed during activity and if their diabetes management strategies were successful.

Additionally, adolescents reported that interacting with peers who also had T1D was a valuable aspect of the program. As T1D is a rare condition in childhood, many adolescents with this condition may feel isolated because they do not have the opportunity to engage with others who share similar experiences.



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The mental burden and constant nature of T1D management can be cumbersome and lead to psychological distress in youth [26]. Participants in this study relayed the complex nature of managing T1D around PA, including the need to consume additional carbohydrates around times of PA, the unpredictable nature of glucose changes, and T1D-specific limitations that arise with the condition. The opportunity to engage with fellow participants and instructors with T1D allowed them to learn from each other and build a sense of community. Sustained peer support programs have also been linked with improved glycemic outcomes [27]; thus, peer support can play a key role in providing motivation and encouragement for managing T1D.

Unlike programs that prescribe PA regimens which are completed independently, our program addresses psychosocial concerns of PA for adolescents by conducting the program in a small-group setting led by peer mentors with T1D rather than automated instructors, which reinforces peer support [28,29]. The setting also promoted diabetes self-management practices, including regular glucose checks before, during, and after PA, and used group discussions by fostering a “safe space” for discussing diabetes challenges. Active video games most effectively increase PA, PA self-efficacy, and PA motivation when focusing on cooperative (ie, cumulative group) scoring [30,31]. In addition, playing through a self-representational figure (ie, avatar) fulfills drivers of motivation for behavior change stipulated by self-determination theory [32].

### Strengths and Limitations

As this was a pilot study, interviews were conducted to evaluate and refine the intervention. We are therefore unable to draw conclusions or propose theories about the effectiveness of the program. Participants were required to own technology to participate, including television, phone, and internet access, which may be a barrier for those with limited financial resources. Participant responses may have been impacted by biases common to many qualitative studies. First, to mitigate social desirability bias, the interviews were conducted by a team member who was not directly involved with any aspect of the program, thus creating a sense of separation from the research team. Second, for recall bias, we scheduled the interviews within 7 days of the completion of the program and provided additional cues to remind participants of specific sessions if appropriate. Third, we also had the same person conduct the interviews to minimize variation in conducting interviews. Fourth, the principal investigator listened to each recording after the interview and debriefed with the interviewer as another quality check. With qualitative studies, although a researcher’s biases may affect the analytic process, we coded the data independently and resolved discrepancies by group discussion to maintain rigor in the analytic process.

### Comparison With Prior Work

Findings from this study further reinforce results from our previous intervention (Bright 1 Bodies), an in-person group PA program for adolescents with T1D [33]. The 18 adolescents in Bright 1 Bodies had similar racial and ethnic diversity and low baseline PA levels to our study. Consistent with comments from this study’s participants, Bright 1 Bodies participants similarly reported experiencing relatedness by meeting others with T1D (in many cases for the first time), learning more about T1D, improving T1D management and experience, and having young adult instructors with T1D as role models. They also reported that the intervention led them to gain and reinforce autonomy and competence in safe, enjoyable PA [34]. In addition, findings from this study suggest it could be beneficial to leverage the clustering of positive health behaviors by initially focusing on the ones that are least stigmatizing (ie, multiple health behavior changes) [35,36]. Structuring the program to be delivered by an instructor living with T1D, in addition to interacting with other participants with T1D, was a key to the success of the intervention. Virtual peer support MVPA interventions may be more effective, acceptable, and implementable than existing options for adolescents with T1D.

Adolescence is a period of development where youths are more vulnerable to psychosocial challenges relevant to MVPA, including avoidant coping behaviors (eg, committing leisure time to sedentary activities) [37] and low self-efficacy (eg, lack of belief that MVPA can be safe and fun) [38]. This intervention is the first program using virtual digital tools to address the bidirectional relationships among psychosocial concerns, glycemic control, and low PA among adolescents with T1D. Prior studies have either focused separately on PA promotion, diabetes management, or psychosocial aspects of T1D. A small number of studies have explored the role of digital tools for adolescents with T1D, with encouraging signals that digital tools may be effective in improving self-efficacy, but evidence for other outcomes is, at best, mixed [23]. Our study was able to shed light on multiple outcomes since this program explored the role of digital support for adolescents with T1D in both PA promotion and psychosocial concerns. In this study, adolescents reported less avoidant coping and greater self-efficacy around MVPA. They also shared that the glucose checks before PA provided safety, comfort, confidence, a sense of normalcy, and awareness of glucose changes during and after PA.

### Future Directions

Findings from this study suggest that targeting T1D self-management skills, particularly in the context of PA, may offer valuable insights for research. The study also underscores the potential benefits of T1D peer support. Given the limited opportunities that adolescents with T1D have to connect with others with shared experiences, peer engagement creates an opportunity for shared learning and social support. Future programs could incorporate more structured opportunities for virtual peer interactions, which are more feasible to implement broadly. While further research is needed to test the effectiveness of such interventions, our study highlights the importance of exploring approaches that integrate practical education, real-time feedback, and peer support to improve self-management of T1D in adolescents.

## Conclusions

Adolescents with T1D experience barriers to engaging in PA. We provided an intervention focused on promoting PA and addressing psychosocial aspects of participating in PA for adolescents with T1D in a virtual setting using digital tools (ie, videoconferencing platform and parallel video gaming) and biosensors (Fitbit and CGM). The intervention provided



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adolescents with T1D with the confidence and peer support to engage in PA, reinforced by diabetes self-management skill development, and facilitated a greater understanding of the effect of PA on glucose levels. Participant feedback indicated the feasibility and high acceptability of this program, providing invaluable insight into the refinement of this approach for future trials.

## Acknowledgments

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## Authors' Contributions

SSM, LMN, and GIA conceptualized the research design and aims with support from MD, KLJ, and SN. GIA acquired funding for the investigation with support from LMN and SN. GIA and LMN conducted the investigation with assistance from JM. SSM designed the methodological approach to data analysis with support from LMN, MD, KLJ, SN, and GIA. SSM supervised data analysis and led data curation, analysis, and validation with assistance from JM and RM. SSM, LMN, and GIA created the manuscript figure. SSM wrote the original manuscript draft, and LMN was the lead reviewer and editor, with additional reviewing and editing by all authors.

## Conflicts of Interest

LMN receives salary support from the National Institutes of Health. She has served as a consultant for Medtronic, WebMD, and Calm. The Yale Children’s Diabetes Center receives free CGM supplies through the Abbott Laboratories clinical sample program, which are distributed to patients, including some who participated in this study. The authors attest that the National Institutes of Health, Medtronic Diabetes, Calm, and Abbott Laboratories had no influence on the design of this study or its outcomes.

Multimedia Appendix 1
Interview guide.
[DOCX File , 20 KB - diabetes_v10i1e65665_app1.docx ]

Multimedia Appendix 2
COREQ (Consolidated Criteria for Reporting in Qualitative Research) checklist.
[DOCX File , 25 KB - diabetes_v10i1e65665_app2.docx ]

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## Abbreviations

**AID:** automated insulin delivery
**CGM:** continuous glucose monitoring
**COREQ:** Consolidated Criteria for Reporting in Qualitative Research
**ExerT1D:** virtual exercise games for youth with type 1 diabetes intervention
**HIPAA:** Health Insurance Portability and Accountability Act
**MDI:** multiple daily injection
**MVPA:** moderate to vigorous physical activity
**PA:** physical activity
**SAP:** sensor-augmented pump
**T1D:** type 1 diabetes


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# A Nurse-Led Telemonitoring Approach in Diabetes During the COVID-19 Pandemic: Prospective Cohort Study

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## Abstract

**Background:** The utility of a nurse-led telemonitoring approach (NLTA) is yet to be firmly established in diabetes management.

**Objective:** This study aims to examine the effect of a 12-month proactive NLTA on metabolic and psychological health indices in individuals with diabetes during the COVID-19 pandemic, and to evaluate it as a new diabetes model of care.

**Methods:** The telemonitoring study group (TSG; n=91) comprised adults who had attended an Australian tertiary hospital diabetes center between January 2019 and March 2020. Telehealth surveillance contact with a diabetes nurse educator was subsequently maintained at approximately 3-month intervals over 12 months. Prospective surveillance measures included glycated hemoglobin $A_{1c}$ ($HbA_{1c}$%), weight, adherence to healthy behaviors, and patient-reported outcomes of diabetes distress, anxiety, and depression using validated instruments. Metabolic changes were compared retrospectively with a comparison group who had not received telemonitoring contact during the study period (non-TSG; n=115).

**Results:** The average participant age was 57.2 (SD 15) years; 63% (129/206) were male, 48% (99/206) had type 1 diabetes, 50% (104/206) had type 2 diabetes, and the mean $HbA_{1c}$% was 8.1% (SD 1.4%). At the end of the 12-month study, the relative percentage reduction in unadjusted $HbA_{1c}$% for the TSG cohort was significantly greater than that observed in the non-TSG cohort (4% vs 1%; *P*=.04). Following adjustment for baseline $HbA_{1c}$%, a significant improvement in $HbA_{1c}$% was observed in the TSG (*P*=.048) but not in the non-TSG (*P*=.61). TSG participants were 40% less likely (odds ratio 0.6, 95% CI 0.5 - 0.7) to experience an unfavorable rise in $HbA_{1c}$% compared to non-TSG participants, after adjusting for sex, age, prepandemic $HbA_{1c}$%, ethnicity, diabetes type, and diabetes duration. The NLTA facilitated assessments of psychological risk, with elevated depression, anxiety and diabetes distress scores significantly increased in women and youth <30 years of age (*P*<.001). Increasing anxiety measures were observed in those with high baseline anxiety scores (*P*<.001).

**Conclusions:** A proactive diabetes NLTA is feasible with positive effects on glycemia and the potential to identify those at psychological risk for targeted intervention. In the context of increasing demand for diabetes-related resources, further study of an NLTA model of care is warranted.

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**KEYWORDS**

diabetes models of care; nurse-led; glycemia; HbA1c; telemonitoring; telehealth; telemedicine; virtual; health care delivery; surveillance; psychological risk; depression; anxiety; diabetes distress; quality of life; COVID-19

## Introduction

The prevalence of type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) is expected to increase by 46% globally, with diabetes predicted to affect approximately 1 in 8 adults by 2045 (~783 million people) [1,2]. Traditional doctor-led care models delivered via ongoing interval assessments now place unsustainable demands on existing health care systems, so that new, sustainable, and scalable models of care are needed.

In the post–COVID-19 pandemic era, there is increasing interest in telehealth for ongoing health care delivery, with a generally high level of patient acceptance [3-8]. In this context, telemonitoring is a relatively new approach in chronic disease



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management, with recognized ability to overcome geographical and transport challenges, to provide greater efficiency and potentially earlier intervention, together with cost savings in the context of limited health care resources [9-16]. In addition, face-to-face nurse-led models of care are effective in the management of both T1DM and T2DM and allow for the efficient, individualized triage of cases to more or less intensive care as required [17,18]. On this background, we hypothesized that a combined nurse-led telemonitoring approach (NLTA) could have clinical utility within a multidisciplinary diabetes chronic care model.

Despite theoretical advantages, there are limited data on the utility of an NLTA in T1DM and T2DM, particularly in an Australian context. We aimed to describe a pragmatic, 12-month, prospective cohort surveillance study, using an NLTA, to examine the trajectory of metabolic and psychological health, and health care usage, in patients with diabetes (Telemonitoring Study Group, TSG), in the context of the COVID-19 pandemic environment. A retrospective contemporary clinic cohort who did not receive regular telemonitoring contact (the non-TSG) was established as a comparator for metabolic indices. We also aimed to examine the clinical features associated with deterioration in psychological and metabolic parameters during telemonitoring, to inform future strategies for surveillance and early intervention.

## Methods

### Recruitment

The Australian New South Wales COVID-19 pandemic response, beginning in March 2020, included strict lockdowns and restrictions on gatherings and movement throughout the state, resulting in changes to access for ambulatory care services, including a pivot toward telehealth. Eligible participants were nonpregnant adults aged 18 years and older with a diagnosis of diabetes mellitus who had attended the Diabetes Centre at Royal Prince Alfred Hospital (RPAH) in Sydney, Australia, in the immediate prepandemic period between January 2019 and March 2020. They were invited to participate in an NLTA as a health surveillance strategy with the specific aim of monitoring well-being over 12 months. The TSG intervention comprised 3-monthly telehealth contacts for 6 months, then again at 12 months post-enrollment. Contact was made via phone or video with a diabetes nurse educator. Baseline data included participant demographics, self-reported medication and medical history, and collection of comprehensive blood and urine tests, including hemoglobin $A_{1c}$ ($HbA_{1c}$%), by standard pathology laboratory protocols. At each subsequent assessment, demographic data, self-reported anthropometric measurements, and medication regimen were gathered; results of recent (ie, within 3 months) blood and urine tests were collected and discussed. A main aim in the nurse consultations was to help avoid deterioration in glycemia through maintenance of self-care and optimizing adherence to prescribed lifestyle and medication regimens. Bespoke health and well-being questionnaires, as well as validated psychological screening tools, were administered, including the EuroQol Visual Analogue Scale (EQ-VAS), Patient Health Questionnaire-9 (PHQ-9), Generalized Anxiety Disorder 7-item (GAD-7) scale, and Problem Areas in Diabetes (PAID-5) scale [19-22]. Following best clinical practice and as recommended by the institutional Human Research Ethics Committee, if psychological inventories revealed concern for the presence of major depression including self-harm, the participant's general practitioner (GP) and community health team were to be contacted. The participant was encouraged to remain in regular contact with their health care team, in addition to telehealth surveillance visits.

Periods for analysis were defined as follows: prepandemic (pre-enrollment) data were captured between January 2019 and February 2020 (T0). Enrollment data (T1) were obtained during the enrollment period beginning from March 2020 onward. Follow-up data were collected at approximately 3 months (T2), 6 months (T3), and 12 months post-enrollment (T4). Final follow-up visits were completed in January 2022.

A retrospective, non-intervention comparison cohort (non-TSG) was established using data collected in the RPAH Diabetes Centre electronic medical record. Criteria for inclusion in the comparison cohort required the participant to have received 4 or more clinical services delivered between 2019 and 2021, aligned with the TSG participants. Assessment time points were matched to those of the intervention group.

### Statistical Analysis

To assess the unadjusted effect of independent variables across metabolic outcomes between the intervention and comparison groups, we used nonparametric analysis of variance for continuous variables and chi-square ($\chi^2$) tests for categorical variables, along with descriptive statistics over time. Fisher exact tests were applied when expected cell frequencies were less than 5. Due to the non-normal distribution of the outcome variables, Wilcoxon rank sum tests were conducted at each time point (T0, T1, T2, T3, and T4) to compare metabolic indices.

A stepwise regression approach was used to identify potential covariates, excluding interaction terms and independent variables that lacked association, introduced model skewness, or were deemed clinically irrelevant. To assess differences in effects across time points, specifically between the prepandemic period (T0) and subsequent assessments, linear regression models were applied, adjusting for key factors such as time, age, sex, diabetes type and duration, ethnicity, perceived personal risk of COVID-19 infection, and food stockpiling. For the regression analyses, the very few individuals with maturity-onset diabetes of the young, pancreatogenic diabetes, or atypical diabetes were classified as either T1DM if on an insulin regimen or T2DM if on an oral hypoglycemic regimen.

For the psychological outcome measures (PHQ-9, GAD-7, and PAID-5), regression models were restricted to the TSG group, as these measures did not apply to the non-TSG group. Results were reported as odds ratios with 95% CIs and corresponding *P* values. Statistical significance was defined as $P<.05$. All analyses were conducted using SAS 9.4 (SAS Institute Inc) software.



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### Ethical Considerations

All TSG participants consented to de-identified data being used for research purposes. This study was approved by the Human Research Ethics Committee (HREC/X20/RPAH/0206) of the Sydney Local Health District. All participant data were handled with strict confidentiality following ethical guidelines, and personal information was de-identified for analysis. Participation was voluntary, with the opportunity to withdraw at any time, and no financial compensation was provided.

## Results

### Glycemic Control in the TSG and Non-TSG Comparison Group

One hundred TSG participants were enrolled, with 91 completing 4 tele-surveillance visits over a 12-month follow-up, comprising the final TSG analysis set (Table 1). Participants were predominantly male (57%, 52/91), Caucasian (63%, 57/91), and had a mean age of 57 years. Overall, 48% (44/91) and 51% (46/91) of the participants had a diagnosis of T1DM and T2DM, respectively. One percent (1/91) were post-pancreatectomy. The median diabetes duration and age of diabetes onset were 14.0 years and 37.1 years, respectively, with 12% (11/91) of participants aged <30 years. Demographic data for the comparison cohort (n=115) are also shown in Table 1. The comparison cohort was also predominantly male, with a similar percentage of T1DM and T2DM, but was slightly older, had a longer diabetes duration, and was more likely to be non-Caucasian.

**Table .** Baseline demographic variables for the telemonitoring study group and non-telemonitoring study group (N=206).

| Characteristic | TSG[a] (n=91) | Non-TSG (n=115) | *P* value |
|---|---|---|---|
| Sex (male), n (%) | 52 (57) | 77 (67) | .19 |
| Age (years), mean (SD) | 53.8 (15.7) | 60 (14) | .004 |
| ≥30 years, n (%) | 80 (88) | 113 (98) | .003 |
| Ethnicity, n (%) | | | |
| Caucasian | 57 (63) | 49 (43) | .01 |
| Type of diabetes, n (%) | | | .93 |
| T1DM[b] | 44 (48) | 55 (48) | |
| T2DM[c] | 46 (51) | 58 (50) | |
| Other | 1 (1) | 2 (2) | |
| Age of onset of diabetes (years), mean (SD) | 37.1 (16.7) | 34.1 (16.4) | .19 |
| Duration of diabetes (years), mean (SD) | 16.7 (11.2) | 25.8 (10.9) | <.001 |
| Insulin use, n (%) | 67 (74) | 101 (88) | .01 |
| Antihypertensives, n (%) | 46 (51) | 49 (43) | 1.00 |

[a]TSG: telemonitoring study group.

[b]T1DM: type 1 diabetes mellitus.

[c]T2DM: type 2 diabetes mellitus.

Over the pandemic period, different trajectories of glycemia were observed in the TSG and non-TSG cohorts; more favorable blood glucose levels were maintained in the TSG cohort throughout the study period (Figure 1). We observed an absolute reduction in $HbA_{1c}$% from pre-enrollment (T0) to 12 months of 0.3% in the TSG and 0.1% in the non-TSG; the percentage reduction in $HbA_{1c}$% over 12 months was significantly greater in the TSG compared to the non-TSG (4% vs 1%, respectively; *P*=.04). It is notable, however, that the prepandemic $HbA_{1c}$% for the non-TSG group was higher, with a mean of 8.2% (SD 1.2%) compared to a mean of 7.8% (SD 1.5%) in the TSG group (*P*=.04; Table 2). After adjusting for prepandemic $HbA_{1c}$% for each cohort separately across all the time points, we observed a significant overall improvement in $HbA_{1c}$% for the TSG, particularly at 3 months (T2*; P*=.02) and 6 months (T3; *P*=.047), with significance sustained across all time points (*P*=.048). In contrast, there was no significant change in $HbA_{1c}$% across any of the time points for the non-TSG (*P*=.61).

Between-group differences were significant between the TSG and non-TSG at each time point (Table 2 and Figure 1). Notably, the final regression model showed that TSG participants were 40% less likely (adjusted odds ratio 0.6, 95% CI 0.5 - 0.7; *P*<.001) to experience an unfavorable rise in $HbA_{1c}$% compared to the non-TSG participants, adjusting for sex, age, prepandemic $HbA_{1c}$%, ethnicity, diabetes type, and duration (Table 3).



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**Figure 1.** Mean glycated hemoglobin A1c% over the study period for the TSG and non-TSG cohorts. $HbA_{1c}$%: glycated hemoglobin $A_{1c}$ expressed as a percentage; TSG: telemonitoring study group.

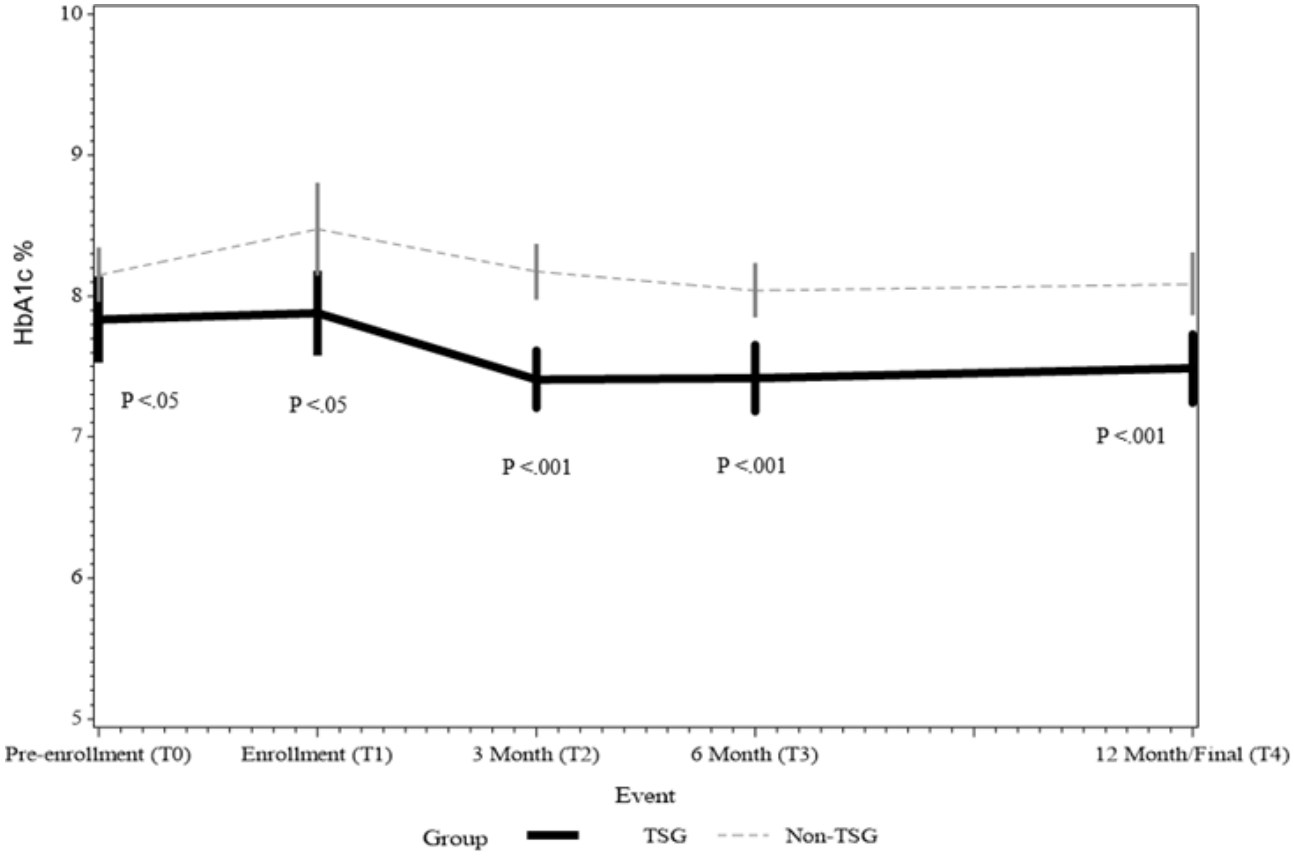



**Table .** Mean (SD) values of glycated hemoglobin $A_{1c}$% and BMI over 12 months for the telemonitoring study group and non-telemonitoring study group cohorts.

| Metabolic index | TSG[a], mean (SD) | TSG, n | Non-TSG, mean (SD) | Non-TSG, n | *P* value |
|---|---|---|---|---|---|
| $HbA_{1c}$ (%)[b] | | | | | |
| T0 (pre-enrollment) | 7.8 (1.5) | 90 | 8.2 (1.2) | 113 | .04 |
| T1 (enrollment) | 7.8 (1.5) | 91 | 8.3 (1.2) | 54 | .04 |
| T2 (3 months) | 7.4 (1.0) | 90 | 8.1 (1.0) | 101 | <.001 |
| T3 (6 months) | 7.4 (1.1) | 90 | 8.0 (1.1) | 106 | <.001 |
| T4 (12 months) | 7.5 (1.2) | 89 | 8.1 (1.3) | 106 | <.001 |
| BMI ($kg/m^2$) | | | | | |
| T0 (pre-enrollment) | 29.4 (7.1) | 38 | 29.2 (5.2) | 113 | .86 |
| T1 (enrollment) | 29.4 (6.1) | 88 | 29.2 (4.8) | 35 | .83 |
| T2 (3 months) | 29.4 (6.2) | 84 | 29.5 (5.3) | 79 | .92 |
| T3 (6 months) | 29.4 (6.2) | 91 | 29.3 (5.7) | 75 | .91 |
| T4 (12 months) | 29.3 (6.2) | 89 | 28.9 (5.8) | 55 | .70 |

[a]TSG: telemonitoring study group.

[b]$HbA_{1c}$: glycated hemoglobin.



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**Table .** Adjusted regression model for change in glycated hemoglobin A1c percent.

| Variable | Adjusted odds ratio (95% CI) | *P* value |
|---|---|---|
| TSG[a] (non-TSG[b]) | 0.6 (0.5-0.7) | <.001 |
| Time (T0[b]) | | |
| T1 (enrollment) | 1.1 (0.8-1.4) | .52 |
| T2 (3 months) | 0.8 (0.6-1.0) | .05 |
| T3 (6 months) | 0.8 (0.6-1.0) | .03 |
| T4 (12 months) | 0.8 (0.7-1.1) | .14 |
| Female (male[b]) | 1.1 (1.0-1.4) | .11 |
| Age <30 yrs (≥30 yrs[b]) | 0.7 (0.5-1.0) | .08 |
| Type 2 diabetes (type 1[b]) | 1.3 (1.1-1.5) | .01 |
| Caucasian (non-Caucasian[b]) | 1.2 (1.0-1.4) | .02 |
| Duration of diabetes (per year) | 1.00 (1.0-1.0) | .70 |

[a]TSG: telemonitoring study group.

[b]Reference group

## BMI and Cardiovascular Disease Risk Factors in the TSG and Non-TSG Comparison Group

For the data points available, we observed stability in BMI of ~29.4 kg/m$^2$ over the 12 months for both the TSG and non-TSG. Mean blood pressure at enrollment compared to the final visit was similar for the TSG and non-TSG. Lipid levels showed similar stability over the pandemic period for both groups. Albuminuria status was progressively more unfavorable in the non-TSG; however, there was more non-TSG data missing for this variable, including cardiac, renal, and liver disease status (Table 2 and Multimedia Appendix 1).

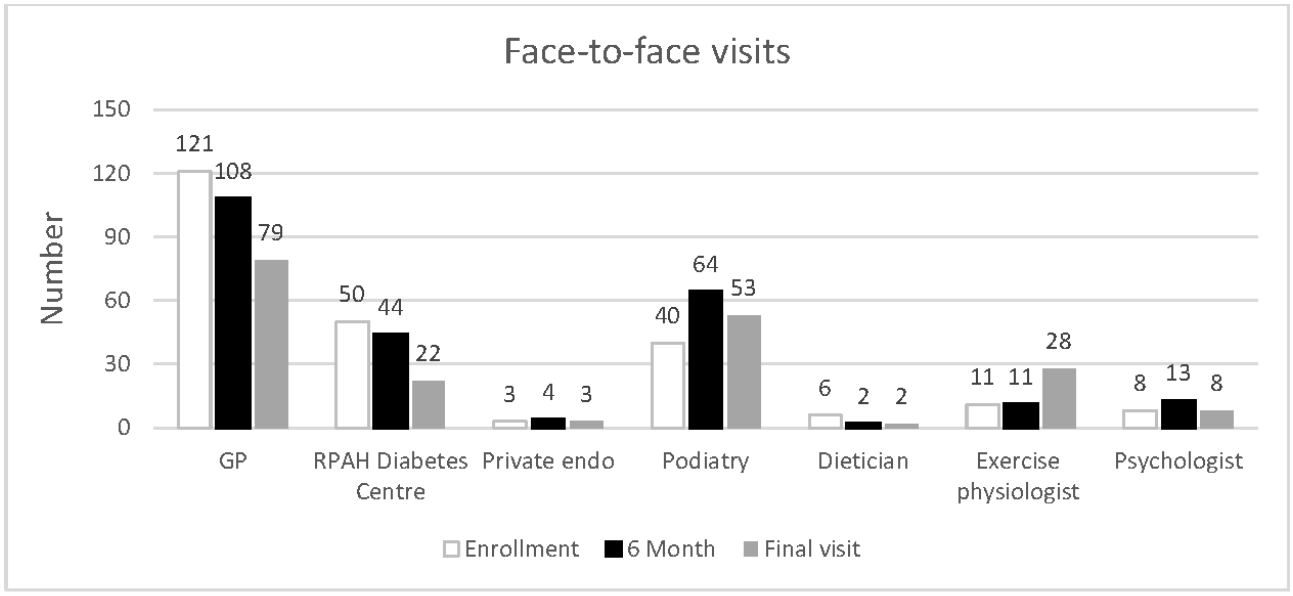
## Health Care Usage: TSG-Specific

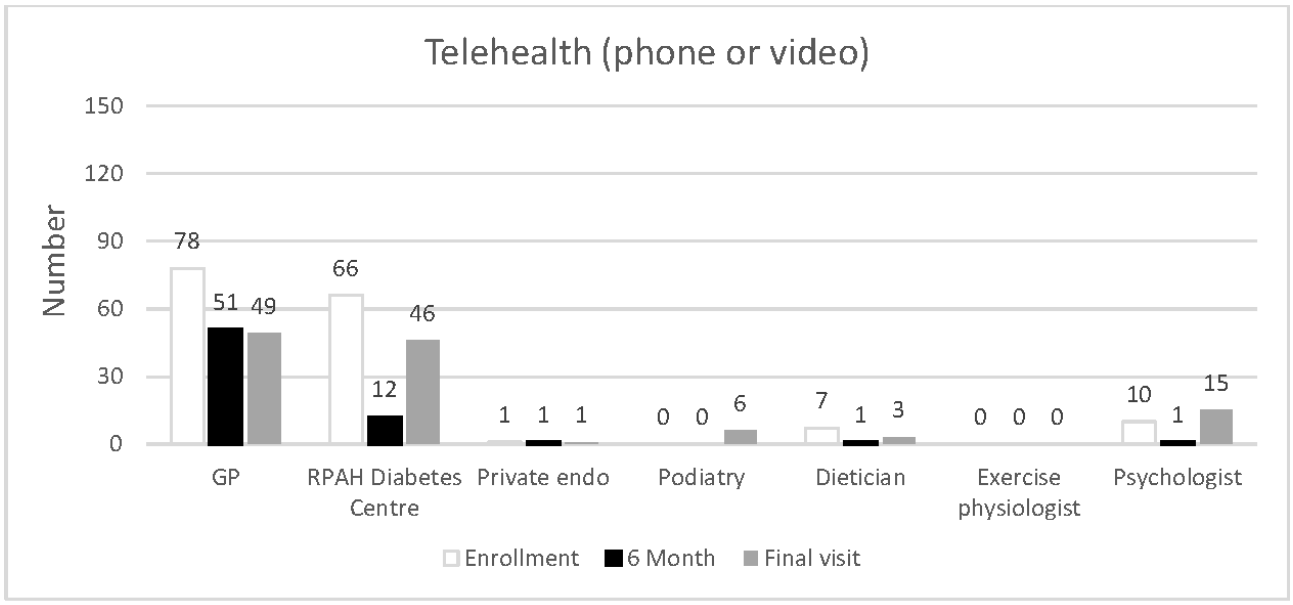
In the TSG alone, we observed a decline in participants reporting having seen their GP or endocrinologist over the observation period (Figure 2). Specifically, we observed a significant decline in diabetes service attendance over time (*P*<.001; Multimedia Appendix 2). This was true for both face-to-face and telehealth visits over the 12 months. In contrast, we observed an increase in email contact with the Diabetes Centre over 12 months. Visits to allied health care practitioners remained low throughout the study period. At enrollment (T1), 13% (12/91) of TSG participants had been to the hospital in the prior 3 months, 5.5% (5/91) had visited the emergency department, and 5.5% (5/91) had been admitted as inpatients. We did not observe any changes in the number of hospital visits, including emergency department, hospital admissions, or day procedures, over the observation period. Eighteen percent (16/91) of participants reported that they had specifically avoided or delayed a diabetes-related health care service, and this remained steady throughout the study period (Multimedia Appendix 2).

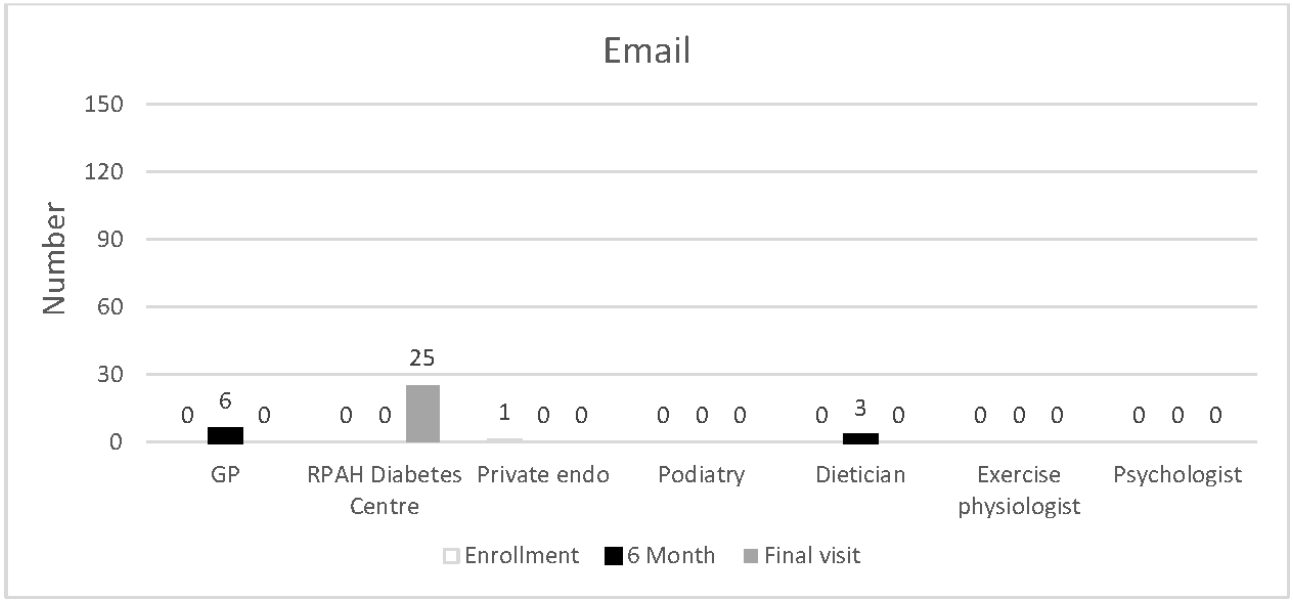


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**Figure 2.** Changes in the number of usual health care visits during the COVID-19 pandemic. endo: endocrinologist; GP: general practitioner; RPAH: Royal Prince Alfred Hospital.






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### Psychosocial Factors: TSG-Specific

At enrollment (T1), the median EQ-VAS to assess participants' health on a scale from 0 to 100 was relatively high at 80. Nevertheless, at T1, 20% (18/91) of participants reported scores indicative of moderate to moderately severe depression (PHQ-9), while 3.3% (3/91) reported scores consistent with severe depression. Twelve percent (11/91) reported moderate to severe anxiety (GAD-7), and 21% (19/91) reported scores suggesting significant diabetes-related emotional distress at T1. All mental health indices generally remained consistent over the 12 months. An exception was the observation of anxiety scores worsening over the 12-month study only in those with an enrollment GAD-7 score ≥10 ($P$<.001; Multimedia Appendix 3).

In the TSG, we observed significant differences over the study period in pandemic-related beliefs and behaviors, including perceived personal risk of clinically contracting COVID-19 and stockpiling additional food (Multimedia Appendix 4). These were adjusted for in the final mental health regression models using backward stepwise elimination (Table 4).

In the final model for PHQ-9 outcomes, adjusting for time, age, sex, type of diabetes, and significant covariates from the univariate analyses (Table 4), females were 9 times ($P$<.001) and those younger than 30 years of age were 42 times ($P$<.001) more likely, respectively, to experience an unfavorable rise in depression score. Similarly, in the GAD-7 outcome model, females and those younger than 30 years of age were 10.3 times ($P$<.001) and 93 times ($P$<.001) more likely, respectively, to experience an unfavorable rise in anxiety score. Finally, in the PAID-5 model, females and those younger than 30 years of age were 4.1 times ($P$<.001) and 12.8 times ($P$<.001) more likely, respectively, to experience an unfavorable rise in diabetes-related distress score. An adverse increase in PHQ-9 and GAD-7 scores was significantly greater for those with T2DM.



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**Table .** Adjusted regression models for change in measures of psychological health.

| Variable | Adjusted odds ratio (95% CI) | *P* value |
|---|---|---|
| PHQ-9[a] unfavorable rise | | |
| Time (T1-enrollment[b]) | | |
| T3 (6 months) | 1.8 (0.4-8.0) | .45 |
| T4 (12 months) | 1.1 (0.2-4.8) | .92 |
| Female (male[b]) | 9.0 (2.6-30) | <.001 |
| Age <30 yrs (≥30 yrs[b]) | 42 (5.7-302) | <.001 |
| Type 2 diabetes (type 1[b]) | 8.2 (2.0-33) | <.001 |
| Caucasian (non-Caucasian[b]) | 5.9 (1.5-23) | .01 |
| Duration of diabetes (per year) | 1.1 (1.0-1.1) | .07 |
| Stocking food (those who do not[b]) | 4.8 (1.2-20) | .03 |
| Perceived COVID-19 personal risk (those with greatly reduced risk[b]) | | |
| Slightly reduced risk | 2.6 (0.4-16.4) | .31 |
| The same risk | 1.5 (0.2-9.2) | .67 |
| Slightly increased risk | 10 (1.4-72) | .02 |
| Greatly increased risk | 112 (10-1310) | <.001 |
| GAD-7[c] unfavorable rise | | |
| Time (T1,enrollment[b]) | | |
| T3 (6 months) | 3.2 (0.9-12) | .08 |
| T4 (12 months) | 1.1 (0.3-4.0) | .90 |
| Female (male[b]) | 10.3 (3.5-30.1) | <.001 |
| Age <30 yrs (≥30 yrs[b]) | 93 (16.1-533) | <.001 |
| Type 2 diabetes (type 1[b]) | 5.9 (1.7-20.1) | .005 |
| Caucasian (non-Caucasian[b]) | 3.3 (1.0-11.1) | .05 |
| Duration of diabetes (per year) | 1.0 (1.0-1.1) | .57 |
| Stocking food (those who do not[b]) | 2.6 (0.8-9.2) | .13 |
| Perceived COVID-19 personal risk (those with greatly reduced risk[b]) | | |
| Slightly reduced risk | 1.5 (0.3-7.6) | .63 |
| The same risk | 1.0 (0.2-5.1) | .97 |
| Slightly increased risk | 4.4 (0.8-25.2) | .1 |
| Greatly increased risk | 21.9 (2.5-192) | .005 |
| PAID-5[d] unfavorable rise | | |
| Time (T1-enrollment[b]) | | |
| T3 (6 months) | 0.4 (0.1-1.3) | .13 |
| T4 (12 months) | 0.4 (0.1-1.2) | .09 |
| Female (male[b]) | 4.1 (1.6-11) | .004 |
| Age <30 yrs (≥30 yrs[b]) | 12.8 (3-62) | .002 |
| Type 2 diabetes (type 1[b]) | 1.3 (0.4-3.8) | .67 |



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| Variable | Adjusted odds ratio (95% CI) | *P* value |
|---|---|---|
| Caucasian (non-Caucasian[b]) | 0.7 (0.2-2.1) | .52 |
| Duration of diabetes (per year) | 1.0 (1.0-1.1) | .66 |
| Stocking food (those who do not[b]) | 6.4 (2.1-19.4) | .001 |

[a]PHQ-9: Patient Health Questionnaire-9.

[b]reference group.

[c]GAD-7: Generalized Anxiety Disorder 7-item.

[d]PAID-5: Problem Areas in Diabetes.

## Discussion

### Principal Findings

Although the COVID-19 pandemic resulted in overall reduced access to usual health services [23], our study observed a more favorable $HbA_{1c}$% trajectory over 12 months in the NLTA group, which differed from the comparison, usual care group. This was achieved in the context of fewer medical physician encounters. The NLTA was effective in monitoring the psychological health of people with diabetes and allowed the identification of patients who were psychologically vulnerable. We observed that the most vulnerable demographic in this cohort comprised women, young people, and those with high baseline GAD-7 scores, with potential implications for future pandemic planning. Perhaps more significantly, this study highlights the feasibility and positive potential for a nurse-led telehealth surveillance model to support traditional doctor-led models of care in diabetes management. Our results suggest that a nurse-led telemonitoring service is also acceptable to patients with diabetes, as evidenced by high participation rates at 12 months.

### Comparison With Prior Work

Our observation that the NLTA achieved stability in glycemic control during the challenging early stages of the COVID-19 pandemic is similar to other studies, including those in Australia, that involved telehealth use [24-28]. These findings are also in contrast to data highlighting deterioration of glycemic control in diabetes cohorts during the COVID-19 pandemic [29,30]. In addition, the intervention cohort achieved glycemic stability despite a significant decline in contact with their usual endocrinologist and usual diabetes educator via face-to-face or telehealth consultations. Contact with primary care providers within the TSG remained consistently unchanged over this period. One might speculate that nurse-led telemonitoring facilitated less frequent endocrinology and diabetes educator contact in the context of relatively stable glycemic control in the TSG, reserving targeted contact for those at higher risk and with complications [31-33]. We also observed stability of cardiovascular risk factors over the 12 months in the nurse-led telemonitoring group, again in contrast to other global reports of deterioration in control and despite reduced contact with auxiliary services [34,35]. Similarly, there was no increase in unplanned hospital attendance throughout the intervention period. Regular nurse-led telehealth surveillance was associated with stability in the overall rates of medication-taking and glucose self-monitoring throughout the pandemic period.

While we did not aim to, nor did we undertake, formal cost-effectiveness comparisons of health care delivery models, based on the NLTA model and reduction in GP and medical specialist consultations, we speculate that the NLTA model would not be more financially costly than the traditional non-TSG model comparator and yet delivered arguably better metabolic outcomes for the study cohort. The potential cost-effectiveness of the NLTA is supported by prior studies. A review paper examining the cost-effectiveness of telehealth for diabetes management found that, despite using different methodologies in varied health care settings, the majority of studies found telehealth to be cost-effective, citing direct costs per patient. The authors concluded that telehealth solutions have vast potential for cost-effective diabetes care [36]. Separately, there is a small body of literature to support the cost-effectiveness of nurse-led services in diabetes. In a study from the Netherlands, diabetes nurse specialists provided care comparable to physicians, with similar health-related quality-of-life measures and favorable costs per QALY gained [37]. Few contemporary studies exist on the cost-effectiveness of the combined approach of nurse-led telemedicine in diabetes. However, a modeling study on patients with heart failure found that nurse-led telephone support improved survival and was cost-effective in comparison with usual care [38]. A 2016 Belgian study reported that a nurse-led telecoaching program for T2DM, compared to usual GP care, was highly cost-effective with a reported incremental cost-effectiveness ratio well below suggested thresholds for the country [39]. Taken together, in the context of our findings, these data support the likely cost benefits of the NLTA but underscore the need for additional cost-effectiveness analysis of this model of care within a robust study design.

Through regular contact and the administration of validated psychological inventories, we were able to capture and track changes in COVID-related beliefs and deterioration in psychological health over the study period. We observed high levels of vaccine acceptance, low COVID infection rates, and postulate that provision of education through regular and reassuring health check-ins may have contributed to pandemic-safe, appropriate behaviors. In addition, the usage of validated standardized screening instruments as a component of the surveillance model enabled us to identify individuals with high levels of anxiety, depression, and diabetes distress—particularly prevalent among women and those aged <30 years. Our findings align with the increasing pandemic-related distress observed in the general UK population, which appears to be driven primarily by changes in



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younger people and women [40,41]. The Progression of Diabetic Complications (PREDICT) cohort study and other studies also observed a similar increased risk of adverse psychological health in younger people with diabetes during the same period [42,43]. The reasons behind the increased psychological vulnerability for these groups are not clear, but it would be reasonable to speculate that high baseline mental health issues in youth and adverse social determinants of health may play a role, as observed in previous studies [44]. Regardless of etiology, this model of care may help to identify at-risk young people with diabetes who may benefit from targeted, evidence-based intervention, such as an enhanced SMS text messaging support program [45]. The alignment of our findings with larger, robust studies suggests that a nurse-led telehealth surveillance model of care was able to accurately identify those most vulnerable and at risk. Beyond psychological health, physical activity and sedentary behavior showed modest changes, and self-care behaviors remained unchanged.

Optimal chronic management of diabetes involves monitoring and ongoing support to facilitate self-management and often behavior change, with a significant time and health resource burden. The COVID-19 pandemic led to innovations in patient care and widespread application of health care delivery via telemonitoring means. A global study found that 80% of providers from many countries adapted to new methods of telemedicine via telephonic or video technology [46]. Nurses in particular have embraced such technological advances, often with higher levels of acceptance than primary care providers [46]. A Canadian national survey found a ninefold increase in nurse involvement in telemonitoring care from prepandemic levels [47]. In the context of the rapid expansion of technologies to deliver health care, there is potential for a new nurse-led diabetes surveillance model of care to be scalable, accessible, and economically beneficial in the postpandemic era.

### Limitations and Future Work

The limitations of this study include its observational and nonrandomized design, with the inherent potential bias. It is important to recognize that baseline differences in age, $HbA_{1c}$%, and diabetes duration between the TSG and non-TSG cohorts could have influenced our results, despite appropriate statistical adjustments, potentially rendering the glycemic benefits observed less significant. We also note that data beyond metabolic indices were not available for the comparator group. In addition, this was a single-center study of predominantly White, English-speaking participants within the context of the Australian Medicare-funded health care system. Thus, our results may not be entirely generalizable to the wider patient population or other health care systems. However, our results support the need for further study in a larger cohort using a robust, randomized, and controlled framework within the prevailing health infrastructure. Furthermore, successful implementation of the NLTA would depend on adequate technological infrastructure, funding, and reimbursement for nurse-led encounters, as well as workforce training.

### Conclusion

Our data suggest that an NLTA in diabetes care is feasible, acceptable, and could have utility in the monitoring of metabolic indices and psychological well-being in people living with diabetes, allowing for appropriate triage and intensification of management—especially in the context of limited access to primary or specialist care. With this in mind, we believe further studies of a diabetes nurse-led telemonitoring model of care are warranted.

## Acknowledgments

We gratefully acknowledge all the study participants and staff of the Royal Prince Alfred Hospital Diabetes Centre, as well as the support of the Sydney Health Partners Diabetes and Obesity Clinical Academic Group (DO-CAG) and the Royal Prince Alfred Hospital Institute of Academic Medicine.

## Data Availability

Data supporting our results is stored securely at the Royal Prince Alfred Hospital Diabetes Centre. This de-identifable data is not publicly available due to the potential risks in identifying the individuals involved and with contraints provided by the consent documentation. However, the data could be available on reasonable request subject to HREC review.

## Authors' Contributions

SN, JW, RKB and AG were involved in the study design. SN contributed to enrollment, interviewing, follow-up, data acquisition, and data analysis. SN, TM, RKB, and JW contributed to interpretation of data. SN and JW drafted the manuscript. AG, MC, MM, IC, LF, ST, and TW assisted in acquisition of data and provided critical review of the manuscript. RKB, SN, TM, and JW contributed to the statistical analysis and critical review of the manuscript while providing technical support. All authors approved the manuscript for submission. SN is the guarantor of this work and, as such, had access to all study data and takes responsibility for data integrity and accuracy of the analyses.

## Conflicts of Interest

None declared.

Multimedia Appendix 1



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Mean (SD) values of blood pressure, renal status, and lipid levels over 12 months for the telemonitoring study group and non-telemonitoring study group cohorts.
[DOCX File, 18 KB - diabetes_v10i1e68214_app1.docx ]

Multimedia Appendix 2
Diabetes self-care, health care usage, behavioral risk factors, and quality of life for the telemonitoring study group only.
[DOCX File, 18 KB - diabetes_v10i1e68214_app2.docx ]

Multimedia Appendix 3
Median (IQR) of selected psychosocial factors for the telemonitoring study group only.
[DOCX File, 17 KB - diabetes_v10i1e68214_app3.docx ]

Multimedia Appendix 4
Self-reported COVID-19 pandemic–related beliefs, behaviors, and worry for the telemonitoring study group only.
[DOCX File, 19 KB - diabetes_v10i1e68214_app4.docx ]

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## Abbreviations

**EQ-VAS:** EuroQl Visual Analogue Scale
**GAD-7:** Generalized Anxiety Disorder 7-item
**endo:** endocrinologist
**GP:** general practitioner
**$HbA_{1c}$:** glycated hemoglobin $A_{1c}$
**NLTA:** nurse-led telemonitoring approach
**PAID-5:** Problem Areas in Diabetes scale
**PHQ-9:** Patient Health Questionnaire-9
**PREDICT:** Progression of Diabetic Complications
**RPAH:** Royal Prince Alfred Hospital
**T1DM:** type 1 diabetes mellitus
**T2DM:** type 2 diabetes mellitus
**TSG:** telemonitoring study group


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Original Paper

# Patient and Clinician Perspectives on the Effectiveness of Current Telemedicine Approaches in Endocrinology Care for Type 2 Diabetes: Qualitative Study

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## Abstract

**Background:** Since the rapid widespread uptake in 2020, the use of telemedicine to deliver diabetes specialty care has persisted. However, evidence evaluating patient and clinician perspectives on benefits, shortcomings, and approaches to improve telemedicine care for type 2 diabetes is limited.

**Objective:** This study aims to assess clinician and patient perspectives on specific benefits and limitations of current telemedicine care delivery for type 2 diabetes and views on approaches to enhance telemedicine effectiveness for patients who rely on it.

**Methods:** We conducted semistructured qualitative interviews with diabetes specialty clinicians and adults with type 2 diabetes. We used a qualitative description approach to characterize participant perspectives on care delivery for type 2 diabetes via telemedicine.

**Results:** Both clinicians (n=15) and patients (n=13) identify significant benefits of telemedicine in overcoming both physical (geographic and transportation) and scheduling (work commitments and wait times) barriers to specialty care for type 2 diabetes. In addition, telemedicine may enhance communication around diabetes care by improving information sharing between patients and clinicians. However, clinicians identify limited availability of home blood glucose data and vital signs as factors, which impair the optimal management of type 2 diabetes and related comorbid conditions via telemedicine. Previsit preparation, involvement of multidisciplinary providers, and frequent brief check-ins were identified by patients and clinicians as potential strategies to improve the quality of telemedicine care for adults with type 2 diabetes.

**Conclusions:** Patients and clinicians identify key strengths of telemedicine in enhancing access to diabetes specialty care for adults with type 2 diabetes and describe approaches to ensure that telemedicine delivers high-quality diabetes care to patients who rely on it.

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**KEYWORDS**

diabetes; telemedicine; video visit; endocrinology; effectiveness; type 2 diabetes mellitus; patient; perspectives; qualitative interviews; clinicians



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## Introduction

The use of telemedicine—synchronous, audiovisual, internet-based communication between patients and clinicians—to provide endocrinology care expanded rapidly in 2020 [1,2]. While many patients have since resumed in-person care, a significant proportion of patients continue to use telemedicine: more than 11% of endocrinology visits in a national sample from January 2022 to March 2023 were conducted via telemedicine [3]. Telemedicine can expand access to endocrinology care for patients in rural areas of the United States, where there are long-standing shortages of endocrinologists [4], and for patients who face transportation, mobility, or other barriers to in-person care. The use of telemedicine to increase access to specialty diabetes care is supported by national guidelines, which also support the need for additional research assessing components of successful implementation of telemedicine programs [5,6]. Evidence from randomized trials of telemedicine interventions for type 2 diabetes (T2D) demonstrates that remote review of blood glucose by care teams [7,8]; active remote medication adjustment [8,9]; patient engagement between visits via phone, text message, or portals [9]; multidisciplinary team involvement in virtual care [8]; and remote diabetes self-management education and support services [10-12] are associated with the greatest hemoglobin $A_{1c}$ improvement and may support diabetes care quality. However, evidence on the benefits and limitations of real-world telemedicine approaches to provide endocrinology care to adults with T2D outside of trial settings is limited.

Retrospective analyses of real-world telemedicine outcomes for adults with T2D in primary care settings have had mixed results, with some studies finding equivalent or superior glycemic outcomes to in-person care [13-16], while others demonstrate inferior care quality [15,17,18]. However, evidence suggests that patients using telemedicine alone to access endocrinology care for T2D may not experience the same glycemic improvements as patients using in-person care [19]. We previously completed a survey study of diabetes specialists on factors impacting the quality of diabetes care delivered via telemedicine, in which clinicians cited clinical complexity, as well as limited clinical resources to support telemedicine, as factors that reduce effectiveness [20]. However, clinician and patient perspectives on the benefits and limitations of current telemedicine care delivery and approaches to improve this care have not been explored. As a result, in this study, we aimed to gain a deeper understanding of the perspectives of both diabetes specialty clinicians and patients on specific benefits and limitations of current telemedicine approaches for T2D and ways to enhance telemedicine effectiveness for patients who rely on it.

## Methods

### Study Design

In this qualitative study, we used a qualitative description approach to data collection and analysis. Qualitative description research studies aim to understand the perspectives or worldviews of participants with the goal of finding actionable insight; qualitative description is a common theoretical orientation for qualitative studies in the health sciences [21]. This theoretical orientation informed our study design, from participant selection to the development of the interview guide and data analysis [21]. Our goals of analysis were to describe the content of the interviews from the perspectives of study participants, without abstracting to the level of social theory [22]. Semistructured qualitative interviews were conducted with diabetes specialty clinicians from endocrinology clinics across the United States and patients from a single academic endocrinology center. The study team included an adult endocrinologist, a primary care provider, a qualitative methodologist, and two qualitative research analysts (one with a Master of Arts degree and one with a Juris Doctor degree, both male). We report our results based on the COREQ (Consolidated Criteria for Reporting Qualitative Research) framework [23].

Interview guides were developed by the study endocrinologist, primary care provider, and qualitative methodologist, based on findings of a previous mixed methods survey study of endocrinology patient and clinician experiences with telemedicine, specifically synchronous audiovisual communication or “video visits” for T2D, and were not pilot-tested [20]. Guides addressed patient and clinician perspectives on the current use of telemedicine to deliver or receive care for T2D, the benefits and shortcomings of telemedicine, and approaches to improve the quality of telemedicine care.

### Recruitment

Diabetes specialty care clinicians were recruited via direct email outreach in June 2023. All 44 clinicians targeted for recruitment worked in adult endocrinology clinics. Patient participants were recruited from respondents to a previous survey study about telemedicine for T2D conducted between August 2022 and March 2023. All 24 patient participants contacted for recruitment were adults aged >18 years with T2D who had used telemedicine in the past year to access endocrinology care at 1 of 7 clinical sites associated with a single large academic medical center.

### Data Collection and Analysis

Interviews with clinicians were conducted between June and August 2023. Interviews with patients were conducted between June and July 2023. Semistructured interviews were conducted by two trained qualitative research analysts via a secure videoconferencing platform and lasted 45-60 minutes. Audio-only transcripts generated via videoconferencing software were reviewed and corrected using notes recorded by each analyst during interviews. Interviews continued until each interviewer determined, through a review of transcripts and notes, that thematic saturation had been reached [24]. Participants did not have previous relationships with interviewers and did not receive any information about interviewers during this study. No one was present at the interviews except for the participant and interviewer. Transcripts were not returned to participants and participants did not provide feedback on the findings.



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Initial codebooks were inductively developed by experienced qualitative research specialists for each dataset based on the content of the interviews. In this process, researchers reviewed transcript data for both patient and clinician interviews, respectively, to identify key concepts within the raw data that could produce a system of codes for categorizing the data. These codebooks were then reviewed and approved by the qualitative methodologist. For both sets of interviews, two coders trained in the codebook co-coded the initial transcripts (3 patient and 4 clinician transcripts, respectively), then met to adjudicate their coding and refine the codebook based on any coding disagreements or discrepancies that arose. Finalized codebooks are included as Multimedia Appendix 1 (patient) and Multimedia Appendix 2 (provider). They then applied the codebook to the remaining transcripts and assessed intercoder reliability via kappa statistics provided by MAXQDA (VERBI Software) coding software. The overall κ score for the provider coding was 0.77, indicating "substantial" agreement, and the overall κ score for the patient coding was 0.92, indicating "near perfect" agreement [25]. All coding differences were adjudicated to full agreement. This finalized coding was used to assist in both conventional content [26] and thematic analysis [27] of the transcripts. Both conventional content analysis and thematic analysis rely on familiarization with and organization of the data through coding. Following coding, a systematic review of all text segments associated with particular codes can yield additional insight. Conventional content analysis was used to summarize and describe what participants said. Thematic analysis, following the steps described by Braun and Clark [27], was then used to identify overarching themes or recurring patterns within the data that might not be identified by the summarization of content alone in the conventional content analysis. Themes were then reviewed and refined to ensure they accurately represented the data in the original context.

### Ethical Considerations

This study was approved by the University of Pittsburgh Institutional Review Board (study number STUDY23030092). All participants provided verbal informed consent before the interview. Audio-only transcripts generated via videoconferencing software were reviewed and corrected using notes recorded by each analyst during interviews, with identifying details redacted. Interviews continued until each interviewer determined, through a review of transcripts and notes, that thematic saturation had been reached [24]. Participants did not have previous relationships with interviewers and did not receive any information about interviewers during this study. No one was present at the interviews except for the participant and interviewer. Transcripts were deidentified and were not returned to participants, and participants did not provide feedback on the findings. Interviews with clinicians were conducted between June and August 2023. Interviews with patients were conducted between June and July 2023. Semistructured interviews were conducted by two trained qualitative research analysts via a secure videoconferencing platform and lasted 45-60 minutes. Participants were compensated with a US $50 cash card.

## Results

### Participants

Diabetes specialty clinicians (n=15) who completed interviews practiced in 12 unique institutions across 8 states (California, Florida, Maryland, Massachusetts, New York, Pennsylvania, Oregon, and Texas). In total, 14 clinicians were endocrinologists, and 1 was a nurse practitioner; 14 practiced at academic medical centers, with 1 in private practice.

Patients (n=13) who completed interviews all received care within a single academic endocrinology division, including 7 clinics across both urban and rural counties, and reported duration of T2D from 3 to 20 years. There were 29 clinicians and 14 patients who did not respond to recruitment emails or phone calls or reported they did not have time to participate.

Many clinician and patient participants reported using telemedicine for the first time during the COVID-19 pandemic. Clinicians described attenuation in use over time with a declining perceived need for social distancing due to patient and institutional preferences. On the other hand, many patient participants described a desire to continue to use telemedicine due to convenience, although some reported a preference for returning to in-person care.

### Findings

We identified 4 major themes around patient and clinician perspectives on key benefits of telemedicine for specialty care of T2D, limitations of current telemedicine practice, and approaches to improve the quality of diabetes care delivered via telemedicine.

#### *Theme 1: Telemedicine Enhances Access to Diabetes Specialty Care by Overcoming Multiple Barriers to In-Person Care*

Clinicians and patients generally agreed that one major benefit of telemedicine is improved access to care. Many clinicians described increasing access to endocrinology care for patients who face barriers to traditional office visits as a main reason for ongoing use. Clinicians cited multiple types of barriers faced by patients that telemedicine can help overcome: long travel times for patients who live at a significant distance from the clinic, transportation availability, and cost of transportation. Additional barriers including scheduling conflicts between in-person visits and work, as well as childcare or eldercare commitments, were also mentioned. Clinicians also perceived telemedicine to be beneficial in specific situations that require increased visit frequency, such as diabetes in pregnancy. In addition, clinicians noted that telemedicine may make it easier for patients with mental health conditions, such as depression, to access care by reducing the burden of attending visits. Importantly, clinicians noted that these factors which reduce barriers to care resulted in significantly lower no-show rates for telemedicine visits (Textbox 1).

Many patients also reported that telemedicine increased access to diabetes specialty care and made that care more convenient. Patients reported that telemedicine allows them to overcome



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the lack of transportation, as well as avoid costs for parking and gas. For example, one patient stated:

> *The pros are…travel time, wait time, you know I'm not using gas, I'm not using a vehicle, I'm not traveling.*

In addition, patients reported significant benefits in saving time, both in traveling to the clinic and waiting to see their clinician, with telemedicine compared to in-person care (Textbox 1).

**Textbox 1.** Select quotes for theme 1: telemedicine enhances access to diabetes care in many ways.

**Clinician perspectives**

- They come in from two, three hours away, and in those cases we'll do telemedicine, just so that they're not having to drive back and forth like five hours.
- We're not in a wealthy area: a lot of people are having transportation issues, having trouble affording gas, um, have other issues like childcare or elder care, or, you know, can't get off from work, so it makes it difficult for them to come to in-person visits.
- Lot of times people cancelled because, for a variety of personal reasons, they can't get into the clinic, and it takes so much time to get into clinic or it costs money. But with telemedicine, I had almost a zero no-show rate.

**Patient perspectives**

- I think is much easier, because sometimes you can do all this money spending to get there, and they say the same thing they say every time.
- It's just more convenient. I got work and I don't have to take, like, a whole day of work off I can just schedule, you know, my lunch break.
- Telemedicine works a lot for me, being that I don't always have transportation to get to my appointments.

### *Theme 2: Telemedicine Can Facilitate Information Sharing in Diabetes Visits*

Clinicians and patients generally agreed that telemedicine can allow for more information-sharing diabetes visits, but had differing views on the specific ways telemedicine was most helpful. Clinicians reported that the ability to have caregivers engaged in visits is one major way telemedicine enhances information sharing, especially with regard to self-management of diabetes including diet and medication regimen (Textbox 2).

Immediate access to medications in the home was cited as another benefit of telemedicine, especially for patients on complex medication regimens:

> *When they are at home, I'm actually able to tell them, why don't you go show me what exactly you're taking, show me the color of the pen…so I think that helps me from a standpoint that if they are on a very complex regimen, I have a better way of assessing.*

On the other hand, many patients focused on improved communication with their clinicians via telemedicine:

> *I think the communication just has improved. I mean [my clinician] can focus on being prepared…for the visit, where we can spend more time just discussing my goals and where I'm at.*

Screen sharing to review glucose trends and other data was also discussed as one benefit of telemedicine visits for diabetes care, which enhances communication and information sharing. In addition, patients described reduced stress associated with telemedicine compared to coming into the clinic, including feeling more at ease and avoiding the hassle associated with navigating health care facilities and procedures. This reduced stress further improved their rapport and communication with their clinician via telemedicine (Textbox 2).

**Textbox 2.** Select quotes for theme 2: telemedicine can facilitate information sharing in diabetes visits.

**Clinician perspectives**

- Having the family member there, knowing that the family member will encourage the patient to do what we've discussed when they leave the visit is very helpful.
- I'll be like, "Hey, can I speak to your spouse or your children? Can they get on the phone? We can go over the plan." That saves me time because it happens synchronously during that same visit, I don't have to call the family member after the patient has left the clinic to update about the plan.
- I exactly know what the patient is taking because they are able to show me the bottles.

**Patient perspectives**

- I'm able to talk with the doctors more; you know…talking, we can get a little more things discussed; she can pull things up and show 'em to me. I guess you can do that in person too, but, you know, it's just really just convenient.
- I was very comfortable talking to her about the things I needed to talk to her about…I like the telemedicine because it's, you know, I'm not like getting judged.
- I just seem more relaxed on the phone…There's no office, you know, office mumbo jumbo, you know, waiting…vital signs at all that, I just don't like any of that.



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### *Theme 3: Clinicians and Patients Perceive Different Limitations of Current Telemedicine in Supporting Successful Diabetes Management*

Clinicians and patients differed in their perspectives on the limitations of current telemedicine approaches for diabetes management. Clinicians described multiple drawbacks of telemedicine, which limit their ability to help patients manage diabetes during routine visits. The lack of glucose data, both from glucometers or when continuous glucose monitor device data are not automatically shared, was commonly cited as a major limitation. In addition, clinicians discussed increased difficulty in delivering care through telemedicine for patients with limited English proficiency due to challenges using interpretation services. For example, one clinician stated:

> *If the interpreter can't log on via the video platform, then I have to…call the patient via the telephone with interpreter…not as seamless as doing an interpreter visit in clinic.*

Clinicians also noted that telemedicine may be less effective for medically complex patients due to the limited ability to obtain vital signs and conduct a physical examination to inform management of comorbid conditions, such as hypertension. In addition, clinicians described how it can be challenging to leverage multidisciplinary care resources, such as diabetes self-management education and support, with current telemedicine protocols compared to in-person office visits (Textbox 3). As these services are often available on a drop-in basis in clinics, current telemedicine approaches may limit the ability of clinicians to provide these resources in an unscheduled manner as needs arise during video visits.

**Textbox 3.** Select quotes for theme 3: clinicians and patients perceive different limitations of current telemedicine in successful diabetes management.

**Clinician perspectives**

- Most of my patients…do not keep a separate glucose log outside of their glucometer, and so it's really challenging to try and understand…if someone's on any, you know, agent that has a potential for hypoglycemia…how can I titrate that safely in the absence of data?
- Hypertension management is trickier via telemedicine unless someone has a blood pressure cuff at home and is checking their blood pressure…so I would say I have very seldom made adjustments to antihypertensives in a telemedicine-only visit.
- A lot of type two diabetes management also focuses on lifestyle, right? Like it focuses on things like you know, their diet, what their regular lifestyle is, the level of activity, etc. So, many times if it's over telemedicine, I can't use the other services that we can offer in person in clinic right then and there when the patient is there.

**Patient perspectives**

- Really is no big difference. The same conversation we would have, in-office, face-to-face, will be the same conversation we would have in, you know, telecommunication.
- I really wish I could have, you know, had my blood work and my blood pressure and everything done.
- Not being able to… get my A1C in person… that's probably one of the…only other hardships that I didn't like about it.

On the other hand, many patients perceived that telemedicine overall delivered a very similar quality of care to in-person visits. For example, one patient stated:

> *The telecommunication visit was good for me…there was nothing that I really needed to see my physician with in-person, that I needed to go over her that I couldn't go over with her on the phone.*

However, some patients described the drawbacks of not receiving in-person diabetes care, including the inability to have a physical exam, vital signs, and lab work done in the office (Textbox 3).

### *Theme 4: Strategies to Enhance the Effectiveness of Telemedicine Diabetes Care in the Future*

Clinicians and patients also had differing, but complementary, perspectives on approaches to improve the current delivery of diabetes care through telemedicine to better help patients successfully manage T2D. Clinicians described two main strategies. The first centered around preparation before telemedicine visits to ensure that all information that would routinely be available in office visits is similarly available to clinicians during telemedicine visits. This could include the collection of glucose data and home-measured vital signs, as well as addressing any potential technological barriers to the successful completion of the visit. The second main approach included the engagement of interdisciplinary team members during visits and ensuring postvisit follow-up. As one clinician stated when asked about the ideal telemedicine visit:

> *I would finish my visit and send patient back to the Zoom waiting room, and then the… CDE or nutrition will join that visit or a psychologist…and… a nurse…to kind of reiterate the instructions that or the plan that we discussed during the visit, and then schedule the follow-up, obviously. That's sort of the, the dream flow of the televisit.*

However, clinicians reported that inadequate staffing is the major barrier that prevents the implementation of these strategies in current practice (Textbox 4). Finally, some clinicians also emphasized the importance of changing policies regarding reimbursement to the future of telemedicine for diabetes care; as one clinician put it, "[if reimbursement rates go down] it's a concern because then we won't be able to do it. And I think care will suffer."



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**Textbox 4.** Select quotes for theme 4: strategies identified to enhance diabetes care through telemedicine in future use.

**Clinician perspectives**

- So before the visit, would have CGM download or glucometer data for like two weeks, an updated list of their medications, episodes of hypoglycemia—that'd be very helpful to have ahead of time—and if they did have vitals from home, so if they were checking their blood pressure or weight if they had that information ahead of time, and then actually checking your blood sugar at the visit if that was part of the protocol, you know, getting…labs they were due for ahead of visit, that would be fantastic.
- So, optimal before the visit, every single person has uploaded data to a cloud… every single person has had necessary labs in order, and everyone has ensured that they can log into the app and have good internet...After the visit, you know, I think in an ideal world is that there would be some system that can prompt patients, remind patients, and then also alert me if they have not completed the next steps.
- I mean, so much of telemedicine success is based on the previsit work that's done, and that's all, you know, non-provider based. So, staffing is the biggest challenge that most practices have with trying to ensure to do the previsit calls, confirmation calls, ensuring all this stuff is done…that's the biggest barrier I think, in ensuring that practices are adequately staffed to support the in-person volume, plus do all of this [telemedicine] stuff.

**Patient perspectives**

- Well, I'd kind of like to have more education, you know, cause I've never seen the diabetes educator through a video visit, and I'd really like to get more education. I think that the education is key to diabetes, And the more you know about it, the better you can control it.
- Once a month check-ins or checkups… or…me being able to send my results to them, like once monthly..., like weight or… things like that.
- I mean, just if there were any, you know, specific follow-up items, that I needed, you know, to do…being, sent a reminder or whatever, electronically, or something along those lines.

While most patients felt that current telemedicine practices worked well for them, some identified additional support that could complement clinicians' approaches above to improve telemedicine care. Some patients reported desiring more of an opportunity to access diabetes education and meet with interdisciplinary team members through video visits (Textbox 4). Others felt that using telemedicine to complete more frequent check-ins on their diabetes or offer reminders between visits could improve their diabetes management by helping them stay on track:

> *A 10-minute checkup maybe once a month, once every other month. 'Hi…What are your numbers? What's your glucose? How are you feeling?'…Especially for those who haven't, you know, been consistent.*

# Discussion

## Principal Findings

This study provides an updated assessment of clinician and patient perspectives on the current use of telemedicine to deliver endocrinology care to adults with T2D more than 3 years after initial widespread uptake in the United States. Our findings add to previous literature by gathering perspectives from patients and endocrinology clinicians practicing in diverse clinics across the country on optimal practices to address the limitations to effective routine clinical diabetes care via synchronous telemedicine. Clinicians emphasized the importance of access to home blood glucose data and discussed how telemedicine can make it difficult to manage common comorbid conditions due to a lack of vital signs or other home monitoring data. These findings align with previous studies in which clinicians report that telemedicine is appropriate for less complex conditions and patients [20,28,29]. As a result, clinicians identify previsit preparation, including the collection of home health data as a key to promoting successful diabetes telemedicine visits, which has also been underscored in previous literature describing telemedicine practices in the United States [30]. In addition, our findings align with existing evidence from other countries, including Australia and the United Kingdom, which supports the importance of multidisciplinary care and access to education in leveraging technology for diabetes care, as well as the benefits of synchronous video visits in improving access, reducing the patient's burden of treatment, and improving clinician-patient communication [31,32]. Clinicians also identified the shortcomings of current telemedicine approaches in integrating allied professionals, including translators, diabetes care and education specialists, and nutritionists, into visits. Both clinicians and patients identified engagement of the multidisciplinary care team as one approach to ensure the delivery of high-quality care remotely, which may be especially important for patients who are clinically complex. Finally, patients also identified that enhanced follow-up after visits and the use of telemedicine for more frequent, brief check-up visits would improve the diabetes care they receive virtually.

In this study, patients generally reported satisfaction with the communication, information sharing, and overall care received through telemedicine. In addition, patients emphasized increased convenience and reduced costs associated with transportation as major benefits. These findings align with and add to previous literature in which patients with diabetes identify time and cost savings as benefits of telemedicine, while generally being satisfied with quality of care [29,33-35]. However, previous literature also underscores patient concerns about the lack of physical examination, vital signs, and in-office laboratory work potentially reducing the quality of diabetes care accessible through telemedicine, issues which were also identified in this study [29,34,35]. Our findings that patients report telemedicine is less stressful and potentially enhances communication around diabetes care contrasts with other studies of adults with T2D [34] and other chronic conditions [36] in the primary care setting, in which inferior communication and rapport building were noted. This may be due to an emphasis on the review of



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home glucose data and increased use of continuous glucose monitoring in the endocrinology setting relative to primary care, which has been emphasized in previous studies as one key component to successful telemedicine visits [29].

Both clinicians and patients describe how telemedicine enhances access to care by removing barriers to in-person visits, consistent with previous literature [28,37]. Clinicians in our study also emphasized that telemedicine results in lower no-show rates than in-person care, a finding seen in previous studies in both diabetes and primary care clinics [37-39]. Adults with T2D who have geographic or transportation barriers to accessing specialty diabetes care already experience worse care quality [40-42] and higher diabetes-related mortality [43-45]. Thus, ensuring that telemedicine delivers care that is at least as high-quality as in-person is crucial to promoting equitable access to care. Policies that preserve reimbursement for telemedicine care and promote improvement of care delivery through telemedicine will be critical to continuing access to diabetes specialty care for underresourced populations.

### Limitations

Strengths of this study include providing an updated assessment of the perspectives of patients and clinicians on the current use of telemedicine for diabetes care more than 3 years after initial use when many centers have refined their virtual care delivery process. Importantly, this study includes diabetes specialty clinicians from across the United States; while most practice in academic centers, diversity in geography, patient populations, and local telemedicine protocols enhances the generalizability of our findings. However, clinicians from private practice are underrepresented in our sample, so findings may not apply to this practice setting. Patient participants were drawn from a single academic endocrinology division, which includes a diversity of geographic areas. However, findings may not apply to patients who receive endocrinology care for T2D at centers with different telemedicine care protocols.

### Conclusions

In conclusion, clinicians and patients perceive the important benefits of telemedicine in increasing access to care, especially for patients who face barriers to in-person care. Given the ongoing shortage of endocrinologists and the prevalence of barriers to in-person endocrinology care, some patients will continue to rely on telemedicine indefinitely in order to access diabetes specialty care for T2D. Thus, it is crucial to use insight from patients and clinicians to inform approaches to improve the quality of care delivered via telemedicine care to reduce existing disparities in diabetes care and outcomes for these populations. Ensuring adequate data sharing through previsit preparation, increased visit frequency based on patient needs, and engaging interdisciplinary teams during and after telemedicine visits can leverage the benefits of virtual care to ensure telemedicine is at least as good as, or even superior to, in-person specialty diabetes care for patients who rely upon it.

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## Authors' Contributions

MZ contributed to conceptualization, methodology, writing—original draft, writing—review and editing, funding acquisition, and supervision. MH was involved in methodology, formal analysis, investigation, and writing—review and editing. LA was responsible for formal analysis, investigation, writing—review and editing. AMR contributed to conceptualization, methodology, and writing—review and editing.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Patient codebook.
[PDF File (Adobe PDF File), 28 KB - diabetes_v10i1e60765_app1.pdf ]

Multimedia Appendix 2
Provider codebook.
[PDF File (Adobe PDF File), 35 KB - diabetes_v10i1e60765_app2.pdf ]

Multimedia Appendix 3
Supplementary File 3: COREQ Checklist.
[PDF File (Adobe PDF File), 89 KB - diabetes_v10i1e60765_app3.pdf ]



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## Abbreviations

**COREQ:** Consolidated Criteria for Reporting Qualitative Research
**T2D:** type 2 diabetes

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# Continuous Glucose Monitors Among Adults With Type 2 Diabetes Mellitus in the Primary Care Setting: Qualitative Study Informed by Technology Acceptance Model and Health Belief Model

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## Abstract

**Background:** Continuous glucose monitors (CGM) reduce the burden of glycemic monitoring and improve glycemic control, quality of life, and decreased health care use. Despite expanded insurance coverage and adoption, barriers remain, especially in primary care. Existing research largely evaluates specific populations or interventions, leaving limited insight into the broader primary care experience.

**Objective:** This study aims to examine the experiences of adults with type 2 diabetes mellitus (T2DM) using CGM in primary care, guided by the Health Belief Model and Technology Acceptance Model.

**Methods:** This qualitative study included in-person semistructured sessions (interviews or a focus group), surveys, and electronic health record data. Participants were recruited from 3 urban primary care (internal medicine and internal medicine-pediatrics) clinics affiliated with a large academic health system in Southwest Ohio, United States, with high rates of public insurance (Medicare or Medicaid). Eligible participants were adults (≥18 y) with T2DM and a CGM prescription. Data were analyzed using theme generation guided by directed content analysis in MAXQDA (VERBI Software GmbH) with codes derived from Health Belief Model and Technology Acceptance Model constructs. Survey data were used to triangulate to enhance validity.

**Results:** Overall, 16 participants (interviews: n=12; 1 focus group: n=4) were recruited for the study with a mean age of 56.9 (SD 10.5) years. In total, 69% (11/16) identified as Black, 100% (16/16) as Non-Hispanic, and 69% (11/16) as female, and 94% (15/16) used public insurance. Six themes emerged: disease susceptibility, disease severity, influential drivers, perceived ease of use, perceived usefulness, and attitude toward using CGM. All participants found CGM helpful and would recommend it to others. While affirming numerous barriers well-described in other populations, this study uniquely describes the burden of comorbidities, the trust in CGM data compared to glucometer-based monitoring, and the reliance on receivers to use CGM technology in this patient population.

**Conclusions:** CGM is valued by adults with T2DM in primary care, yet barriers remain. Tailored support for initiation, troubleshooting, and education (especially alarm management and data interpretation) is needed. These insights can inform scalable strategies to enhance CGM use and experience in primary care.

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**KEYWORDS**

continuous glucose monitors; CGM; primary care; qualitative research; Technology Acceptance Model; type 2 diabetes mellitus



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## Introduction

### Background

Continuous glucose monitors (CGM), approved by the US Food and Drug Administration in 1999 [1], use a subcutaneous sensor to measure interstitial fluid glucose, reducing monitoring burden and revealing fluctuations that might otherwise be missed. This technology reduced the need for painful fingerstick testing with glucometers that require several steps and supplies [2]. CGM use improves glycemic control [3-10], reduces hypoglycemia and variability, enhances the quality of life [5], and lowers health care use and costs [6-10]. Since diabetes affects 10.5% of the global adult population [11], remains the seventh leading cause of death in the United States [12], and is associated with substantial disease-related distress [13], harnessing the potential of CGM and other emerging technologies may be key to improving outcomes.

Previously, broad CGM use was limited in patients with type 2 diabetes mellitus (T2DM) by a variety of factors. Access to specialized endocrinology care [14] is limited, and despite increased prescribing [15], primary care staff and providers need additional training to be comfortable with the technology [16]. Additionally, CGM use was previously emphasized for patients with insulin-dependent T2DM, and insurance coverage was limited. Policy changes have expanded CGM coverage and accessibility [17,18], making broader CGM use, especially in primary care, more realistic. Many patients with T2DM and prediabetes are managed in primary care settings, and CGM can serve as a patient education tool [19].

In order to maximize CGM use for T2DM in primary care, more work is needed. To date, little is known about the adult patient experience using CGM as part of primary care T2DM management. Without this knowledge, barriers to optimal use cannot be adequately addressed. Recent qualitative work in the United States on outpatient CGM use focused on youth-onset T2DM [20-22], Hispanic adults [23-25], federally qualified health centers [25], or CGM use in combination with other interventions [26]. More work is needed to better understand the common barriers to CGM use in primary care and the issues that primary care providers and staff must help patients overcome. For instance, CGM cost, wearability, discomfort, or fear related to sensor insertion, lack of support, need for guidance on data interpretation, educational needs, and other physical or social factors may all influence CGM use [27,28].

We sought to identify disease- and technology-specific factors influencing CGM use in primary care. Therefore, to guide this work, we chose the Health Belief Model (HBM) [29,30] and the Technology Acceptance Model (TAM) [31]. HBM explains health behaviors through constructs, such as perceived susceptibility, perceived severity, perceived benefits, perceived barriers, self-efficacy, and cues to action. The TAM complements HBM by addressing technology adoption through external variables, perceived usefulness and ease of use, attitude toward using, behavioral intention to use, and actual system use. Combining TAM and HBM enables a holistic evaluation of factors influencing CGM use.

### Objective

This study aims to understand the perspective of adults with T2DM using CGM in primary care.

## Methods

### Study Design

This is a qualitative study using directed content analysis examining the experiences of adults with T2DM using CGM in primary care in the United States, using in-person sessions (interview or focus group) with a survey; diabetes-related health data were extracted from the electronic health record (EHR) for each respective participant. We sought to complete 3 focus groups in addition to individual interviews. Study design was guided by the TAM [31] and HBM [30] with an interpretivism paradigm [32]. The interview guide in Multimedia Appendix 1 was internally developed and included questions adjusted to meet fifth-grade reading level. It was internally reviewed but not pilot tested. The interview guide was submitted and approved by the University of Cincinnati Institutional Review Board.

The COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [33] is available in Checklist 1.

### Setting

We recruited participants from 3 urban primary care clinics affiliated with a large academic health care system in Southwest Ohio, United States: (1) an internal medicine resident clinic, approximately 7000 patients, 30% have diabetes (80% have hemoglobin $A_{1c}$ [$HbA_{1c}$] <8%, ~18% use CGM); (2) an internal medicine attending clinic, approximately 3500 patients, 24 % have diabetes (81% have $HbA_{1c}$ <8%); and (3) a combined attending and resident internal medicine-pediatrics clinic, approximately 6000 patients, 11% have diabetes (84% have $HbA_{1c}$<8%). These clinic populations are approximately 70% publicly insured (Medicaid, Managed Medicaid, Medicare, or Managed Medicare) and 25% privately insured. The participating clinics were purposively selected due to high public insurance rates, a known marker in the United States for lower socioeconomic status. All clinics are supported by an in-house pharmacy team and nurse practitioners. Providers in all 3 clinics routinely care for patients with T2DM. All sessions took place in-person in an on-site location used for diabetes education.

### Recruitment

Participants were recruited by MIK via convenience sampling from the 3 purposively selected clinics. We recruited patients using flyers posted in clinics, announcements to primary care providers and pharmacists, and identifying eligible participants on clinic schedules. MIK contacted potential participants via patient portal messages and phone calls. Eligibility criteria included a diagnosis of T2DM, CGM prescription, 18 years and older, nonpregnant, and the ability to participate in a 1-hour in-person session in English. Participants were assigned to a session type based on their availability.



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### Research Team

The research team included an internal medicine primary care physician with clinical informatics training (MIK), a psychology doctorate student (AMC), an internal medicine resident (AS), an undergraduate student (JBW), a senior endocrinology attending (MF), an endocrinology fellow (AZ), and a senior physician scientist in biomedical informatics (EAM). Some team members have first-hand experience monitoring glucose via CGM and glucometers. This work is informed by the belief that chronic disease leads to a significant burden for patients and that technology can help reduce that burden. However, often technical, societal, structural, and individual factors prevent technology from optimizing disease management. This study was developed from MIK's experience working with patients in primary care and recognition that, while access to CGM was improving, the clinical impact described in the literature seemed to be lagging. MIK served as a supervising physician in the Internal Medicine clinic, where most patients were recruited but did not provide direct care to the patients recruited for this study. The team was supported by the University of Cincinnati Evaluation Services Center (ESC), which provides knowledge, expertise, and experience to serve as an evaluation and applied research partner. ESC provided interviewer training to MIK and supported the development of the protocol, codebook, and overall evaluation. Initial interviews included virtual support from the ESC to ensure quality and provide training for the primary interviewer (MIK).

### Data Collection

We conducted 1-hour in-person semistructured sessions (interviews and a focus group). Interviews were conducted by MIK, while the focus group was facilitated by the ESC (EM and AMC). No repeat interviews were conducted. Sessions were audio-recorded and transcribed via conferencing software (Microsoft Teams or Zoom). Transcripts were manually reviewed and edited by study staff. Identifying information was removed. As most sessions included only 1 study interviewer, field notes were limited. No nonparticipants were present during sessions. Transcripts were not returned to patients. Recruitment was terminated when data saturation [34] was achieved, as determined by no new themes, insights, or perspectives emerging from subsequent interviews (MIK and EAM).

Participants completed a paper survey after the session that included questions around perception of CGM using a Likert scale [22], usage habits, and social determinants of health, which was later transcribed into REDCap (Research Electronic Data Capture; Vanderbilt University) by MIK. EHR data were manually extracted via chart review to a REDCap form by MIK. Fields included demographics (age, ethnicity, race, sex, insurance type, and smoking), medical history (length of diabetes diagnosis, complications, and comorbidities), medications, appointment information (number of primary care physician, emergency department, and endocrinology visits in the last year), laboratory data (estimated glomerular filtration rate, cholesterol, $HbA_{1c}$ at first CGM prescription, and most recent $HbA_{1c}$), and completion status of health care maintenance tasks (eye exam, $HbA_{1c}$, urine protein, and foot exam). Study data were managed using REDCap [35,36].

### Statistical Analysis

Transcripts were coded using MAXQDA [37] (VERBI Software GmbH) and analyzed using a qualitative content analysis [38,39]. A priori codes were based on TAM and HBM, with inductive codes added during review of the first 3 transcripts (MIK and AMC; Multimedia Appendix 2). A total of 2 team members independently coded each transcript. Coding discrepancies were resolved by discussion and consensus. Theme generation was guided by directed content analysis [40] starting with the a priori codes. Inductive codes were evaluated (JBW) and combined with larger themes as appropriate. Data were examined for patterns within and across codes to identify potential themes and subthemes. Iterations of themes and subthemes were validated by team review (MIK, ACZ, AS, JBW, and EAM). Member checking was not performed. An audit trail documented coding and theme development. To strengthen rigor, we used methodological triangulation by comparing survey data on CGM perceptions with quantitative themes. Survey and EHR data were aggregated by session type. Categorical data are reported as counts, percentages; continuous data as mean, standard deviation, range (minimum - maximum).

### Ethical Considerations

This study was approved by the University of Cincinnati Institutional Review Board (study number 2023 - 0593). The protocol was deemed to be no greater than minimal risk. Written informed consent was obtained from all participants, including disclosure of the study goals. Participants could opt out at any time. Non-essential identifying information has been removed for publication. Participants were informed that direct quotes from the session may be used. Techniques to reduce power imbalances and promote equitable participation were used [38,41], such as using first names, removing badges, and wearing casual business clothing. Participants were compensated with a US $50 cash card.

## Results

### Overview

A total of 46 candidates initiated or received correspondence from the principal investigator; 16 participants (12 interviews and one 4-person focus group) were enrolled between December 2023 and June 2024 (Table 1), when data saturation was reached. Reasons for nonparticipation included inability to be reached, scheduling conflicts, and missed appointments.



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**Table .** Participant characteristics.

| Characteristics | Interview (n=12) | Focus group (n=4) | Overall (N=16) |
|---|---|---|---|
| Age (years), mean (SD), range | 57.3 (8.6), 44-69 | 56 (16.8), 40-75 | 56.9 (10.5), 40-75 |
| Race, n (%) | | | |
| White or Caucasian | 4 (33) | 0 (0) | 4 (25) |
| Black or African American | 8 (67) | 3 (75) | 11 (69) |
| Multiracial | 0 (0) | 1 (25) | 1 (6) |
| Ethnicity (interview and focus group total), n (%) | | | |
| Non-Hispanic | 12 (100) | 4 (100) | 16 (100) |
| Hispanic | 0 (0) | 0 (0) | 0 (0) |
| Sex, n (%) | | | |
| Female | 8 (67) | 3 (75) | 11 (69) |
| Male | 4 (33) | 1 (25) | 5 (31) |
| Insurance, n (%) | | | |
| Commercial | 1 (8) | 0 (0) | 1 (6) |
| Medicare | 4 (33) | 2 (50) | 6 (38) |
| Medicaid | 7 (58) | 2 (50) | 9 (56) |
| Have device, n (%)[a] | | | |
| Desktop or laptop | 5 (42) | 2 (50) | 7 (44) |
| Smart phone | 10 (83) | 2 (50) | 12 (75) |
| Tablet | 6 (50) | 0 (0) | 6 (38) |
| None | 1 (8.3) | 0 (0) | 1 (6) |
| Internet access at home, n (%)[a] | | | |
| Cellular plan | 5 (42) | 2 (50) | 7 (44) |
| Broadband | 10 (83) | 2 (50) | 12 (75) |
| Primary mode of transportation, n (%) | | | |
| Personally owned car | 7 (58) | 3 (75) | 10 (63) |
| Insurance provided transportation service | 2 (17) | 0 (0) | 2 (13) |
| Public transportation | 3 (25) | 1 (25) | 4 (25) |
| Diabetes medications, n (%)[a] | | | |
| Basal insulin | 6 (50) | 4 (100) | 10 (62) |
| Bolus insulin | 4 (33) | 4 (100) | 8 (50) |
| Metformin | 5 (42) | 2 (50) | 7 (44) |
| SGLT2[b] | 6 (50) | 1 (25) | 7 (44) |
| GLP1[c] | 8 (66) | 1 (25) | 9 (56) |
| Thiazolidinedione | 1 (8) | 0 (0) | 1 (6) |
| Statin | 11 (92) | 3 (75) | 14 (88) |
| Complications, n (%)[a] | | | |
| Neuropathy | 4 (33) | 2 (50) | 6 (38) |
| Nephropathy | 2 (17) | 1 (25) | 3 (19) |
| Cardiovascular | 5 (42) | 0 (0) | 5 (31) |
| Retinopathy | 1 (17) | 2 (50) | 3 (19) |



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| Characteristics | Interview (n=12) | Focus group (n=4) | Overall (N=16) |
|---|---|---|---|
| Years of CGM[d] use, mean (SD), range | 1.4 (0.8), 0.1-3 | 3.4 (1.9), 1.5-5.2 | 1.9 (1.4), 0.1-5.2 |
| Sensor type, n (%)[a] | | | |
| FreeStyle Libre 14 Day | 1 (8) | 0 (0) | 1 (6) |
| FreeStyle Libre 2 | 5 (42) | 2 (50) | 7 (44) |
| FreeStyle Libre 3 | 2 (17) | 1 (25) | 3 (19) |
| Dexcom G6 | 3 (25) | 1 (25) | 4 (25) |
| Dexcom G7 | 4 (33) | 0 (0) | 4 (25) |
| Connected device, n (%) | | | |
| Receiver | 9 (75) | 3 (75) | 12 (75) |
| Phone | 3 (25) | 1 (25) | 4 (25) |
| Years since DM[e] diagnosis, mean (SD), range | 12.2 (6.1), 3-22 | 12.8 (2.2), 10-15 | 12.3 (5.4), 3-22 |
| $HbA_{1c}$[f] at first CGM prescription, mean (SD), range | 9.2 (3.3), 5.2-16.9 | 9.3 (2.8), 6.3-13 | 9.2 (3.1), 5.2-16.9 |
| Most recent $HbA_{1c}$, mean (SD), range | 7.7 (1.7), 5.4-10.4 | 8.6 (1.2), 7.6-9.7 | 7.9 (1.6), 5.4-10.4 |
| Endocrinology appointment in last year?, n (%) | 2 (17) | 0 (0) | 2 (13) |

[a]Select all that apply, therefore columns may add up to more than 100%.

[b]SGLT2: sodium-glucose cotransporter 2.

[c]GLP1: glucagon-like peptide-1.

[d]CGM: continuous glucose monitoring.

[e]DM: diabetes mellitus.

[f]$HbA_{1c}$: hemoglobin $A_{1c}$.

The mean age was 56.9 (SD 10.5; range 40 - 75) years, 69% (11/16) identified as Black, 100% (16/16) identified as non-Hispanic, and 69% (11/16) as female. Most (15/16, 94%) use public insurance. The mean diabetes duration was 12.3 (SD 5.4; range 3 - 22) years, with initial $HbA_{1c}$ of 9.2% (SD 3.1; range 5.2 - 16.9) and most recent $HbA_{1c}$ of 7.9% (SD 1.9; range 5.4 - 10.4). Only 2 participants had an endocrinology visit in the past year. Ten participants used insulin. Mean CGM use was 1.9 (SD 1.4; range 0.1 - 5.2) years. Devices included FreeStyle Libre 14 Day, FreeStyle Libre 2, FreeStyle Libre 3, Dexcom G6, and Dexcom G7. Most (12/16, 75%) used a receiver rather than a phone for glucose viewing.

Survey results showed all participants strongly agreed that CGM was useful and would recommend it to a friend. Additionally, 93% (15/16) strongly agreed that CGM was helpful, and 87% (14/16) reported (agreed or strongly agreed) a positive experience using CGM.

## Qualitative Results

Informed by TAM and HBM, 6 themes emerged (Table 2): disease susceptibility, disease severity, influential drivers, perceived ease of use, perceived usefulness, and attitude toward using CGM. Triangulation with survey data confirmed that despite challenges, participants valued CGM and would recommend it.



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**Table .** Summary of themes and subthemes.

| Themes | Subthemes |
|---|---|
| Disease susceptibility | • Diagnosis<br>• Emotional response to diagnosis<br>• Contribution of lifestyle |
| Disease severity | • Unstable disease control<br>• Medication burden<br>• Fear of complications |
| Influential drivers | • Insurance coverage<br>• Support system<br>• Motivation<br>• Information sources<br>• Comorbidities |
| Perceived ease of use | • Model differences<br>• Initiation<br>• Sensor<br>• Receiver<br>• Alarms<br>• Skin reaction |
| Perceived usefulness | • Access to continuous data<br>• Trust in the data<br>• Data sharing |
| Attitude toward using CGM[a] | • Empowering disease management<br>• Recommend to others<br>• Improvement over Glucometer-based monitoring<br>• Further opportunities |

[a]CGM: continuous glucose monitor.

## Disease Susceptibility

Disease susceptibility, a component of the HBM, refers to a person's perception of the risk of acquiring a disease. Subthemes include context of diagnosis, emotional response, and contribution of lifestyle factors (Table 3).



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**Table .** Disease susceptibility and severity subthemes and pertinent quotes.

| Themes and subthemes | Quotes |
|---|---|
| Disease susceptibility | |
| Context of diagnosis | • "It's probably been 15 years, since more of the like the pre diabetes kind of ramping up into the Type 2. So they're slowly watching of the A1C kind of going up." [Participant 9] |
| Emotional response to diagnosis | • "I've been pre diabetic for a very long time and I guess I kind of jinxed myself by telling myself I'm will eventually be a diabetic just because everybody in my family has type 2 diabetes." [Participant 7]<br>• "It was a shock when I found out I had diabetes, you know, cause I think I'm the first person in our family." [Participant 1] |
| Contribution of lifestyle | • "I'm just assuming that the key is in not being as active as I used to be led to the sugar diabetes." [Participant 8]<br>• "I was borderline diabetic for a very long time before they actually made the full diagnosis… because I was overweight child, overweight teenager." [Participant 12] |
| Disease severity | |
| Unstable disease control | • "I have moments where I just throw it up in the air and say screw it. You know especially if I'm real depressed or upset about something, I just don't care. I'll be honest, just lose it for a while." [Participant 2] |
| Medication burden | • "I haven't been the best at the medicine... I just don't want to take [them]. I'll wrestle with myself for a while… I hear all these side effects that like that it's more problem taking it then if I don't." [Participant 5]<br>• "I wish you guys could be a guinea pig for one day to see what patients go through and that's what gets them discouraged is the side effects. Yep, I think that discourages a lot of people because people don't have the patience." [Participant 1] |
| Fear of complications | • "I have a neuropathy in my feet. When I take my shoes off, my feet tingles. It feels like somebody stabbing a 1000 needles. Horrible" [Participant 6] |

Participants described varied contexts of diagnosis, including specific events, family history, and progression from prediabetes. Reactions to diagnosis ranged from denial and surprise to inevitability, especially among those with a family history. Additionally, participants recognized the impact of lifestyle factors such as obesity and limited exercise on diabetes development.

## Disease Severity

Disease severity, a component of HBM, captures a person's feelings on the seriousness and consequences of diabetes. Subthemes include the unstable disease control, medication burden, and fear of complications (Table 3).

Participants noted the unstable nature of disease control, with difficulties such as "sugar addiction" and the potential for life events to derail progress. Despite the focus not being on medications, participants discussed side effects, drug shortages, dose uncertainty, and distrust leading to self-discontinuation. Fear of complications, such as blindness, neuropathy, and death due to poor diabetes control, was prevalent.

## Influential Drivers

Influential drivers, combining cues to action from HBM and external variables from TAM, look at drivers that improve diabetes management and the acceptance of CGM. Subthemes include insurance coverage, support systems, motivation, information sources, and comorbidities (Table 4).



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**Table .** Influential drivers subthemes and quotes.

| Influential drivers | Quotes |
|---|---|
| Insurance coverage | • "The only thing I don't like … it's not the [CGM][a], it is the insurance company. The insurance company that I have, they won't pay for [certain brand of CGM]. The one I have, it's not compatible to my phone and it won't alert me when it's going low." [Participant 3] |
| Support system | • "I love [primary care doctor] she's excellent. She gets on my case, which I need it cause sometimes and I know better, I'm a nurse. I know what [diabetes] does to you, but sometimes you know I drop the ball a little bit and then maybe after just short time, I get back on the ball again." [Participant 2]<br>• "Well, I like her [Pharmacist] a lot better than the doctors trying to explain it because this is not their forte and she seems to know what she's talking about… She's patient and she explains things to you know, and she knows me." [Participant 1] |
| Information sources | • "I know there's commercials on TV, but I don't know if they [people with diabetes] really understand what the commercials is telling them. It would be a big improvement. You don't have to stick your fingers no more. How it lets you know when your blood sugars are high or low. I don't think everybody, all diabetics, really understand that." [Focus Group Participant 2]<br>• "Sometimes I look on YouTube. I don't know how accurate it is, but I look at it and I say that might work…I have just been trying to find the things that work for me." [Participant 5] |
| Comorbidities | • "And it's hard for me to see. Yes, with that thing [receiver] is like the numbers kind of a little bit bigger than that [on phone]." [Participant 4] |

[a]CGM: continuous glucose monitor.

Participants highlighted the critical role of insurance coverage, noting they couldn't use CGM without it and that device choice was often dictated by coverage. Support systems, including family, community, and health care team members, were also significant. Motivation for disease control stemmed from the desire to live for loved ones, manage symptoms, and optimize $HbA_{1c}$. Information about CGM came from advertisements, health care teams, family and friends, and YouTube (Google; 3/16, 19%). Participants reported comorbidities in mental health, cardiovascular, musculoskeletal, neurological, vision, and obesity, with mental health and vision preventing optimal CGM use.

## Perceived Ease of Use

Perceived ease of use, from the TAM, examines how easy or difficult individuals find CGM to use. Subthemes include model differences, initiation, sensor, receiver, alarms, and skin reactions (Table 5).



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**Table .** Perceived ease of use subthemes and quotes.

| Perceived ease of use | Quotes |
|---|---|
| Initiation | • "I've had nobody to really teach me anything about it. Everybody's too busy." [Participant 2]<br>• "The first time I didn't understand it. When I first did it. So when it fell off, I said I don't know what to do. And my son ain't here to stick me. So I just let it go." [Participant 8]<br>• "My phone has told me "your phone is too old to download apps." How embarrassing? But I can't afford to get one right now, so I'm just sticking with it [receiver]." [Participant 1] |
| Sensor | • "I've had a couple fall off like taking off a shirt" (Participant 2)<br>• "I'm good with the arm because I stick myself in the stomach with my insulin." [Participant 3] |
| Receiver | • "I had a few issues with it cause the machine wants to act up or keep saying like I can't locate you". [Participant 1]<br>• "Well, first it was a problem because now I got to carry this. I got to carry this thing, you know, I'm forgetting it when I come out the door. Now I can't check it if I don't have the monitor. Tried hooking it up to the phone initially. That didn't work." [Participant 5]<br>"And it's hard for me to see. Yes, with that thing is like the number's kind of a little bit bigger [on receiver than on phone] than that, trying to …connect it and programming all that. That's kind of frustrating to me." [Participant 4] |
| Alarms | • "I stopped using it cause of the dinging so much, I cut my phone off and don't wanna hear." [Participant 8] |
| Skin reaction | • "I noticed that I was using the same area, probably a little bit more than I should have. I only say that because you know the entry point starts to show up. It doesn't get a chance to heal before you're putting another one either right over top of it or right in the same area where it's at. So having to stop using it temporarily to give that area a chance to heal up and use another area, or go back to the sticking for a short period of time." [Participant 5] |

Participants who used multiple models (19%, 3/16) reported significant differences and strong preferences. Initiation challenges included logistics, troubleshooting, fear of needles, and phone compatibility issues. Sensor barriers involved a lack of application help, optimal location, and water resistance. Receiver issues included connectivity problems, frequent misplacement, and a preference for receivers over phones. Alarms caused significant annoyance, leading some to discontinue use. Various skin reactions required troubleshooting.

## Perceived Usefulness

Perceived usefulness, from TAM, describes how individuals believe CGM helps manage diabetes. Subthemes include access to continuous data, trust in the data, and data sharing (Table 6).



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**Table .** Perceived usefulness subthemes and pertinent quotes.

| Perceived usefulness | Quotes |
|---|---|
| Access to continuous data | • "This meter, it helps me keep track of myself and where I am. Honestly, I have to be honest with myself where I am at all times. 24 hours a day. It keeps me on point. Period. It's just plain and simple." [Participant 6]<br>• "It helped me a lot because it made me learn a lot from the [CGM][a]… I had it for so long that I can tell when my sugar is high or low." [Focus Group Participant 1]<br>• "This [CGM] is better than, almost better than … my heart defibrillator because it's …keeping me alive, but this [CGM] has helped keeping me from going into a coma or getting that to where I have to come to the hospital. I can pretty much take care of it [diabetes]…. this little device here I love it. I just love it." [Participant 3] |
| Trust in the data | • "it's more accurate to me because when I used to stick my fingers, it would say one thing and then I'll check it on another finger and it says something totally different. So if I check it two or three times within the couple minutes, it's saying the same thing and unless its changed. It's not a big change but I really love it. I love it." [Participant 3] |
| Data sharing | • "I like the fact that the doctors can see it. I can't reiterate that enough. It helps when they can read your blood sugars … then they can figure out what medications to prescribe." [Participant 12]<br>• "My son, he got the notification on his phone too. So anything I ain't doing right, he get notified. He either call me first or come on out". [Participant 8] |

[a]CGM: continuous glucose monitor.

Participants valued continuous data for constant feedback, learning, responding to extreme values, optimizing medications, and behavior change. They noted improved glucose values and better understanding of their body's reactions, which kept them motivated. Trust in CGM data was higher compared to traditional glucometer-based monitoring. While few (13%, 2/16) mentioned CGM-specific metrics, most discussed $HbA_{1c}$ and current glucose values. Data sharing with family and providers was also highly valued.

## Attitude Toward Using CGM

Attitude toward using CGM, derived from the TAM, captures an individual's overall views on CGM for diabetes management. Subthemes include empowering disease management, recommendations to others, improvements over glucometer-based monitoring, and further opportunities (Table 7).



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**Table .** Attitude toward using continuous glucose monitor subthemes and quotes.

| Attitude toward using CGM | Quotes |
|---|---|
| Empowering disease management | • "I can appreciate the [CGM][a]. I really do. It's changed my life in so many ways. It's helped me to live a better, smoother life, you know, so that I can stay on track with myself and I can be good for my kids, my wife and my family." [Participant 6]<br>• "I stopped wearing the monitor for a while. That's when I fell off the bandwagon again, because you don't have that, that constant reminder of being able are you in the green, are you in the yellow, are you in the red? I definitely attribute compliance to that continuous monitor." [Participant 9]<br>• "[if someone starts CMG] they're going to learn so much about the diet and how their body responds to food." [Participant 9] |
| Recommend to others | • "Don't hesitate. Get it. Go with your first thought. Get it. Get it. Get it." [Participant 3] |
| Improvement over Glucometer-based monitoring | • "I'm a little happy because my fingers are not sore and I can do you can do what you love to do, which is I like to sew. I like to play games on my tablet and if my fingers are sore, I'm not gonna do all that... I don't have to worry about sticking myself. I can just go grab my little meter and scan and there it is and not have to sit and figure out which finger I wanna use and all that so it's made a little happier…I don't have to worry about… do I have enough test strips or you know, is my meter working or do I need batteries or anything like that. With this all you do is charge it and that's it." [Participant 3] |
| Further opportunities | • "14 days is good, but if it [sensor] could last about 30 days, I'll be on board with that." [Participant 3]<br>• "Well, I know that it's not going to be able to do this, but help me with my self-discipline." [Participant 7] |

[a]CGM: continuous glucose monitor.

Participants felt empowered by CGM, as it allowed easier glucose tracking and understanding of food impact. They adjusted their diets by reducing sweetened beverages, candy, simple carbs, and certain fruits, while increasing fresh produce, grains, diet soda, water, fiber, and lean proteins. All participants highly recommended CGM to others, noting reduced stress in diabetes management. They preferred CGM over traditional glucometer-based monitoring due to no pain, fewer supplies, and less stress. Participants had limited suggestions for future CGM improvements, but desired longer-lasting sensors and more concrete advice around diet and self-motivation.

# Discussion

## Principal Findings

In this study, we gained insight into the experience of adults with T2DM using CGM in primary care, guided by the HBM and TAM. Participants found that CGM was helpful, empowered them to manage their disease, was an improvement over glucometer-based monitoring, and they would recommend it. Disease susceptibility and severity appeared to motivate diabetes management and influence attitudes toward monitoring blood glucose. Influential drivers include insurance coverage, support systems, motivation, information sources, and comorbidities. The perceived ease of using the technology is related to CGM model differences, initiation process, sensors, receivers, alarms, and skin reactions. Perceived usefulness centers on continuous data, trust in readings, and data sharing. Attitude toward using CGM was generally positive. Our results confirm barriers noted in other populations and uniquely demonstrate the role comorbidities play in interfering with optimal use, strong trust in CGM data versus glucometer-based monitoring, and heavy reliance on receivers rather than phones among adults with T2DM using CGM in primary care.

## Comparison With Previous Work

### *Disease Susceptibility and Severity*

Those with a family history of diabetes expressed a sense of inevitability about their diagnosis, underscoring the need for early intervention and opportunities for CGM to alter disease trajectory [42]. Since disease severity influences monitoring approaches, understanding a patient's disease experience is critical for guiding CGM discussions.

### *Influential Drivers*

This work demonstrates multiple system- and individual-level factors affecting CGM use. Insurance coverage is a well-documented barrier [43-45], particularly for certain populations [27]. Adherence and cost also vary by CGM source (pharmacy vs durable medical equipment supplier) [46]. Participants emphasized that diabetes is only 1 component of their daily life, shaped by support systems and comorbidities. The importance of support systems noted in youth-onset T2DM [20] and in Hispanic adults [24] holds true for the general primary care population.



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Limited in the literature is how comorbidities impact optimal CGM use. While participants in this study highlight numerous comorbidities, vision and mental health directly impact CGM use. Patients report difficulty reading values due to poor vision. Mental health and diabetes distress often prevent participants from fully engaging in CGM use. Recognizing and intervening in these factors is critical for supporting patients.

This work also highlights numerous sources that expose patients to health information (TV advertisements, health care team, family, friends, and YouTube), identifying potential avenues to share CGM-related information with patients beyond the clinic setting.

### *Perceived Ease of Use*

Our study offers insight into usability challenges across CGM models and factors influencing adoption. Optimal use requires matching the best CGM model to each patient, supporting initiation, enabling troubleshooting, and leveraging alarm benefits. Because models differ in capabilities, informed decision-making is essential for acceptance. Some tools have been developed for people with type 1 diabetes [47]; however, due to the rapidly evolving nature of diabetes technology, maintaining tools to support informed decision-making remains difficult.

Notably, most participants (12/16, 75%) used receivers and preferred receivers. This significantly impacts the ability to use CGM for population health management asynchronously, as receivers neither automatically nor remotely upload data for clinician review, necessitating in-person encounters. This has not been previously described in the literature. In our clinical workflows, the CGM Order Set defaults to prescribing patients a receiver, which may have some impact on the overall high receiver use. However, participants described sensors not being compatible with the phone they have, both as a function of the age and model of their phone, and of insurance coverage for sensors. Many participants needed replacement receivers due to loss or damage, so pathways for replacement receivers are critical for consistent CGM use. Therefore, for successful CGM use in primary care, clinics will need to develop support for receivers, troubleshoot phone compatibility, and identify pathways to compatible phones for patients.

Despite the difficulties in initiation, current literature does not provide optimal strategies to address this barrier. Some programs use an interprofessional team to assist with CGM initiation [48], but these have not been widely implemented.

As with any technology, end users need ways to solve problems. This mirrors findings from CGM initiation in adults with type 1 diabetes who expressed a desire for support during initiation (insertion, adhesive, and common pitfalls), guidance on contacting the manufacturer's customer support, data management strategies, attention to the mental and emotional side of CGM use, real-time troubleshooting advice, and access to advice from other users [49]. It is important to recognize the large treatment team involved in a patient's care, including the primary care physician, endocrinologist, diabetes educator, pharmacist, insurance company, durable medical equipment supplier, and vendor. Navigating this team to get the right questions to the right person can be challenging, especially as only a few team members in primary care are often fully familiar with the technology and troubleshooting pathways.

Alarm burden [50] continues to hinder optimal use and leads to discontinuation for some participants. Research shows that high glucose alarms on CGM improve glycemic control [51]. Additionally, CGM education has been shown to enhance the use of low glucose alarms [52], suggesting the potential impact of CGM alarm education; however, best practices for primary care have not yet been developed.

### *Perceived Usefulness*

The impact of any technology depends on the understanding of the user. Challenges in T2DM self-management include comprehension, skill development, and leveraging personal strengths [53]. Some participants reported difficulty interpreting numerical data, relying instead on alarms or color indicators. This highlights the need to enhance patient education and alarm management to optimize CGM use.

A recent community project demonstrated that CGM has the opportunity to make the invisible visible, support effective decision-making, enhance self-efficacy, diabetes-related diet modification, changes in physical activity, and changes in medication taking [54]. These findings were reinforced in this study with similarly identified subthemes.

Notably, unlike other work that reports privacy concerns [25] and lack of trust in the CGM data [24], participants in this study trusted CGM more than the variability of glucometer-based monitoring. Participants liked having only 1 value rather than trying to reconcile different values around the same time from glucometer-based monitoring due to blood from different fingers or the influence of contaminants on fingers. While CGM accuracy has improved, there remains a 15% variability around 100 mg/dL [55], which participants do not seem to fully appreciate. While patient trust in data is encouraging, ensuring that patients are not misguided will be critical to ensure safety.

This work is part of the broader effort to optimize the clinical use of CGM. The Integration of Continuous Glucose Monitoring Data into the Electronic Health Record project [56] developed standards for incorporating CGM data into clinical practice, which are now being used [57]. Opportunities to improve CGM effectiveness include education, modified EHR, team-based approaches, expanded coverage of CGM with decreased documentation burden, and improved access to diabetes self-management education [58]. Additionally, provider education [16] is critical to optimize prescribing, use, and overcoming provider discomfort with technology [58].

## Strengths and Limitations

This study examines the experiences of adults with T2DM using CGM in primary care, most of whom had public insurance (Medicare or Medicaid). Including participants with varied disease severity, insurance type, medication regimens, and CGM use durations provides insights into factors relevant to the complexity of primary care clinics.

Recruitment primarily occurred through primary care physician outreach, but many patients were unreachable or missed



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scheduled sessions, reflecting the complexity of their lives in which diabetes management is only 1 concern. Convenience sampling underrepresented patients less engaged in care or those who discontinued CGM. Thus, findings are not generalizable for less engaged patients, warranting further study. Purposive sampling was preferred but infeasible due to inaccurate contact information and resource constraints. While it was our intention to complete 3 focus groups, participants opted for the convenience of scheduling interviews.

Although participants received diabetes care in primary care, some may have initially obtained CGM from endocrinology. However, only 2 had endocrinology visits in the past year, suggesting minimal ongoing influence.

## Conclusions

Our findings highlight that while adults with T2DM highly value CGM for diabetes management, opportunities to optimize the experience, support, and use of CGM in primary care are numerous. While affirming barriers well-described in other populations in the literature, this study uniquely demonstrates the impact of comorbidities, the trust in CGM data compared to glucometer monitoring, and the reliance on receivers to use CGM technology in an adult T2DM population in primary care.

Successful use of CGM in primary care will require efforts around (1) assessing a patient's openness and ability to access CGM, (2) developing initiation processes, (3) supporting ongoing troubleshooting, including alarm optimization, and (4) improving the use of data from CGM. The results of this study provide valuable insight for enhancing CGM use for adults with T2DM in primary care by supporting future intervention trials.

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## Data Availability

The datasets generated or analyzed during this study are not publicly available as they could be used to identify participants; however, they may be available from the corresponding author on reasonable request and approval from the University of Cincinnati Institutional Review Board.

## Authors' Contributions

Conceptualization, methodology, funding acquisition, investigation, data curation, formal analysis, writing – original draft, writing – review and editing: MIK
Methodology, data curation, formal analysis, writing – review and editing: AMC
Formal analysis, writing – review and editing: AS
Formal analysis, writing – review and editing: JBW
Conceptualization, writing – review and editing: MF
Formal analysis, writing – review and editing: AZ
Conceptualization, methodology, funding acquisition, supervision, writing – review and editing: EM

## Conflicts of Interest

MIK serves as a clinical informatics consultant for the Diabetes Clinic Innovation (ConnecT1D) grant at Cincinnati Children's Hospital Medical Center funded by the Hemsley Foundation.

Multimedia Appendix 1
Session questions.
[PDF File, 94 KB - diabetes_v10i1e73446_app1.pdf ]

Multimedia Appendix 2
Code book.
[PDF File, 46 KB - diabetes_v10i1e73446_app2.pdf ]



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Checklist 1
COREQ checklist.
[PDF File, 325 KB - diabetes_v10i1e73446_app3.pdf ]

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## Abbreviations

**CGM:** continuous glucose monitor
**COREQ:** Consolidated Criteria for Reporting Qualitative Research
**EHR:** electronic health record
**ESC:** University of Cincinnati Evaluation Service Center
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**HBM:** Health Belief Model
**T2DM:** type 2 diabetes mellitus
**TAM:** Technology Acceptance Model


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# Physicians' Experiences Using Secure Messaging for Diabetes Management: A Qualitative Study

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## Abstract

**Background:** The COVID-19 pandemic led to increased demand for remote management of type 2 diabetes using secure messaging, or patient-provider text-based communication. Prior research on secure messaging has described the content of messages sent for type 2 diabetes management and demonstrated its impact on clinical outcomes. However, there is a gap in knowledge about how secure messaging performs as a communication medium for specific tasks in clinical care (eg, prescription management and discussing medical questions). Additional research is needed to understand physicians' experiences using secure messaging to communicate with patients about clinical tasks that support diabetes management.

**Objective:** This study aims to investigate physicians' experience using secure messaging to communicate with patients about specific clinical tasks for type 2 diabetes management.

**Methods:** We interviewed a sample of endocrinologists and internists from 2 different medical facilities who have used secure messaging to communicate with adult patients about type 2 diabetes management. Semistructured interviews were used to solicit physicians' experience using secure messaging for 6 specific tasks that support diabetes management: refilling prescriptions, answering nonurgent medical questions, scheduling appointments, discussing test results, making referral requests, and discussing visit follow-up. Interviews were conducted until we achieved saturation of themes for these tasks. Interview data were collected between 2021 and 2023. Qualitative data were analyzed using the framework method for thematic analysis.

**Results:** We interviewed 6 internists and 4 endocrinologists (n=10). Physicians reported spending between 2 and 5 hours per day messaging with patients. They observed that secure messaging increased the frequency and timeliness of communication, which improved care coordination and facilitated care delivery between visits. This served as a time-efficient way to iterate specific components of treatment plans, including discussing test results, visit follow-up, scheduling, and prescription refill. Physicians were frustrated with the unstructured nature of secure messages. Patients wrote messages that were often disorganized, confusing, or did not have enough information for the provider to take action. This often made answering nonurgent medical questions difficult. In many cases, poorly structured secure messages resulted in lengthy back-and-forth communications between patients and physicians, which sometimes required a phone call or an office visit to resolve.

**Conclusions:** Physicians reported that secure messaging supports a longitudinal model of care, where patients can iterate their treatment plan between visits. For tasks with well-defined information boundaries, such as scheduling and prescription refill, physicians reported that secure messaging improved the time efficiency of care delivery. Providers experienced challenges using secure messaging for more complex tasks and often reported not receiving sufficient clinical information. We identified a demand for workflow technologies to process incoming secure messages to improve clarity and ensure that messages have sufficient information to inform decisions on the best course of action.

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**KEYWORDS**

secure messaging; digital health; patient portals; diabetes; endocrinology; primary care; care coordination

## Introduction

### Overview

Diabetes has the highest total annual cost of any chronic disease in the United States, with 1 in 4 health care dollars (US $412.9 billion) spent on treating individuals with type 2 diabetes in 2022 [1]. Successful management of type 2 diabetes can be supported by secure messaging, or patient-provider text-based communication through a patient portal [2-11]. Secure messaging offers patients a digital platform to ask providers questions and manage components of their treatment plan between appointments. Patient use of secure messaging has been associated with better diabetes management outcomes [2-9], as well as improved care coordination and communication [9-11]. However, secure messaging has significant limitations in part due to its asynchronous and text-based nature. Studies have shown that secure messaging can lead to miscommunication and delayed or unresolved care [8,12]. This makes secure messaging inappropriate for certain tasks that require immediate action or lengthy communication. In this study, we interviewed physicians to understand their experience using secure messaging as a communication tool to support 6 specific tasks that promote the management of type 2 diabetes: prescription refill, answering nonurgent medical questions, scheduling appointments, discussing test results, making referral requests, and discussing visit follow-up.

### Secure Messaging Increase

Use of secure messaging has increased substantially in recent years, largely spurred by the push to virtual care during the COVID-19 pandemic. During this time, provider adoption of secure messaging was facilitated by changes in billing codes published by the Centers for Medicare & Medicaid Services (CMS) in January 2020 [13]. This was the first time that CMS published incentives for providers and hospitals to engage with secure messaging. Studies indicated that since 2020, patient and/or provider use of secure messaging increased between 50% and 75% across all specialties [14-16], with more than a 50% increase in primary care [17,18]. Looking at provider engagement with secure messaging, a large retrospective study of outpatient messages sent to patients from 2022 to 2023 found that physicians were responsible for the majority of secure messages sent to patients (33%), and that fewer messages came from medical assistants/technicians (26%), nurses (23%), or pharmacists (1%) [19].

### Composition of Secure Messages

Secure messages have been manually coded for themes by teams at the Department of Veterans Affairs [5,6,8,20]. Robinson et al [5,7] and Heisey-Grove and Carretta [20] conducted the only identified studies that analyzed the content of secure messages specifically for diabetes management. Robinson et al [5] found scheduling, referrals, and administrative messages to account for the majority of messages (36%), followed by medication issues (31%), test results (17%), test issues (11%), health issues (3%), and care coordination (1%). In a second study, they found that 91% (293/323) of patients used secure messaging to discuss medication refills, and that 81% (263/323) of patients engaged in at least one thread about referrals, scheduling, or other administrative tasks, while fewer patients used secure messaging to discuss health issues (96/323, 30%) and test results (79/323, 25%) [7]. They found that use of secure messaging by patients with poorly controlled HbA1c largely mirrored trends in the broader sample of patients with type 2 diabetes. Among patients with poorly controlled HbA1C, a majority (161/177, 91%) engaged in medication refill, followed by scheduling/referral/consult (148/177, 84%), medication/equipment issues (117/177, 66%), health issues (60/177, 34%), and test results (47/177, 27%) [7]. Additional research is needed to assess the performance of secure messaging as a communication medium to address specific components of care delivery discussed in the above themes.

### Media Richness Theory

Media richness theory, developed by Daft and Lengel [21] and expanded by Byron [22], is a seminal communication theory that predicts how media (text, video, phone, etc) perform for different types of communication. Media richness theory breaks down communication into a dyadic continuum, ranging from low-complexity to high-complexity communications. Daft and Lengel [21] define low-complexity communication as discussing technical information, such as scheduling, that has well-defined boundaries and little room for ambiguity. High-complexity communication is defined as having poorly defined informational boundaries, greater potential for ambiguity, often requiring iteration, and being necessary for adaptive tasks such as problem-solving.

Media richness theory argues that text-based communications, such as email and secure messaging, are more time-efficient than their "richer" counterparts for low-complexity communications. They argue that a higher-order medium, such as phone or video calls, is overly complex for low-complexity interactions, ultimately creating a time-efficiency mismatch. Two specific categories of secure messaging that fit Daft and Lengel's [21] description of low-complexity communication are scheduling and prescription management. Both categories gather routine objective data in well-defined situations and are assisted by templates that facilitate information gathering. This informs hypothesis 1: *physicians will report that using secure messaging to accomplish scheduling and prescription management reduces time spent on communication about these tasks*.

Byron [22] argues that text-based mediums such as email and secure messaging are not well suited for high-complexity communications because they do not have the capacity for subtle cues and rapid feedback that is characteristic of phone calls, in-person office visits, and other "richer" mediums. Media richness theory predicts that using text-based mediums for high-complexity communications is less time-efficient compared to using other mediums, such as phone or in-person meetings. The secure messaging categories that meet Daft and Lengel's



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[21] definition of high-complexity communications include nonurgent medical questions, discussing test results, visit follow-up, and referral requests. This leads to hypothesis 2: *physicians will report that using secure messaging to discuss nonurgent medical questions, test results, visit follow-up, and referral requests does not reduce provider time spent on communication about these tasks*.

We test these hypotheses using a deductive approach to qualitative analysis, described in the framework method [23]. This allows us to describe the benefits and drawbacks of using secure messaging for specific tasks in the management of type 2 diabetes.

## Methods

### Study Design

This study used a cross-sectional design where semistructured interviews were conducted to solicit physicians' experience using secure messaging for specific medical tasks in diabetes management. Each physician was interviewed once for approximately 30 - 45 minutes. We analyzed this qualitative data using content analysis [24]; data were analyzed by 2 coders through an iterative process using a deductive coding guide and generating inductive codes that emerged during the analysis.

### Study Setting

This study was conducted at 2 health care facilities that serve a catchment of patients in central and western Massachusetts: (1) Baystate Endocrinology in Springfield, Massachusetts, a small outpatient medical center consisting of 9 medical doctors, 4 nurses, and a pharmacist [25]. Baystate Endocrinology is associated with Baystate Health System, a not-for-profit integrated health care system comprising 5 hospitals and over 115 practices [26]. (2) UMass Memorial Medical Center, University Campus, in Worcester, Massachusetts, a large hospital with 1856 clinicians and over 780 staffed beds [27,28]. UMass Memorial Medical Center, University Campus is associated with UMass Memorial Health, an integrated health care system comprising 5 hospitals [29] and over 70 practices [30]. Patients were not charged a copay for secure messaging in either setting. Though CMS billing codes existed for provider reimbursement, these codes were not being used by providers in either setting. Patients receiving care in both settings were able to use secure messaging for the tasks discussed in this paper (ie, prescription refill, discussing nonurgent medical questions, test results, scheduling, referral requests, and visit follow-up).

### Recruitment

Physicians were eligible for recruitment if they were (1) internists or endocrinologists, (2) had adult patients with type 2 diabetes in their panel, (3) spoke English, (4) used secure messaging to communicate with patients about diabetes management, and (5) worked at either Baystate Medical Center Division of Endocrinology or UMass Memorial Medical Center, University Campus. We used snowball sampling to recruit physicians who met the above eligibility criteria. Physicians were contacted up to 3 times by email for recruitment. At the outset of interviews, physicians were notified that their involvement was completely voluntary and that their responses would remain anonymous outside of the research team. Two participants were asked to provide additional feedback on findings once the paper was written.

We used data saturation to define our sample size. To do this, we interviewed physicians until we heard repeated narratives about the use of secure messaging for specific clinical tasks (prescription requests, nonurgent medical questions, test results, scheduling, referral requests, and visit follow-up). Thus, data saturation was defined as the point where interviews stopped illuminating large gaps in knowledge about these clinical tasks (deductive themes) that defined the scope of the study [31]. We achieved data saturation early in the interview process, by the fifth interview, and did 5 additional interviews to confirm that we had identified the major subthemes regarding the challenges and benefits of using secure messaging for the defined clinical tasks.

### Data Collection

Semistructured interviews were conducted with physicians over Zoom (Zoom Video Communications, Inc) videoconferencing app between December 2021 and February 2023. MZ led 3 interviews and BK led 7 interviews. Interviews lasted between 30 and 45 minutes. Interview questions were shared with the participants via email approximately 1 week prior to the meeting. The agenda of the interview was as follows: we began by asking about physicians' experience using secure messaging to communicate with patients about 6 specific tasks that support diabetes management: visit follow-up, test results, nonurgent medical questions, referral requests, prescription requests, and scheduling requests. These 6 tasks were identified as the deductive themes of interest. This is because these tasks were offered in a dropdown menu as 6 possible subject headers that patients can use to title their secure messages at both UMass Memorial Health and Baystate Health. We then asked physicians about the workflow of messages sent between patients and providers. This section was exploratory and yielded inductive themes.

Interviews were captured on Zoom video recording software and were transcribed using Zoom autogenerated transcripts. Two team members (BK and MZ) edited the autogenerated transcripts for obvious mistakes on the part of the transcription software (eg, autoreplacing "insulin" with "in sullen"), while maintaining a high degree of naturalization [32]. The authors uploaded transcriptions to the 2 qualitative analysis software programs, Atlas.ti 8 (ATLAS.ti Scientific Software Development GmbH) and Nvivo 12 (QSR International).

### Analysis

Data were coded for themes using Atlas.ti [33] and Nvivo 12 [34], then analyzed using the framework method [23]. This involved a combined deductive-inductive approach discussed by Gale et al [23]. We used deductive content analysis to isolate descriptions of how secure messaging performed as a medium for communication about specific clinical tasks (prescription requests, nonurgent medical questions, test results, scheduling, referral requests, and visit follow-up) which were offered to patients as subject headers for secure messages. We used these descriptions to assess whether the data supported hypotheses 1



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and 2 described in the "Media Richness Theory" subsection of the "Introduction". Simultaneously, we used inductive content analysis to highlight additional major themes related to hospital policy that emerged as relevant to physicians' experience using secure messaging to communicate with patients about diabetes management.

Team members (BK and MZ) developed the code book. Interrater reliability was established by adapting framework-based thematic analysis for semistructured interviews in multidisciplinary teams [23], where initial coding consensus is prioritized over quantitative metrics. Due to the limited number of items coded together and the different backgrounds of coders, no formal reliability coefficient was calculated. The process of establishing interrater reliability involved 2 cycles [35]. During the first cycle of coding, BK and MZ coded the same 2 interviews separately, then met to discuss and achieve consensus on the deductive and inductive themes to develop a working analytic framework. Once interrater reliability was established, remaining transcripts were divided between BK and MZ for a second cycle of content analysis. During this second cycle, these 2 team members had ad hoc communications to discuss additional emergent themes and iterate the analytic framework.

Once all transcripts were coded, BK and MZ each compiled a list of final themes with a definition of each code, interviewer reflections about the code, and 3 to 5 representative quotes for each code. BK and MZ shared the list of codes, definitions, and quotes with all members of the research team, who then met with coders to review and consolidate themes for presentation as results of the study.

### Ensuring Rigor and Trustworthiness

We used established methods to strengthen the rigor and trustworthiness of the data collection, analysis, and reporting. Our interview guide (Multimedia Appendix 1) was informed by theory [21] and co-developed by JAC and BK. The interview guide was then submitted to the Brandeis Institutional Review Board (IRB) for approval. Interviewers BK and MZ used the approved interview guide to conduct semistructured interviews with participants. BK and MZ then used the framework method for the analysis of qualitative data to inform data analysis [23]. The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist [36] was used to ensure complete and detailed reporting on the study design (Checklist 1).

### Ethical Considerations

This study was determined to be exempt by the IRB for Brandeis University (#22110R-E). Written informed consent was waived by the Brandeis IRB, and verbal consent was collected at the time of the interviews. Interviews took place during working hours, and no compensation was provided to participants. Video files and interview transcripts were stored on an encrypted web platform. Interviews were anonymized at the time of transcription, which were then transferred to Atlas.TI for analysis. BK and MZ had access to the identified data. Data were deidentified before it was shared with the remaining members of the research team.

## Results

### Descriptive Statistics

A total of 10 interviews were conducted with physicians (endocrinologists: n=4, internists: n=6), representing 40% of the 25 physicians who were contacted to participate. Descriptive statistics of the sample are shown in Table 1.

**Table .** Sample characteristics (n=10).

| Characteristics | Physicians, n (%) |
|---|---|
| Specialty | |
| Endocrinology | 4 (40) |
| Internal Medicine | 6 (60) |
| Healthcare facility | |
| UMass Memorial Medical Center, University Campus | 8 (80) |
| Baystate Endocrinology | 2 (20) |
| Legal sex | |
| Female | 4 (40) |
| Male | 6 (60) |
| Years in practice | |
| 0 - 10 | 2 (20) |
| 11 - 20 | 3 (30) |
| 20+ | 5 (50) |



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## Themes Observed in Interviews

We achieved data saturation early in the interview process, by the fifth interview, and did 5 additional interviews to confirm that we had identified major components in the deductive themes of interest. In addition to deductive themes, qualitative analysis of interviews revealed several notable inductive themes displayed in Textbox 1.

**Textbox 1.** Deductive and inductive themes observed in interviews.

Deductive themes

- Prescription requests
- Nonurgent medical questions
- Test results
- Scheduling
- Referral requests
- Visit follow-up

Inductive themes

- Extra work for the physician
- Lack of knowledge or uncertainty about billing
- Impacts on timeliness of communication
- Expanded record of management

## Deductive Themes

### *Prescription Requests*

Secure messaging was widely reported to save time on prescription management. The main time efficiency comes from the fact that secure messaging is well integrated with prescription management workflow templates offered by the 2 hospital systems. Once submitted by patients, prescription refill requests were automatically transferred to staff, who checked the order against the active medication list and ensured that the patient's lab results were up to date. The prescription management portal displayed the refill protocol as well as gave access to the patient's electronic health records, providing all the information in one place.

Challenges arose with prescription refill when patients and/or front desk staff missed critical information, such as the preferred pharmacy. Prescribing opioids and other controlled substances further complicated the process and required a phone call from the physician. One physician reported preferring a phone call for all prescriptions because it allowed them to have a conversation with the patient and correct misunderstandings about the medication regimen. Some exemplar quotes regarding prescription requests are as follows:

> *A physician can authorize five medications with one click if they have been queued up properly.*

> *I think it's convenient for patients to actually just request their medication refill rather than having to call and wait on the phone. Not everybody's gonna have the opportunity to be able to ask for prescriptions and things during the day when the office is open, so it becomes easier for them to communicate directly through the portal.*

> *One patient had headaches and was wondering about refilling a prescription from a neurologist. We talked on the phone and found out that the patient was not taking the prescription correctly.*

### *Nonurgent Medical Questions*

Physicians found that secure messaging was more time-efficient than a phone call or an office visit for a question with well-defined parameters, such as the frequency or dosage of medication. They also spoke about secure messaging, saving patients the hassle of having to wait in a phone queue to talk to a provider, which both improved patient experience and made communication possible for patients with busy schedules.

We heard a repeated theme across physicians that patients' education level and familiarity with text-based communication moderated their ability to use secure messaging to discuss nonurgent medical questions. Patients' ability to write concisely and include necessary medical information varied widely. In addition, physicians reported that many patients do not know what physicians need to make a decision or take clinical action. In some cases, medical questions initiated a long back-and-forth exchange that would have been better served by a phone call. Physicians offered suggestions to improve communication, including (1) developing a program to coach physicians and patients about the most effective way to communicate over secure messaging, and (2) modifying the secure messaging template to solicit necessary clinical information. Some exemplar quotes regarding prescription requests are as follows:

> *I'm so glad to have that ability [to communicate with a patient through secure messaging], because otherwise either they call and they can't get through and it's phone tag and it won't be until I see them in three months or six months or a year that we correct*



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*that very straightforward problem. For those types of things, it's really great.*

*But if it's a simple um, for example, there are patients that we see that are on a specific regiment for diabetes. They send. They say, Okay, can you look at my [glucometer] download, or at my continuous glucose? And do you recommend any changes, since it's not anything urgent. I will just respond to them [at my convenience].*

*Others are 20 questions that go back and forth where they send one sentence at a time. A lot of people using the portal have not had to communicate electronically for a living.*

### Test Results

Secure messaging gave physicians the ability to quickly add their interpretation to test results, which are automatically shared with patients in accordance with the 21st Century Cures Act. Several physicians noted this legislation posed a challenge; often, patients receive test results before physicians have a chance to interpret results for them, which causes undue anxiety for the patient. Secure messaging facilitated timely interpretation, which improved patient experience. In addition, opening a dialog via secure messaging gave patients the opportunity to ask follow-up questions and coordinate a treatment plan in response to the test result, which could replace an additional follow-up visit.

Patient comprehension was often cited as a reason to use a phone call or office visit instead of secure messaging to explain test results. For more complicated results, such as a magnetic resonance imaging or a computed tomography scan, physicians reported that a phone call was more efficient. One physician talked about preferring phone calls because they facilitated a teach-back method which allowed the physician to gauge patient comprehension. "OK I explained it to you, now explain it back to me." In other instances, physicians talked about preferring a phone call to explain more sensitive test results, such as a challenging diagnosis, because the phone allowed for more expression of empathy. Some exemplar quotes regarding prescription requests are as follows:

*It's a race to put your comments on a result so patients don't get anxious and interpret it on their own. Secure messaging helps with this speed. This helps to head off the anxious phone call, or even worse, the anxious phone call to the on-call doctor.*

*Providers love forwarding test results with interpretation. It's a huge positive, especially since the Cures Act.*

*So the patient, when they open up the results, they'll see my message attached to it, so I... I can either do it that way, or I could send them a separate message, saying, I saw your results of your $HbA_{1c}$ and it was high, and I think you need to increase your dose of metformin.*

### Scheduling

There was consistent agreement among physicians that using secure messaging made scheduling more time-efficient. The benefit of secure messaging for scheduling was discussed by all (10/10) interviewees. Participants reported that most of the scheduling messages were handled by hospital administrative staff. One observed drawback was that patients were often given an appointment several months in the future when they could have gotten an earlier appointment if they had spoken with the administrative staff. A second drawback was that scheduling systems varied by provider group; some provider groups allowed patients to schedule appointments with specialists without first seeing a primary care provider, which resulted in patients attending appointments with providers who were not equipped to solve a particular medical challenge. Some exemplar quotes regarding prescription requests are as follows:

*I think scheduling [over secure messaging] is better for offices and for patients because you don't have to wait for someone to pick up the phone or get the right person on the phone. Scheduling staff don't have to try to track the patient down. This is important because if people are working 8 - 5 and the office is open 8 - 5 it will take 8 phone calls to track the patient down to confirm scheduling.*

*But someone at [HOSPITAL] who's working with my office. They look at what was scheduled by the patient and make sure the patient scheduled it appropriately. So, for example, I'm a specialist [endocrinologist], and if a patient scheduled an appointment to see me and wrote the reason for the appointment as skin rash … they will call the patient back and say, "You know you didn't pick the right, doctor."*

### Referral Requests

Secure messaging facilitated referral requests for issues that physicians already knew about, but it was often not helpful for new issues. In cases where physicians had already seen a patient for a particular medical issue, staff were able to put in the order for a referral and send it over to the physician to review, making the process of referring only take "a few seconds." Physicians reported that secure messaging posed a challenge for addressing new symptoms. They often did not have enough information about a new symptom to make a decision about the best course of treatment for the patient. In these instances, physicians would either call the patient or have the patient schedule an appointment. Some exemplar quotes regarding prescription requests are as follows:

*Patients will say something like "I want to see a specialist" and 95% of the time I just refer them.*

*Physical therapy is easy. Other specialists are challenging. For example, I need to know what exactly they want to see a neurologist for, and is it a new thing that is going on. Is the problem something that I've evaluated before? I want to do certain tests so that when they see the neurologist the preliminary workup has been done. For a lot of those I need to call them and find out what exactly is going on.*



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> *... if I look at their numbers [$HbA_{1c}$], and I say, well, maybe you need to see the diabetes educator. I'll say, are you okay with that?*

### *Visit Follow-Up*

Physicians reported that secure messaging allowed patients to bring up questions that they forgot to ask during an appointment. This was particularly important when patients received a new prescription and had a question about how to dose the medication. Often, small questions about adjusting a treatment plan would go unasked if it meant that the patient had to book another appointment. In this way, secure messaging lowered the barrier to communication, facilitated timely communication, and often avoided an in-person visit for follow-up. Some exemplar quotes regarding prescription requests are as follows:

> *For certain things it's very useful. It's extremely useful for pictures/images. I had a patient with shoulder pain and I was going to give shoulder exercises but I forgot to give it before he left. I sent the exercises from Epic in a secure message.*

> *Especially if it's a weekend... if it's Friday, and I'm messaging somebody, and I don't want to wait until Monday until somebody [from the office] comes back to look at it. I... I might just say, okay, well send the reply directly to me because it's easier in that situation.*

## Inductive Themes

### *Extra Work for Physicians*

All physicians who were interviewed (10/10) reported that their provider group was struggling to manage the additional work created by the increase in secure messaging since the COVID-19 pandemic. Time spent engaging with messages does not factor into physicians' official volume of work, termed relative value units, and therefore is not acknowledged by their health care system. Instead, physicians discussed being expected to spend time outside of their work schedules responding to messages. We heard that physicians were spending between 2 and 5 hours per day on secure messaging, with 1 to 4 hours happening after-hours, a phenomenon that several physicians referred to as "pajama time." Several physicians reported that they were unable to keep up with the increased workload and left secure messages unanswered. Some exemplar quotes regarding prescription requests are as follows:

> *Messaging [since the start of COVID-19 pandemic] does create extra work for the provider, and I think the vast majority of extra work tends to fall in primary care so it's a big big big primary care issue and, right now I'm positive, I'm young, I'm early in my career I'm OK, but I can see how it would build up… there may be a need for protected time for providers. An additional half day may ultimately be needed for some of those really high volume providers who are getting a lot of messages.*

> *I can just tell you the volume of inbox messages from the patient portal has just gone up dramatically… I spend two to three hours outside of work answering messages and still have another two hours every single day that I don't get to see. So there are a lot of messages that go unanswered.*

> *At the end of the month physicians get a statement—how many visits they saw, how many RVUs they billed. This shows up on their report card. One of my missions in life that I keep telling my chairperson about is to measure this new type of work [secure messaging]. This is hurting primary care providers.*

### *Lack of Knowledge or Uncertainty About Billing*

None of the interviewed physicians (0/10) reported billing for secure messaging. When asked about the CMS billing codes for secure messaging, physicians generally had 1 of 2 responses: they either did not know about the existence of billing codes or said that the current billing scheme was clunky and that it was not worth the small amount of money per message.

Several physicians talked about how the billing structure incentivized them to turn conversations into phone calls or in-person visits that are more easily measured and rewarded. This happened even when physicians thought that secure messaging might provide a better, more timely, or more efficient way to communicate. Some exemplar quotes regarding prescription requests are as follows:

> *Unlike lawyers, we do not get to bill by time. If someone asks a complex question, it's effectively the same as them coming into the office. We have the ability to charge for that, but we have not implemented it yet. It is on our roadmap.*

> *I don't have a solution [for billing for secure messaging], but I think that the first step is to measure the amount of effort.*

> *Yeah, I have not billed for any secure messages. I think we're supposed to be documenting it as a phone encounter.*

> *Phone calls have been able to be billed for years and providers are not billing for them because it's a small amount of money and it's not worth the time to click around.*

### *Timeliness of Communication*

Several physicians reported that secure messaging greatly improved the longitudinal model of care delivery, or care that extends beyond scheduled encounters. Secure messaging gave patients the opportunity to ask questions that otherwise would have been forgotten and would not come up at the next appointment, which was especially important for physicians who scheduled weeks or months out. The asynchronous nature of secure messaging further supported timely communication because physicians could respond to messages at a time that was convenient for them. This gave physicians flexibility to send communications to patients after business hours, when they would otherwise not be comfortable calling.

In other instances, secure messaging was found to increase the time needed to communicate about a challenge. They talked



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about disjointed message conversations that went back and forth over several days.

In terms of reaching patients, physicians found that secure messaging was sometimes much faster, and other times unreliable. We saw variation in providers' ability to view patients' "read receipts," when a patient saw a message. Some physicians talked about a function in the portal that alerted them when patients had not opened emails within 72 hours of receiving a message. Others said that they did not know how to view the "read receipt," which caused them to frequently feel obligated to follow up the message with a phone call. Some exemplar quotes regarding prescription requests are as follows:

> *This really advances the whole longitudinal fluid kind of model of medicine. Before secure messaging, providers would perform a procedure, and then not see the patient for six months. Now care is extended; the services are more fluid.*
>
> *It [secure messaging] helps patients feel more connected, heard, and secure.*
>
> *So I mean they I... I personally find it easier. Some people find it harder. Um. The thing I like about secure messaging is that it's asynchronous. So they are… asking their question on their time. I'm answering the question on my time. Uh, and we don't have to sync up our schedules to have that conversation.*

### *Expanded Record of Management*

Physicians reported that a unique strength of secure messaging was that it created a digital paper trail of conversations and communications. Four providers observed that secure messaging made it possible to connect their notes to pictures and other email attachments, such as a log of blood sugars, lab results, or a readout from a remote patient monitoring device. Connecting text to these images helped physicians to communicate the story of the treatment to patients. Similarly, secure messaging facilitated sending brochures and other content that was translated into several languages in addition to English, which increases equity of care delivery.

> *Secure messaging facilitates sending email attachments [log of blood sugars as a picture/screenshot, or readouts from aglucometer] which increases adherence. This allows for more timely coordination around getting patients to diabetes control.*
>
> *[I do not need to]… rely on my memory to figure out what happened in between [visits]. This is all in the chart. I can Just look at all my visits and all my messages and all my communications with the patient.*

## Discussion

### Secure Messaging for Low- and High-Complexity Communications

We used qualitative interviews to investigate physicians' experiences communicating with patients about type 2 diabetes management using secure messaging. For low-complexity communications (scheduling and prescription management), we found that secure messaging was effective and efficient in most of the scenarios. Both facilities offered scheduling and prescription order templates that solicited the necessary information for physicians to make a decision or complete a request. This is a common best practice for hospital systems [37].

Findings were mixed about the use of secure messaging for high-complexity communications (nonurgent medical questions, visit follow-up, discussing test results, and referral requests). The chief advantage over in-person, video, or phone encounters was that secure messaging facilitated rapid communication; the asynchronous nature of the medium allowed both parties to bypass the barrier of scheduling a future encounter to discuss medical questions, test results, or other follow-up topics. This builds on findings from Wade-Vuturo et al [38] that secure messaging improves the longitudinal model of care. Advantages include better continuity with providers and more efficient, time-limited patient-physician interactions. Secure messaging further created a record of a conversation that was visible to patients and physicians. This allows for better clarity, coordination, and understanding of the treatment plan and visit follow-up by both the patient, physician, and primary care team [10-12]. The centralized email thread further allowed for the sharing of lab results and imaging with attached annotations that highlighted and explained specific findings. For example, a physician could attach notes directly to lab results to explain findings to a patient. This use of multimedia (image+text) adds nuance to Daft and Lengel's [21] position and supports the notion that communication media are mutually reinforcing, rather than hierarchical, as explained in media richness theory [38,39]. This concept of high and low richness mediums being mutually reinforcing is explored in other frameworks such as media synchronicity theory and relational coordination theory [40,41]. In this project, we found that the use of secure messaging for multimedia communication varied widely by physician comfort with the medium. At one extreme, physicians reported using secure messaging to send up to 4 different types of information, including test results, images, informational brochures, and readouts from remote patient monitoring devices. At the other extreme, a physician reported not knowing how to use secure messaging to share documents with patients.

Our findings agreed with prior research that secure messaging for high-complexity communication made it possible to iterate treatments between appointments [10,11,38]. Improved timeliness may directly address clinical inertia that impedes diabetes management [42,43]. However, in many cases, the advantage of timeliness came at the cost of inefficient use of clinician time when the patient asked multiple questions, asked a confusing question, and/or did not include all the information the physician needed to make a decision. This resulted in lengthy back-and-forth communications that physicians often turned into phone calls or office visits for clarification. This is consistent with the predictions of Daft and Lengel [21] and supports the findings of Lee [12]. In these instances, the conversation was often duplicated in the second meeting, making secure messaging redundant. Future work is needed to identify strategies to avoid this repeated work (eg, prompts for patients,



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or use of natural language processing to identify missing information) [44].

Physicians in our study perceived that the capacity for secure messaging to support high-complexity communications varies across patients. Some patients appear able to use text to communicate challenging concepts, while others do not. This agrees with critics of media richness theory, who argue that it is not the medium itself, but instead an individual's familiarity with the medium that predicts its ability to support high-complexity communications [22,45-48]. In this way, individual characteristics such as the patient's health literacy or familiarity with email could potentially moderate the success of secure messaging as a medium for complex communications; this could widen health disparities if more vulnerable patients have a higher likelihood of secure message exchanges that fail to successfully result in an appropriate health care action. There is a need for mechanisms that standardize expectations about the content of secure messages to support clear and concise communication. Some possible technologies include a prompt for patients that requests key information, voice entry for those who cannot type easily, and the use of artificial intelligence to review patient messages and suggest additional information to include.

## Practice Implications: Opportunities to Structure Incoming Secure Messages

### *Develop Message Prompts*

Physicians are frustrated by the lack of structure in secure messages. It may be helpful to supplement an open-ended secure message with prompts at the top of the open-ended textbox to ask the patient to include specific information in their message [1]. Prompts could either be kept broad or developed as a list of information needed for specific tasks, such as discussing a prescription, discussing test results, or following up after a visit. This would help to communicate expectations about information to include in the message. Specific prompts have been successful in the context of e-visits for referral requests, or messages sent between primary care providers and specialists [49,50].

### *Develop Workflows to Screen Information*

Physicians observed that secure messages were often processed by administrative staff, technicians, and/or nurses, and that their engagement was highly varied. For example, one physician described a front desk staff member who would screen messages for information gaps and reach out to patients for additional information. Other front desk staff would not feel comfortable interceding and responding to the patient. Instead, they would forward messages directly to physicians. Developing consistent guidelines/training for administrative staff to read messages, summarize key information, and follow up with patients for additional information may help to reduce physician burden. Workflows for messaging triaging and message summary can be further aided by natural language processing and other machine learning methods that process information [51]. Together, these strategies have the potential to help reduce the burden on physicians, which in turn will reduce burnout and the overall cost of care. However, the quality of care and propensity for medical errors should be studied in this context prior to widespread implementation.

## Practice Implications: Opportunities to Facilitate Outgoing Secure Messages

### *Train Providers on Best Practices in Secure Message Use*

We found that some physicians do not consistently use secure messaging for 2 main reasons: (1) lack of best practices about how to use the medium and (2) lack of incentives. There is a well-documented absence of best practices for the use of secure messaging [52-55]. Training focused on the process of secure messaging would help providers to maximize the benefits of messaging and avoid repeated tasks. For example, teaching providers to use read receipts would avoid a follow-up phone call to see if a patient received a message. Similarly, teaching physicians to connect messages to lab results and/or imaging would avoid the need to retype test results in the message.

### *Give Providers Time and Credit for Secure Messaging*

Physicians in this study observed that there was (1) no widely-used internal metrics to track their use of secure messaging and (2) no dedicated time to manage their inboxes. Instead, physicians were expected to use downtime between appointments or stay late to complete this work. This highlights a need for practice-level strategies to acknowledge secure messaging-related tasks. One approach to record this work is to educate providers about the billing codes established by CMS [13]. However, providing incentives without changes to workload is not sufficient and can widen inequality in health care delivery. Prior work has found that federal incentives for secure messaging were associated with increased secure messaging in high-resource settings, but no change in low-resource settings [56]. Providers serving underresourced communities may be too busy or lack adequate knowledge or resources to engage with messaging [56]. At the patient level, billing for secure messaging has been associated with a decrease in message use by underserved populations, including patients who are Latinx and/or self-insured [14]. Charging patients a copay for secure messaging may limit engagement among low socioeconomic groups and exacerbate existing disparities in access. Additional work is needed to develop a mechanism to acknowledge provider work without adding financial burden to patients.

## Limitations

There were several limitations to note. First, our study had a limited sample size. We achieved thematic saturation and were hearing the deductive themes highlighted in this paper repeated by the fifth interview. However, the inductive themes discussed in this paper did not reach saturation, as they were not the primary focus of the paper. It would have been helpful to interview additional endocrinologists and primary care providers to improve the transferability of and confidence in our findings. Moreover, this research is limited to the case of diabetes management in 2 hospital settings in Massachusetts. Additional research is needed to understand how secure messaging performs for clinical tasks in other regions and among other clinical subspecialties. Further, the study is prone to response bias as



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several providers chose not to be interviewed. A last limitation is that the semistructured interviews conducted for this study were exploratory in nature. While they were successful in uncovering the breadth of challenges that physicians faced when they used secure messaging for specific tasks, this approach did not make it possible to infer the percent of physicians who experienced these challenges. Future survey work is needed to investigate the generalizability of our findings among a larger, randomly selected cohort of physicians.

## Conclusions

This study investigates physicians' experience using secure messaging to communicate with patients about specific tasks for type 2 diabetes management. Physicians felt that secure messaging provided timely and efficient care to patients with type 2 diabetes, and that this medium supported both high- and low-complexity communications. However, messages that were confusing or disorganized often resulted in decreased efficiency of communication with patients as compared to other mediums, such as phone or video. While this study provides insights for virtual health and health care redesign, additional information is required to develop best practice guidelines for secure messaging and to optimize the organizational resources allocated for its implementation. Future work is needed to investigate interventions to improve the organization and clarity of messages (ie, messaging prompts, or the use of artificial intelligence to help patients fill in gaps in content).

## Acknowledgments

We present this article in loving memory of JAC, a brilliant academic, supportive mentor, and dear friend. His innovative spirit lives on in this work.

BK and MZ were members of the research team who were involved in data collection and analysis. BK is a health services researcher who identifies as a White male. His training and experience working in hospitals, state, and national health policy during the COVID-19 pandemic led him to become curious about the usefulness of asynchronous telehealth technologies as a substitute and/or supplement for in-person care. Throughout the interview process, he was particularly attentive to his preconceived biases around the benefits and shortfalls of telehealth that surfaced in other COVID-19 era research projects. This was something that he acknowledged as his positionality and took active measures to overcome in data collection, by avoiding leading questions and in qualitative analysis, by following an analytical framework. MZ was part of the data collection and analysis team. She teaches in a school of nursing and focuses on using health information technology to enhance patient-centered communication among culturally and linguistically diverse populations. MZ identifies as a Southeast Asian woman with English as her second language, and she acknowledges that her background may influence her perspective, particularly an assumption that secure messaging could better support culturally and linguistically diverse individuals by offering them more time to reflect and formulate questions, compared to real-time, in-person exchanges with the providers. To mitigate potential bias, she maintained a neutral tone and avoided leading questions during interviews. JAC was a health services researcher who identified as a White male. He was an international expert in health policy and organizational management and contributed to the development of the hypotheses for this study. He maintained a neutral position on secure messaging and developed hypotheses based on media richness theory, which he believed would illuminate both the strengths and weaknesses of secure messaging as a communication medium for diabetes management.

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## Data Availability

The datasets generated or analyzed during this study are not publicly available as they could be used to identify participants; however, they are available from the corresponding author on reasonable request and approval from the Brandeis Institutional Review Board.

## Authors' Contributions

BK, MZ, and JAC developed the framing and study design. BSG, CL, and MZ helped with sample recruitment. BK and MZ conducted and coded interviews. BK, MZ, SLS, and BSG contributed to writing and editing. BK, MZ, BSG, SLS, and CL reviewed the final draft.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File, 13 KB - diabetes_v10i1e70816_app1.docx ]



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Checklist
COREQ checklist.
[DOCX File, 23 KB - diabetes_v10i1e70816_app2.docx ]

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## Abbreviations

**CMS:** Centers for Medicare & Medicaid Services
**COREQ:** Consolidated Criteria for Reporting Qualitative Research
**IRB:** institutional review board


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# Low-Carbohydrate Nutrition Counseling With Continuous Glucose Monitoring to Improve Metabolic Health Among Veterans With Type 2 Diabetes: Pilot Quality Improvement Initiative Study

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## Abstract

**Background:** One in 4 Veterans who receive care through the Veterans Health Administration has type 2 diabetes (T2D). Dietary carbohydrate restriction can promote weight loss and improve blood glucose control, but Veterans taking certain medications (eg, insulin) may experience serious complications (eg, hypoglycemia) without adequate support and monitoring.

**Objective:** This study aims to develop and evaluate the feasibility, acceptability, and clinical effectiveness of a pilot low-carbohydrate (LC) nutrition counseling program guided by continuous glucose monitoring (CGM) for Veterans with T2D receiving insulin (ie, LC-CGM).

**Methods:** This is a pragmatic, nonrandomized, pre-post quality improvement pilot program. Eligible patients were Veterans with T2D who were prescribed ≥3 daily injections of insulin. The 24-week LC-CGM program consisted of virtual visits with a registered dietitian (RD) and clinical pharmacy practitioner (CPP); CGM data were used to guide tailored nutrition counseling and de-escalation or cessation of glucose-lowering medications. To evaluate changes from baseline, intention-to-treat analyses were conducted for all enrollees, with separate analyses for program completers. Primary outcomes were program feasibility and acceptability (ie, program enrollment and completion rates and mean number of RD and CPP visits). Secondary outcomes included mean weight change, percent weight loss, achievement of ≥5% and ≥10% weight loss, change in glucose-lowering medication use, and change in laboratory measures (eg, hemoglobin $A_{1c}$ [$HbA_{1c}$]).

**Results:** Program evaluation occurred from March 19, 2021, to May 3, 2024. Among 43 Veterans referred to the LC-CGM program, 38 (88%) enrolled. Most were men (37/38, 97%), white (29/38, 76%), with an average age of 63.7 (SD 9.6) years. Mean BMI and $HbA_{1c}$ were 38.1 (SD 5.8) $kg/m^2$ and 7.8% (SD 1.3). Of 38 enrollees, 27 (71%) completed the program. Enrollees averaged 9.5 (SD 3.3) RD visits and 12.8 (SD 4.7) CPP visits. In intention-to-treat analyses, mean weight change was −11.5 kilograms (SD 8.7; 95% CI −14.4 to −8.6), corresponding to 9.5% weight loss (SD 7.2; 95% CI −14.9 to −4.2), with 58% (22/38) achieving ≥5% weight loss and 32% (12/38) achieving ≥10% weight loss. Overall, use of glucose-lowering medications decreased from 3.5 (SD 0.8) per patient at baseline to 2.4 (SD 0.9) per patient at 24 weeks ($P$<.001), with 72% (26/36) of Veterans



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discontinuing short-acting insulin and 50% (18/36; *P*<.001) discontinuing long-acting insulin. Use of glucagon-like peptide-1 receptor agonists increased from 39% (15/38) at baseline to 61% (23/38) at 24 weeks (*P*=.02). Among program completers (n=27), mean percent weight loss was −11.8% (SD 6.5) and median $HbA_{1c}$ decreased by 0.7% (95% CI −0.9 to −0.3; *P*=.001).

**Conclusions:** This pilot program provides preliminary evidence that supports feasibility, acceptability, and clinical effectiveness among Veterans with T2D. Additional research is needed to rigorously test longer-term clinical and cost-effectiveness among a larger cohort of eligible Veterans.

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**KEYWORDS**

digital health; behavior change; type 2 diabetes; low carbohydrate dietary counseling; veterans; de-prescription; cardiometabolic health; personalized health

## Introduction

Globally, type 2 diabetes (T2D) is a leading cause of morbidity, mortality, and health care spending [1-3]. In the US, rates of T2D are particularly high among Veterans who receive care through the Veterans Health Administration (VHA), with estimates suggesting that 25% of Veterans (1.6 million) have the condition [4], due, in part, to high rates of overweight and obesity (78%) [5]. Among people with T2D, weight loss can improve glycemic control, reduce or eliminate the need for antihyperglycemic medications including insulin, and improve key laboratory measures of cardiometabolic health, including lipids, inflammatory markers, and insulin resistance [6,7].

Certain dietary interventions, including low- and very low-carbohydrate (VLC) ketogenic diets, defined as <130 grams of total carbohydrate per day and <50 grams of total carbohydrate per day, respectively [8], may be particularly effective for supporting weight loss and glycemic control among patients with T2D [9,10]. Accordingly, Veterans Affairs (VA) and Department of Defense Clinical Practice Guideline Recommendations for the management of T2D support patient-centered use of carbohydrate-restricted eating patterns [11], which may be preferred by some Veterans with T2D [12] and prediabetes [13]. However, carbohydrate-restricted eating patterns are not routinely offered to Veterans with T2D due, in part, to limited strategies to support their effective and safe implementation in real-world clinical settings. Specifically, patients commonly require intensive, personalized nutrition counseling to ensure adherence to a well-formulated, low-carbohydrate diet and timely adjustments of certain medications (eg, insulin, sulfonylureas, and antihypertensive agents) to mitigate risks of hypoglycemia and hypotension [14-16].

Novel and scalable strategies are thus needed to enhance patients' access to effective carbohydrate-restricted nutrition counseling while minimizing potential risks. Continuous glucose monitoring (CGM) may be one highly promising tool to accomplish these dual priorities [17-19]. CGM provides real-time data on blood glucose levels and insight into how specific foods and behaviors (eg, physical activity, sleep, and stress) influence individual patients' glycemic status. CGM is a key component of effective digital health interventions for T2D self-management [20] and can improve glycemic control while reducing the risk of hypoglycemia [21-24].

The use of CGM to support safe and effective carbohydrate-restricted nutrition counseling for Veterans aligns with existing local VA priorities to deliver patient-centered, evidence-based treatment to Veterans using team-based care models that support innovation and continuous improvement [25]. To advance these priorities, we aimed to develop and evaluate a pilot quality improvement (QI) program to deliver tailored, low-carbohydrate nutrition counseling guided by CGM to Veterans with T2D in a single VA health care system. We hypothesize that this program will be feasible and acceptable among Veterans and that it will support weight loss and improved glycemic control while reducing the use of glucose-lowering medications. These data may inform future efforts to support a weight-focused approach to T2D management within VHA.

## Methods

### Study Design

We conducted a pragmatic, nonrandomized, pre-post evaluation of a QI pilot to examine the feasibility and effectiveness of low-carbohydrate nutrition counseling guided by continuous glucose monitoring (referred to hereafter as LC-CGM) among Veterans with T2D receiving insulin. The intervention was 24 weeks in duration, and all procedures, including patient recruitment, enrollment, education, and monitoring, were integrated into usual clinical care operations. The program evaluation was conducted from March 19, 2021, to May 3, 2024, with data analyzed from February 2024 through March 2025.

### Setting

This program was implemented within the VA Ann Arbor Healthcare System, which includes the Lieutenant Colonel Charles S. Kettles VA Medical Center and 6 other freestanding VA outpatient health clinics serving a diverse patient population throughout southeast Michigan and northwest Ohio [26]. The program was delivered remotely using the VA Video Connect (VVC) platform or telephone, depending on patients' preferences.

### QI Team and Training

The QI team consisted of 1 clinical pharmacist practitioner (CPP), 2 registered dietitians (RD), 2 primary care physicians, and 1 endocrinologist. The CPP dedicated 0.1 full-time equivalent to 4 hours per week, and the RDs dedicated a combined 0.15 full-time equivalent to 6 hours per week to the



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program; the physicians did not have a dedicated program effort and devoted less than 1 hour per week, on average, to supporting the CPP and RDs. RDs and CPPs were trained to support Veterans' adherence to a low-carbohydrate diet using materials previously developed by the study team [13,27], online resources [28], and case-based discussions during monthly team meetings.

## Participants and Recruitment

For this pilot program, we aimed to recruit at least 20 Veterans meeting study inclusion criteria; we limited enrollment to 10 Veterans at one time due to staffing capacity. Inclusion criteria were: (1) Veterans with T2D, (2) use of ≥3 insulin injections per day (based on the VA criteria for use of CGM during the program evaluation period), (3) BMI≥25 kg/m$^2$, (4) desire to lose weight or improve metabolic health, (5) willingness and ability to use CGM technology, (6) willingness and ability to modify dietary intake to follow a carbohydrate-restricted eating pattern, (7) willingness to self-weigh at least once weekly and report weight information to the program team, and (8) willingness to engage in regular virtual visits with clinical team members, including a RD and clinical pharmacist. Exclusion criteria were (1) type 1 diabetes, (2) chronic kidney disease stage 4 or greater, (3) advanced heart failure, and (4) pregnant or breastfeeding.

Primary care clinicians or CPPs identified potentially eligible patients during routine clinical encounters, assessed their interest in LC-CGM program participation, and alerted QI team members via an electronic health record (EHR) message if patients desired to learn more about the opportunity. Within 2 weeks of receiving the EHR alert, a QI team member (DHG or KF) called patients by phone to discuss the program, address any questions or concerns, and initiate enrollment if desired; the enrollment phone script is shown in Multimedia Appendix 1.

## Intervention

### *Visits With CPP*

The initial visit with the CPP was 30 minutes in duration. During this visit, the clinical pharmacist reviewed (1) patients' active medications, including insulin dosing regimen, (2) patients' adherence to prescribed medications, and (3) LC-CGM program expectations (eg, regular attendance at virtual visits) and goals (eg, to reduce dietary carbohydrate intake to support weight loss and glycemic control with fewer medications). The CPP also ensured patients appropriately used CGM, including regularly transmitting data to the clinical review platform; use of CGM tracking features for dietary intake, weight, and physical activity was encouraged but not required.

The CPP informed patients of common side effects that may occur when transitioning from a high-carbohydrate to a low-carbohydrate eating pattern (eg, headache, fatigue, lightheadedness, constipation, and muscle cramps) and strategies to minimize these events (eg, gradual carbohydrate reduction with increased intake of water, electrolytes, and nonstarchy vegetables). Patients were also informed of signs and symptoms of hypoglycemia and hypotension, if taking antihypertensive medication, and counseled on strategies to prevent and treat these events [29]. Veterans were advised to contact the CPP by phone or EHR-based portal messaging if (1) they experienced signs or symptoms of hypoglycemia or hypotension, (2) fasting blood sugar levels <100 mg/dL, or (3) blood pressure <110/70 mm Hg, if using antihypertensive medication. Patients were advised to seek emergency care for severe symptoms.

Use of VLC diets (<50 g of total carbohydrate per day) is relatively contraindicated in patients taking sodium glucose cotransporter-2 (SGLT2 inhibitors) due to the rare risk of euglycemic diabetic ketoacidosis [30]. SGLT2 inhibitors may be indicated for patients with T2D, renal disease, or cardiovascular disease. In general, if LC-CGM patients were prescribed an SGLT2 inhibitor for T2D in the absence of cardiovascular or renal disease and desired to follow a VLC diet, the SGLT2 inhibitor was discontinued during the first visit with the CPP. If patients were prescribed an SGLT2 inhibitor for cardiovascular or renal disease, the SGLT2 inhibitor was generally continued, and patients were counseled to consume 70 - 100 grams of total carbohydrate per day. Additional antihyperglycemic changes, including a reduction in insulin dose, were informed by clinical practice guideline recommendations and patients' baseline glycemic control [31].

Subsequent 30-minute visits with the CPP were scheduled at 3, 6, 12, 18, and 24 weeks. Between scheduled visits, the CPP reviewed patients' CGM data at least once per week and initiated outreach via telephone call or EHR portal message to adjust medications, if needed. The CPP communicated medication changes and issues of concern to the LC-CGM program RD and, if needed, to QI team physicians, via EHR-based messaging or phone call.

### *Visits With RD*

The first RD visit was scheduled within 2 weeks following the initial CPP visit. All patients met virtually with the RD once per week for 4 consecutive weeks; visit frequency was then tailored to individual patients' needs and preferences. For example, patients struggling to follow a carbohydrate-restricted eating pattern continued with weekly visits, whereas patients who easily transitioned to this eating pattern reduced visit frequency to every other week or once monthly. All visits were 30 minutes in duration. In general, RDs taught patients to follow a VLC diet consisting of 20 - 35 net carbohydrates per day (net carbohydrates=total carbohydrates – fiber in g). Patients prescribed an SGLT2 inhibitor were advised to consume 70 - 100 grams of total carbohydrate per day.

Consistent with our team's prior work among Veterans with prediabetes [13], LC-CGM patients were not provided with an explicit calorie limit. Rather, patients were encouraged to eat when hungry and stop when satisfied. Patients were taught to change 1 meal per week from a high- to a VLC option, starting with breakfast and aiming for approximately 10 grams of net carbohydrates per meal or less. Patients were encouraged to consume foods such as meat, fish, poultry, eggs, cheese, seeds, nuts, leafy greens, nonstarchy vegetables, and some fruits (eg, berries). Patients who preferred plant-based sources of protein were encouraged to consume tofu and tempeh. In general, participants were not provided with specific meal plans but rather provided with a variety of low-carbohydrate alternatives to high-carbohydrate foods and meals.



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Patients were encouraged to maintain food logs; these were reviewed in conjunction with CGM data during RD visits. RDs used these data to help patients understand how specific foods influenced their blood sugar levels. If patients reported signs or symptoms of hypoglycemia or if CGM data revealed blood glucose <70 mg/dL, the RD reiterated hypoglycemia management strategies and communicated directly by telephone or a secure messaging platform with the CPP or QI team physician to ensure timely adjustments to patients' anti-hyperglycemic regimen.

### *Discharge From LC-CGM Program*

Veterans were able to stop program participation at any time if they did not desire to use CGM or receive carbohydrate-restricted dietary counseling. Veterans were discharged from the program if they were unable to complete regular follow-up visits or engage in self-monitoring with CGM. Veterans were also discharged after completing the 6-month program. In all cases, Veterans' primary care teams were notified through EHR-based messaging of patients' progress and clinical needs at the time of LC-CGM discharge (eg, ongoing follow-up with primary care CPP). All patients who completed the LC-CGM program were offered optional participation in a virtual, once-monthly low-carbohydrate maintenance group.

## Data Collection

Prior to initiating the LC-CGM program, patients completed baseline fasting laboratory testing, including a comprehensive metabolic panel, hemoglobin $A_{1c}$ ($HbA_{1c}$), lipids, and c-peptide (to confirm endogenous insulin production). At 24 weeks, patients were asked to complete repeat laboratory testing for $HbA_{1c}$ and fasting lipids.

Patients were advised to self-weigh at least once weekly [24]. Veterans without access to a home scale were provided with one, per usual clinical procedures. Patients reported weight change data to the RD during scheduled visits; these data were entered into patients' medical records.

The following data were collected from the EHR: sociodemographic factors (age, sex, race, and ethnicity), anthropometric measures (height, weight, and BMI), laboratory test results ($HbA_{1c}$, total cholesterol, high-density lipoprotein [HDL], low-density lipoprotein [LDL], and triglycerides), and T2D medications prescriptions, including biguanides (eg, metformin), sulfonylureas, thiazolidinediones, meglitinides (eg, repaglinide), glucagon-like peptide 1 receptor agonists (GLP-1 RAs), dipeptidyl peptidase-4 (DPP-4) inhibitors, and SGLT2 inhibitors, and insulins. We also collected data on insulin type (eg, short-acting and long-acting) and total daily dosages (TDD) for each type.

## Outcome Measures

Primary outcomes include measures of feasibility and acceptability:

1. Program enrollment rate, defined as the number of referred patients who enrolled in the program divided by the total number of referred patients.
2. Mean program engagement, defined as the number of weeks engaged in LC-CGM.
3. Program completion rate, defined as the number of patients who completed the 24-week program divided by the number of program enrollees.
4. Mean number of CPP visits among all program enrollees and among program completers.
5. Mean number of RD visits among all program enrollees and among program completers.

Secondary outcomes include the following clinical effectiveness measures:

1. Mean change in self-reported weight at 4, 12, and 24 weeks compared to baseline. Veterans were advised to self-weigh at least once weekly and report the most recent measure at each scheduled visit.
2. Mean percent weight change at 4, 12, and 24 weeks compared to baseline.
3. Achievement of ≥5% and ≥10% weight loss at 4, 12, and 24 weeks, defined as the percentage of participants who achieved these weight thresholds divided by the total number of participants.
4. Change in glucose-lowering medication use at 24 weeks.
5. Change in TDD of insulin at 24 weeks.
6. Mean change in $HbA_{1c}$, LDL, HDL, and triglycerides among program completers at 24 weeks.

## Statistical Analysis

We evaluated weight and medication change outcomes for all program enrollees using data available in their final LC-CGM clinic note. Laboratory data were evaluated if available within 30 days of the final LC-CGM visit.

We assessed baseline characteristics of those who enrolled and compared baseline characteristics of those who enrolled and completed the program to those who enrolled but did not complete the program.

We computed descriptive statistics for collected variables, including means, medians, and IQRs for continuous variables and counts and proportions for categorical variables. To assess differences, we conducted intention-to-treat analyses and used the last observation carried forward method for missing data from noncompleters. We also assessed differences among those who completed the program. For continuous variables, we used the Shapiro-Wilk test to assess the normality of the distribution of differences. We compared baseline to 24-week changes using paired samples 2-tailed *t* tests or paired Wilcoxon exact signed rank tests with continuity correction. To compare differences in proportions, we constructed contingency tables and completed McNemar difference in paired proportions tests with continuity correction to improve the approximation of the discrete probability distribution with a continuous one [32]. To determine statistical significance, we used a 2-sided $P<.05$. All analyses were completed in R (version 4.1.3; R Core Team).

## Ethical Considerations

This program was reviewed by the VA Ann Arbor Healthcare System's Quality Management Office, which reviews QI program applications to determine whether Institutional Review



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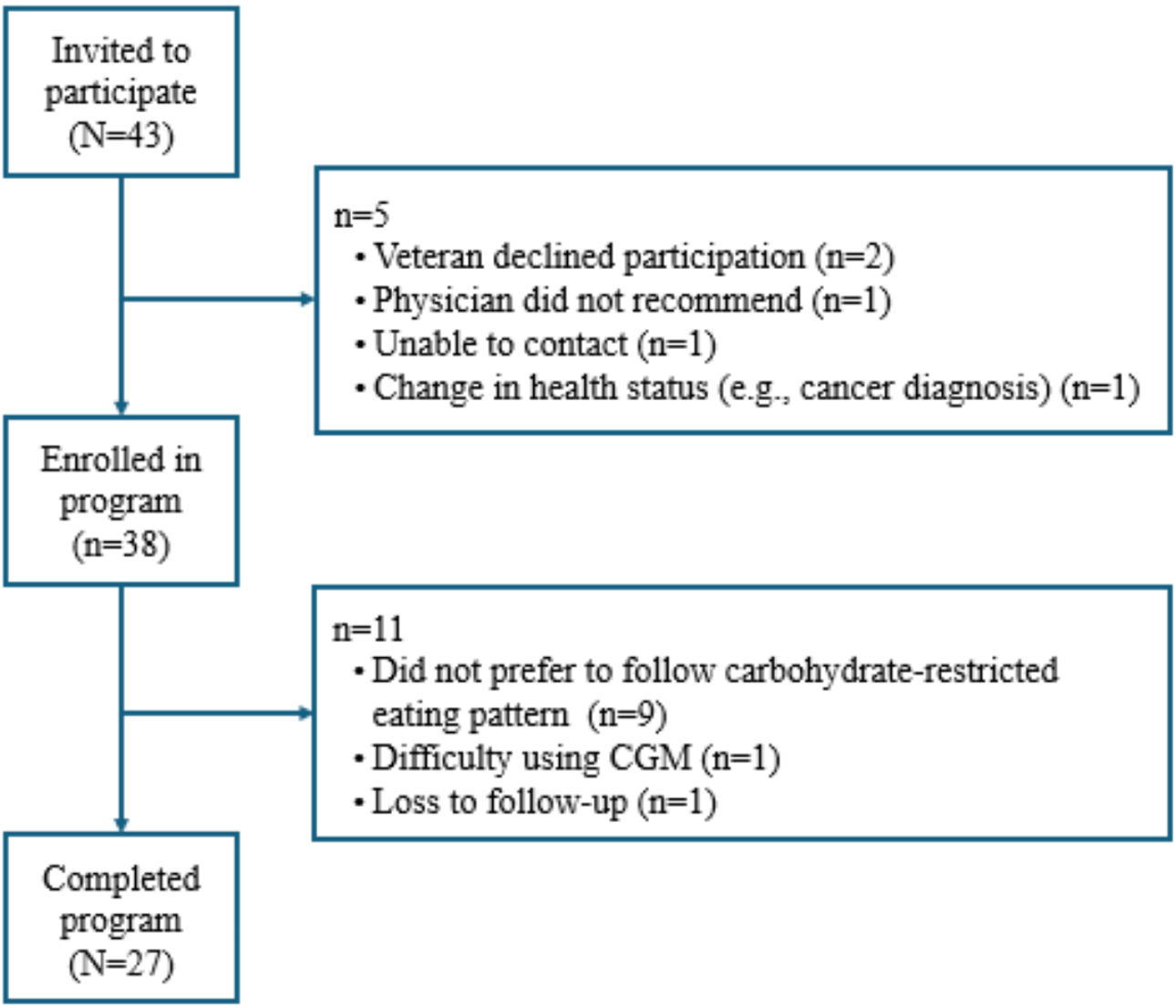
Board oversight is required. This project was approved as a nonresearch, QI initiative. As such, patients were informed that participation was voluntary and were also provided the opportunity to verbally accept or decline participation prior to data collection (Multimedia Appendix 1). To safeguard patient information, extracted data were deidentified and aggregated for analysis.

## Results

### Overview

Overall, 43 Veterans were referred to the LC-CGM program during the evaluation period and 38 (88%) enrolled. Among program enrollees, 27/38 (71%) completed the 24-week program. Reasons for program nonenrollment and noncompletion are shown in Figure 1. The main reason for program noncompletion was Veterans' preference not to follow a carbohydrate-restricted eating pattern (9/11, 81.8%).

**Figure 1.** Study flow diagram. CGM: continuous glucose monitoring.




### Baseline Characteristics

Baseline sociodemographic and clinical characteristics for program enrollees, stratified by program completion status, are shown in Table 1. Most program enrollees were men (37/38, 97%), white (29/38, 76%), and the average age was 63.7 (SD 9.6) years. Mean BMI was 38.1 (SD 5.8) kg/m$^2$ and mean $HbA_{1c}$ was 7.8% (SD 1.3%). There were no significant differences in baseline characteristics of program completers versus noncompleters. Overall, patients were prescribed an average of 3.5 (SD 0.8) glucose-lowering medications, and all were prescribed insulin.



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**Table .** Baseline characteristics of program enrollees, stratified by program completers and noncompleters.

| Variables | Program enrollees (n=38) | Program completers (n=27) | Program noncompleters (n=11) | *P* value |
|---|---|---|---|---|
| Sociodemographic characteristics | | | | |
| Age (years) | | | | .91 |
| Mean (SD) | 63.7 (9.6) | 63.7 (9.4) | 63.7 (10.5) | |
| Median (IQR) | 67 (56 - 72) | 66 (56 - 72) | 67 (58 - 72) | |
| Sex, n (%) | | | | |
| Male | 37 (97) | 26 (96) | 11 (100) | >.99 |
| Race, n (%) | | | | .14 |
| Black or African American | 3 (8) | 1 (4) | 2 (18) | |
| White or Caucasian | 29 (76) | 22 (81) | 7 (64) | |
| Other | 1 (3) | 0 (0) | 1 (9) | |
| Missing | 5 (13) | 4 (15) | 1 (9) | |
| Ethnicity, n (%) | | | | .80 |
| Hispanic | 2 (5) | 1 (4) | 1 (9) | |
| Non-Hispanic | 34 (89) | 24 (89) | 10 (91) | |
| Missing | 2 (5) | 2 (7) | 0 (0) | |
| Anthropometric characteristics | | | | |
| Weight (kg) | | | | .50 |
| Mean (SD) | 121.2 (24) | 122.7 (25.1) | 117.5 (21.5) | |
| Median (IQR) | 115 (101.4 - 137.6) | 119.1 (100.8 - 142.4) | 112.9 (105.5 - 128.1) | |
| BMI ($kg/m^2$) | | | | .92 |
| Mean (SD) | 38.1 (5.8) | 38.2 (6.2) | 37.9 (5.1) | |
| Median (IQR) | 37.2 (34.1 - 42.5) | 36.6 (34 - 42.7) | 37.7 (34.7 - 40.6) | |
| Cardiometabolic laboratory data | | | | |
| $HbA_{1c}$[a](%) | | | | .30 |
| Mean (SD) | 7.8 (1.3) | 7.7 (1.5) | 8 (0.9) | |
| Median (IQR) | 7.8 (7.1 - 8.3) | 7.5 (7 - 8.2) | 8 (7.5 - 8.2) | |
| HDL[b] (mg/dL) | | | | .07 |
| Mean (SD) | 36.6 (8) | 35 (7.2) | 40.8 (8.8) | |
| Median (IQR) | 35 (31 - 38) | 34 (30.5 - 37) | 37 (33.5 - 49.8) | |
| LDL[c] (mg/dL) | | | | .40 |
| Mean (SD) | 76.1 (40.5) | 74.1 (43) | 80.7 (35.4) | |
| Median (IQR) | 61.5 (43.2 - 94.8) | 56 (40 - 92.2) | 77 (56.5 - 94.5) | |
| Cholesterol (mg/dL) | | | | .64 |
| Mean (SD) | 156.4 (54) | 157.3 (60.2) | 153.8 (34.5) | |
| Median (IQR) | 137 (118 - 174) | 135 (113.5 - 178.5) | 143.5 (133 - 168.2) | |
| Triglycerides (mg/dL) | | | | .20 |
| Mean (SD) | 232 (135) | 250.7 (145.6) | 182 (88.8) | |
| Median (IQR) | 199 (149 - 281) | 201 (160.5 - 330) | 175 (101.8 - 254.5) | |
| Glucose-lowering medications | | | | |
| Number of prescriptions | | | | |



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| Variables | Program enrollees (n=38) | Program completers (n=27) | Program noncompleters (n=11) | *P* value |
|---|---|---|---|---|
| Mean (SD) | 3.5 (0.8) | 3.4 (0.8) | 3.6 (0.9) | .78 |
| Median (IQR) | 3 (3 - 4) | 3 (3 - 4) | 3 (3 - 4) | .78 |
| Patients with ≤2 prescriptions, n (%) | 4 (11) | 3 (11) | 1 (9) | .80 |
| Patients with 3 prescriptions, n (%) | 16 (42) | 11 (41) | 5 (45) | .80 |
| Patients with 4 or more prescriptions, n (%) | 18 (47) | 13 (48) | 5 (45) | .80 |
| Glucose-lowering medication type, n (%) | | | | |
| Long-acting insulin | 36 (95) | 26 (96) | 10 (91) | .50 |
| Short-acting insulin | 35 (92) | 26 (96) | 9 (82) | .20 |
| U-500 insulin | 2 (5) | 1 (3.7) | 1 (9) | .50 |
| Biguanide (metformin) | 25 (66) | 18 (67) | 7 (64) | >.99 |
| Sodium-glucose cotransporter 2 inhibitor | 17 (45) | 12 (44) | 5 (45) | >.99 |
| Glucagon-like peptide 1 receptor agonist | 15 (39) | 9 (33) | 6 (55) | .30 |
| Sulfonylureas | 2 (5) | 1 (4) | 1 (9) | .50 |
| Dipeptidyl peptidase 4 inhibitor | 0 (0) | 0 (0) | 0 (0) | —[d] |
| Meglitinides | 1 (3) | 1 (4) | 0 (0) | — |
| TDD[e] of insulin in units, mean (SD) | | | | |
| Long-acting insulin | 78.4 (39.3) | 76.5 (39.2) | 83.4 (41.2) | .70 |
| Short-acting insulin | 42.5 (28.3) | 40.9 (27.4) | 46.9 (32) | .60 |
| U-500 concentrated insulin | 420 (113.1) | 340 (—) | 500 (—) | >.99 |

[a]$HbA_{1c}$: hemoglobin $A_{1c}$.

[b]HDL: high-density lipoprotein.

[c]LDL: low-density lipoprotein.

[d]Not available.

[e]TDD: total daily dose.

## Primary Outcomes

The number of program enrollees and completers is shown in Figure 1. Among program enrollees, the mean number of weeks engaged in the LC-CGM was 20.7 (SD 5.6). As shown in Table 2, the mean number of program visits with the RD was 10.7 (SD 2.4) among program completers and 6.5 (SD 3.4) among program noncompleters (*P*<.001). The mean number of program visits with the CPP was 15.1 (SD 3) among program completers and 7.2 (SD 2.8) among program noncompleters (*P*<.001).

**Table .** Engagement in registered dietitian and clinical pharmacy practitioner visits among program enrollees, stratified by program completers and program noncompleters.

| Variables | Program enrollees (n=38) | Program completers (n=27) | Program noncompleters (n=11) | *P* value |
|---|---|---|---|---|
| Registered dietitian visits | | | | <.001 |
| Mean (SD) | 9.5 (3.3) | 10.7 (2.4) | 6.5 (3.4) | |
| Median (IQR) | 10 (3-17) | 10 (7-17) | 6 (3-14) | |
| Clinical pharmacy practitioner visits | | | | <.001 |
| Mean (SD) | 12.8 (4.7) | 15.1 (3) | 7.2 (2.8) | |
| Median (IQR) | 13 (3-24) | 15 (11-24) | 7 (3-11) | |



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### Secondary Outcomes

Table 3 shows weight change for the program at 4, 12, and 24 weeks among program enrollees, stratified by program noncompleters who discontinued the program at 4 and 12 weeks.



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**Table .** Weight change at 4, 12, and 24 weeks among program enrollees, stratified by program noncompleters who discontinued the program at 4 and 12 weeks.

| Weight change | Program enrollees | 95% CI for difference | Weight change among patients who remained in the program | Weight change among patients who discontinued the program | 95% CI for difference | *P* value[a] |
|---|---|---|---|---|---|---|
| Weight change at week 4 | | | | | | |
| Number of enrollees | 38 | —[e] | 33 | 5 | — | — |
| Weight change (kg), mean (SD)[b] | −4.5 (4.6) | −6 to −3[c] | −4.9 (4.7) | −0.5 (0.9) | −4.4 (−6.1 to −1.2) | .006 |
| Weight change (kg), median (IQR)[d] | −4.1 (−6.8 to −1.5) | −5.9 to −3.2[c] | −4.5 (−6.9 to −2.7) | −1.3 (1.8) | −3.2 (−6.8 to −0.5) | .03 |
| Weight change (%), mean (SD) | −3.8 (3.7) | — | −4.2 (3.7) | −1.4 (2) | −2.8 (−5.3 to −0.3) | .03 |
| ≥5% weight loss, n (%) | 13 (34) | — | 13 (39) | 0 (0) | 11 - 68 | .20 |
| ≥10% weight loss, n (%) | 1 (3) | — | 1 (3) | 0 (0) | 0 - 11.9 | >.99 |
| Weight change at week 12 | | | | | | |
| Number of enrollees | 38 | — | 27 | 6 | — | — |
| Weight change (kg), mean (SD)[b] | −8.5 (6.2) | −10.5 to −6.4[c] | −9.9 (5.6) | −8.3 (7.8) | −1.6 (−7.1 to 4) | .66 |
| Weight change (kg), median (IQR)[d] | −6.5 (−11.8 to −3.6) | −10.7 to −6.6[c] | −9.5 (−13.5 to −6.3) | −4.3 (−12.1 to −3) | −5.2 (−8.8 to 6.3) | .30 |
| Weight change (%), mean (SD) | −7.2 (5.4) | — | −8.4 (5) | −6.8 (6.3) | −2 (−8 to 5) | .59 |
| ≥5% weight loss, n (%) | 22 (58) | — | 20 (74) | 2 (33) | 0 - 92 | .20 |
| ≥10% weight loss, n (%) | 12 (32) | — | 10 (37) | 2 (33) | 0 - 49 | >.99 |
| Weight change at week 24 | | | | | | |
| Number of enrollees | 38 | — | 27 | 11 | — | — |
| Weight change (kg), mean (SD)[b] | −11.5 (8.7) | −14.4 to −8.6[c] | −14.3 (7.9) | −4.7 (6.9) | −9.6 (−14.9 to −4.2) | .001 |
| Weight change (kg), median (IQR)[d] | −10.9 (−18 to −3.8) | −14.5 to −8.6[c] | −14.7 (−18.9 to −9.3) | −2.7 (−4.3,−0.5) | −12 (−15.7 to −5.4) | .001 |
| Weight change (%), mean (SD) | −9.5 (7.2) | — | −11.8 (6.5) | −3.9 (5.6) | −7.9 (−12.4 to −3.3) | .001 |
| ≥5% weight loss n (%) | 26 (68) | — | 24 (89) | 2 (18) | 38.6 - 100 | <.001 |
| ≥10% weight loss n (%) | 19 (50) | — | 17 (63) | 2 (18) | 9.2 - 80.4 | .03 |

[a]2-sample *t* test.



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[b]Paired samples *t* test.

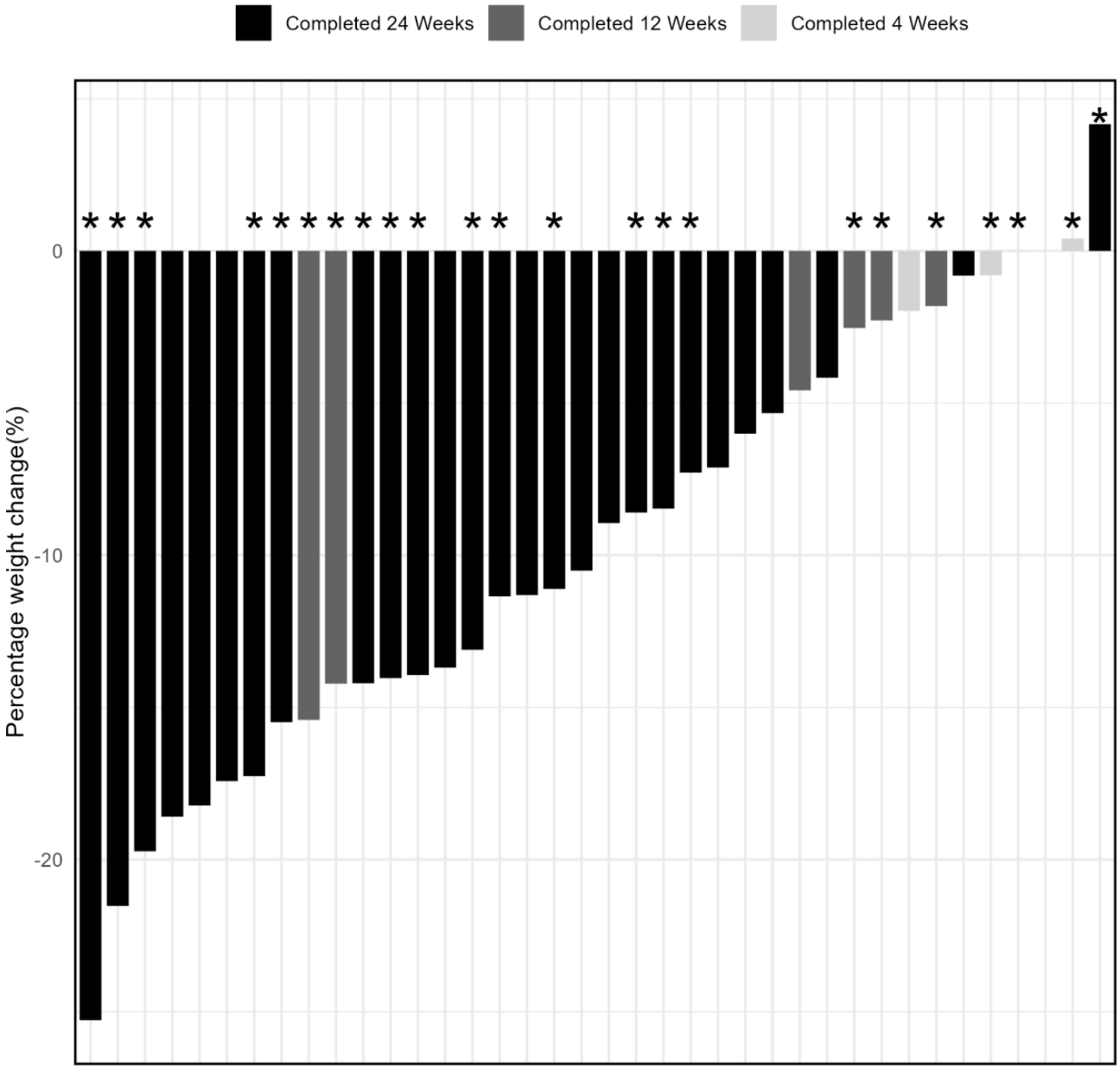
[c]Statistically significant at *P*≤.001.

[d]Paired Wilcoxon exact signed rank test with continuity correction.

[e]Not available.

Overall, among 38 enrollees, mean weight change was −11.5 kg (SD 8.7) and mean percent weight change was 9.5% (SD 7.2%), with 68% (26/38) achieving ≥ 5% weight loss and 50% (19/38) achieving ≥ 10% weight loss at 24 weeks. Among 27 program completers, mean percent weight loss was 11.8% (SD 6.5%) at 24 weeks, with most achieving ≥5% weight loss (89%, 24/27) and approximately two-thirds achieving ≥10% weight loss (63%, 17/27). At week 4, weight change was significantly greater among those who completed the program compared to those who did not (−4.2% vs 1.4%; *P*=.03). A waterfall plot of weight change for each patient is shown in Figure 2.

**Figure 2.** Waterfall plot showing percent weight change for individual program enrollees, with glucagon-like 1 peptide receptor agonist use at 24 weeks designated with an asterisk (*). Each bar corresponds to 1 participant.




Changes in cardiometabolic laboratory data at 24 weeks compared to baseline for program completers who had follow-up laboratory data are shown in Multimedia Appendix 2. Mean $HbA_{1c}$ decreased by 0.7% (CI −0.9% to −0.3%), from 7.7% (SD 1.5%) to 7% (SD 0.9%), with 6 patients (22%) having an $HbA_{1c}$ less than 6.5. On average, patients had significant reductions in total cholesterol (−18.9 mg/dL, SD 28) and triglyceride levels (−80.8 mg/dL, SD 103.2). Mean changes in LDL and HDL cholesterol levels were nonsignificant. In total, 42% (8/19) had a mean increase in LDL cholesterol of 15.8 mg/dL, and 58% (11/19) had a mean decrease in LDL cholesterol of −19.6 mg/dl. Waterfall plots of change in $HbA_{1c}$



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and LDL cholesterol for each patient are shown in Multimedia Appendices 3 and 4.

Table 4 shows changes in glucose-lowering medication use among program enrollees and program completers. At baseline, patients were prescribed an average of 3.5 (SD 0.8) glucose-lowering medications, which decreased to 2.4 (SD 0.9) at 24 weeks. Program completers were prescribed an average of 2.2 (SD 0.9) glucose-lowering medications at 24 weeks. Those who discontinued at 12 weeks were prescribed an average of 2.7 (SD 0.5) glucose-lowering medication, while those who discontinued the program after 4 weeks did not have any medication changes. Among those who completed the program, 21/27 (78%) were prescribed 2 or fewer medications at 24 weeks compared to 3 of 27 (11%) at baseline (Table 4 and Multimedia Appendix 5). Most patients discontinued use of short-acting insulin (24/27, 89%) and long-acting insulin (18/27, 67%) during the program period (Table 4). Changes in TDD of insulin are in Multimedia Appendix 6. Also, fewer patients used SGLT2 inhibitors, sulfonylureas, and meglitinides compared to baseline; however, these changes were nonsignificant (Table 4).



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**Table .** Change in glucose-lowering medication use among program enrollees and program completers.

| | Baseline ITT[a], n (%), (n=38) | 24 Weeks ITT, n (%), (n=38) | Difference (95% CI)[b] | *P* value[b] | Baseline completers n (%), (n=27) | 24 Weeks completers n (%), (n=27) | Difference (95% CI)[b] | *P* value[b] |
|---|---|---|---|---|---|---|---|---|
| Number of prescriptions, for glucose-lowering medications, mean (SD) | 3.5 (0.8) | 2.4 (0.9) | −1.1 (−1.4 to −0.73) | <.001 | 3.4 (0.8) | 2.2 (0.9) | −1.5[c] (−1 to −2)[d] | <.001 |
| Patients with ≤2 prescriptions for glucose-lowering medications, n (%) | 4 (11) | 23 (61) | 50 (31 - 69) | <.001 | 3 (11) | 21 (78) | 67 (45 - 88) | <.001 |
| Biguanides (eg, metformin) | 25 (66) | 25 (66) | 0 (−13 to 13) | .62 | 18 (67) | 18 (67) | 0 (−18 to 18) | .62 |
| Short-acting insulin | 36 (95) | 10 (26) | −66 (−87 to −45) | <.001 | 26 (96) | 3 (11) | −85 (−100 to −68) | <.001 |
| Long-acting insulin | 36 (95) | 18 (47) | −47 (−67 to −27) | <.001 | 26 (96) | 9 (33) | −63 (−88 to −38) | <.001 |
| Both short- and long-acting insulin | 36 (95) | 9 (24) | −70 (−90 to −51) | <.001 | 26 (96) | 3 (11) | −88 (−100 to −72) | <.001 |
| U500[d] | 2 (5) | 0 (0) | −5.3 (−15 to 4.5) | .48 | 1 (4) | 0 (0) | −3.7 (−14.5 to 7.1) | >.99 |
| Sulfonylureas | 2 (5) | 0 (0) | −5.3 (−15 to 4.5) | .48 | 1 (4) | 0(0) | −3.7 (−14.5 to 7.1) | >.99 |
| DPP-4[e] inhibitor | 0 (0) | 7 (18) | -18 (3.5 - 33) | .02 | 0 (0) | 6 (22.2) | 22.2 (2.8 - 41.6) | .04 |
| GLP-1 RA[f] | 15 (39) | 23 (61) | 24 (7.5 - 40) | .008 | 8 (30) | 15 (56) | 26 (5.8 - 46) | .02 |
| SGLT2[g] Inhibitors | 17 (45) | 8 (21) | −24 (−43 to −4) | .03 | 12 (44) | 7 (25.9) | −18.5 (−42.9 to 6) | .18 |
| Meglitinides | 1 (3) | 0 (0) | −2.6 (−10 to 5.1) | >.99 | 1 (4) | 0 (0) | −3.7 (−14.5 to 7.1) | >.99 |

[a]ITT: intention to treat.

[b]McNemar difference in paired proportions test with continuity correction to improve the approximation of the discrete probability distribution with a continuous one.

[c]Paired Wilcoxon exact signed rank test with continuity correction due to *P* value <.05 on Shapiro-Wilk test (suggesting distribution of differences is not normal). Median difference and confidence interval for median are reported instead of the mean difference for total number of anti-hyperglycemic medications (mean of −1.3 and SD of 1.1) and short-acting insulin (mean of −36.1 mg/dl and SD of 28.8).

[d]U500 is highly concentrated insulin, 500 units/mL, typically used for highly insulin-resistant patients.

[e]DPP-4: dipeptidyl peptidase 4.

[f]GLP-1 RA: glucagon-like peptide 1 receptor agonists.

[g]SGLT2: sodium glucose cotransporter-2.

Notably, of the 27 participants who completed the program, 15 (56%) were prescribed a GLP-1 RA. Those who were prescribed a GLP-1 RA lost an average of 13% body weight (16.4 kg), compared to 10% (11.6 kg) for those (n=12) who were not prescribed a GLP-1 RA. Of the 24 participants who achieved at least 5% body weight loss, 14 (58%) were prescribed a GLP-1 RA at week 2. Of the 17 people who achieved at least 10% body weight loss, 11 (65%) were prescribed a GLP-1 RA at week 24.

Figure 2 shows patient-level weight change stratified by prescription of GLP-1 RA for those who completed the program.

## Adverse Events and Side Effects

There were no serious adverse events during the evaluation period. Overall, 18% of patients (7/38) experienced mild (level 1) hypoglycemia (blood glucose level between 54 mg/dL and 70 mg/dL), which was managed as an outpatient using standard protocols and medication de-escalation [29]. Side effects



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included mild gastrointestinal upset, including belching (n=1), diarrhea with use of semaglutide, resulting in medication discontinuation (n=1), nausea due to metformin, resulting in dose de-escalation (n=1), and increased feelings of anger (n=1).

## Discussion

### Principal Results and Comparison With Prior Work

This QI pilot evaluated the feasibility, acceptability, and clinical effectiveness of tailored low-carbohydrate nutrition counseling supported by continuous glucose monitoring (LC-CGM) among Veterans with T2D using insulin. Most Veterans referred to the LC-CGM program enrolled (38/43, 88%) and, among enrollees, mean engagement was 20 weeks, with approximately 3-quarters (27/38, 71%) completing the 24-week program. Additionally, the LC-CGM program appeared to be an effective and safe intervention to support significant reductions in weight, $HbA_{1c}$, and use of glucose-lowering medications, including insulin.

Our team previously observed high levels of engagement (77%) in a local pilot evaluation of a group-based, VLC diabetes prevention program for Veterans with prediabetes [13]. In contrast, only 25% of Veterans who enroll in the VHA's MOVE! Weight Management Program, a comprehensive lifestyle intervention that teaches Veterans to follow a conventional, calorie-restricted diet, complete 8 or more sessions within 6 months [33]. Taken together, these findings support prior literature suggesting that some Veterans may prefer a carbohydrate-restricted approach to dietary change [12,13,34].

Prior work has similarly demonstrated the effectiveness of VLC nutrition counseling among individuals who chose to participate in a continuous care intervention (Virta Health) consisting of individualized low-carbohydrate nutrition counseling focused on achieving nutritional ketosis, health coaching, and remote data monitoring (eg, weight and finger-stick blood glucose) [35,36]. A long-term (24-month) evaluation of this intervention demonstrated high levels of program retention (194/262, 74%), with sustained reductions in weight (−10%), $HbA_{1c}$ (−0.9%), and prescriptions for T2D medications (−67%) compared to baseline (vs no change in the usual care group) [37]. In 2019, the Department of Veterans Affairs initiated a partnership with Virta Health to pilot test the intervention among Veterans with T2D and overweight or obesity to provide "a more comprehensive approach to care." [38] At 24 months, weight loss was significantly greater among Veterans in the intervention versus waitlist control group (−12 kg vs 3 kg). Both groups had a reduction in $HbA_{1c}$ (−0.79 % and −0.59% respectively). However, among intervention participants, this was achieved through dietary carbohydrate restriction with concomitant de-escalation of glucose-lowering medications; control participants required the use of more glucose-lowering medications to reduce $HbA_{1c}$ [39]. Accordingly, monthly per-patient outpatient and pharmacy drug costs were significantly lower among intervention versus usual care participants [39]. Additional work is needed to evaluate the cost-effectiveness of low-carbohydrate nutrition counseling programs, including LC-CGM, which often require intensive support in the near term but may ultimately reduce health care and medication use.

Although overall use of glucose-lowering medications, including insulin, decreased during the study period, there was a significant increase in use of GLP-1 RAs, with 39% (15/38) of LC-CGM patients using a GLP-1 RA at baseline and 61% (23/38) using a GLP-1 RA at 24 weeks. This finding contrasts with recent literature demonstrating that carbohydrate-restricted diets can be used to de-escalate or avoid GLP-1 RA prescriptions [40] and support T2D remission, defined as $HbA_{1c}$ <6.5% at least 3 months after stopping glucose-lowering medications [9,41]. This is due, at least in part, to 2 key factors. First, the LC-CGM program was intended to optimize Veterans' glucose-lowering medication regimen to support weight loss and improved metabolic health; T2D remission was not an explicit goal of this program, though 22% (6/27) of program completers achieved $HbA_{1c}$ <6.5% (Multimedia Appendix 7 for medication use among participants with $HbA_{1c}$ <6.5% at 24 wk). Second, this was a highly pragmatic quality initiative with inclusion of patients who are less likely to achieve T2D remission (eg, older age, suboptimal glycemic control, use of multiple glucose-lowering medications, and the use of insulin) [42]. Notably, mean weight loss among Veterans prescribed a GLP-1 RA in the LC-CGM program (–10.2%) was greater than expected from clinical efficacy trials of GLP-1 RAs among patients with T2D, with the greatest weight loss (−9.6%) achieved with semaglutide [43]. Given the high cost of GLP-1 RAs [44] and prior reports of their attenuated effectiveness in general practice settings [45,46], further work is warranted to examine the clinical and cost-effectiveness of the LC-CGM program in a large-scale trial.

A key strength of the LC-CGM program is its use of existing VA infrastructure and resources, including clinical team members, and its alignment with VHA's priorities to deliver team-based, coordinated, and patient-centered care to help Veterans achieve their personal health goals [47,48]. Due to the intensive nature of the program, inclusion of Veterans at high risk for adverse events (eg, hypoglycemia and hypotension), and need for proactive, early deprescribing of glucose-lowering medications [16,49], we were able to support a maximum of 10 Veterans at a time with 6 hours per week of dedicated RD effort and 4 hours per week of dedicated CPP effort. Additional work is needed to explore opportunities to increase LC-CGM capacity; this may include use of group-based and asynchronous education sessions, integration of digital health interventions (eg, text messages and artificial intelligence) [50], and inclusion of patients at lower risk for hypoglycemia (eg, individuals with prediabetes, new diagnosis of T2D, or T2D not requiring insulin) [51]. If offered as a group-based program, LC-CGM's visit frequency and overall duration would align with other group-based comprehensive lifestyle interventions, including the Centers for Disease Control and Prevention's Diabetes Prevention Program and the VHA's MOVE! Weight Management Program. Notably, MOVE! is also offered as a one-on-one program, with 12 sessions more than 12 months with a dietitian. LC-CGM's involvement of a CPP increases staffing requirements compared to MOVE! but it may not be required if the LC-CGM program was offered to patients at



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lower risk for hypoglycemia. Additional work is needed to understand if LC-CGM's short-term, resource-intensive nature is offset by future reductions in health care use, including primary care visits, emergency department encounters, and inpatient hospitalizations.

### Limitations

This study had several limitations. First, this was a QI program evaluation from a single VA health care system; the results may not be generalizable to other VA sites or non-Veteran populations. Second, due to the pragmatic nature of the LC-CGM program referral process, we do not know the number of Veterans who were offered LC-CGM participation but declined referral; this information should be collected in a larger scale trial to further discern the program's acceptability. Third, we did not evaluate outcomes beyond 6 months, and we are therefore unable to assess the program's long-term clinical effectiveness. Prior literature demonstrates sustained clinical benefits of dietary carbohydrate restriction for up to 5 years among a non-Veteran population [52]. Fourth, we did not formally assess dietary carbohydrate intake using validated measures. Rather, we considered reductions in weight, $HbA_{1c}$, and medication use as surrogate indicators of dietary adherence. Fifth, due to the virtual nature of the program, most weight data were obtained through the Veteran's self-report and may differ from in-clinic measured weight. Notably, prior literature suggests concordance between self-reported and measured weight [53], and objective favorable changes in $HbA_{1c}$ and medication use among LC-CGM patients suggest accuracy of self-reported weight in this cohort. Sixth, we were unable to assess the program's cost-effectiveness due to the limited, short-term nature of the available data and the nonpublic availability of the VA's negotiated drug prices, which are often substantially lower than those in non-VA settings. Notably, other intensive lifestyle interventions focused on carbohydrate restriction and medication de-prescription have demonstrated cost savings [54].

### Conclusions

This QI program evaluation demonstrates that individually tailored, LC-CGM can reduce body weight, $HbA_{1c}$, and use of glucose-lowering medications among Veterans with T2D on insulin. This approach aligns with clinical practice guideline recommendations that encourage preference-sensitive nutrition counseling using evidence-based approaches, including low- and VLC diets [11,55]. To inform approaches to T2D management in other VA Medical Centers nationwide and enhance Veterans' access to guideline-adherent carbohydrate-restricted nutrition counseling, the LC-CGM program should be evaluated in a larger scale implementation initiative with examination of longer term clinical outcomes and program costs, including use of GLP-1 RAs.

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## Data Availability

The datasets generated or analyzed during this study are not publicly available due to the quality improvement nature of the work; the goal was to evaluate a local program not to generate generalizable data or a publicly available dataset. The data may be available from the corresponding author on reasonable request and only if the necessary VA regulatory permissions are obtained by the requesting individual.

## Authors' Contributions

CDT: data curation, formal analysis, investigation, methodology, project administration, software, validation, visualization, writing – original draft, and writing – review and editing
KP: conceptualization, data curation, investigation, methodology, project administration, resources, writing – original draft, and writing – review and editing
KF: conceptualization, data curation, investigation, methodology, project administration, resources, supervision, writing – original draft, and writing – review and editing
LR: conceptualization, data curation, investigation, methodology, project administration, resources, supervision, writing – original draft, and writing – review and editing
JM: conceptualization, data curation, investigation, methodology, project administration, resources, supervision, writing – original draft, and writing – review and editing
TB: conceptualization, data curation, investigation, methodology, project administration, resources, supervision, writing – original draft, and writing – review and editing
LRS: supervision, writing – original draft, and writing – review and editing
JH: data curation, methodology, project administration, supervision, writing – original draft, and writing and review and editing
LO: supervision, writing – original draft, and writing – review and editing
CRR: supervision, writing – original draft, and writing – review and editing



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DM: supervision, writing – original draft, and writing – review and editing
AMF: supervision, writing – original draft, and writing – review and editing
GS: supervision, writing – original draft, and writing – review and editing
DHG: conceptualization, investigation, methodology, project administration, resources, supervision, validation, writing – original draft, and writing-review and editing.

## Conflicts of Interest

LO reports owning stock in Merck Stock, AbbVie, Eli Lilly, and Abbott Laboratories outside the submitted work. CRR reports consulting for Dexcom, American Diabetes Association, and Coordinate DM trial consultant - conducted by the Duke Clinical Research Institute (Durham, NC). MF reports serving as a consultant to AbbVie, Centivo, the Community Oncology Association, EmblemHealth, the Employee Benefits Research Institute, Exact Sciences, GRAIL, Health at Scale Technologies (equity interest), HealthCorum, the Hopewell Fund, Johnson & Johnson, Medtronic, MedZed, Merck, MotherGoose (equity interest), Phathom Pharmaceuticals, Proton Intelligence, Sempre Health (equity interest), Silver Fern HealthCare (equity interest), the US Department of Defense, the Virginia Center for Health Innovation, the Washington Health Benefit Exchange, Wellth (equity interest), the Yale New Haven Health System, and Zansors (equity interest). Dr Fendrick reports receipt of research funding from Arnold Ventures, the State of Michigan, the Centers for Medicare & Medicaid Services, the West Health Policy Center, the Agency for Healthcare Research and Quality, the National Pharmaceutical Council, the Patient-Centered Outcomes Research Institute, the Pharmaceutical Research and Manufacturers of America, and the Robert Wood Johnson Foundation and holding outside positions as co-editor in chief of The *American Journal of Managed Care*, as past member of the Medicare Evidence Development and Coverage Advisory Committee, and as partner at VBID Health LLC.

Multimedia Appendix 1
Veterans Affairs low-carbohydrate nutrition counseling guided by continuous glucose monitoring quality improvement pilot recruitment phone script.
[DOCX File, 16 KB - diabetes_v10i1e75672_app1.docx ]

Multimedia Appendix 2
Cardiometabolic laboratory changes among program completers.
[DOCX File, 17 KB - diabetes_v10i1e75672_app2.docx ]

Multimedia Appendix 3
Waterfall plot of low-density lipoprotein cholesterol change from baseline to 24 weeks (n=19).
[DOCX File, 30 KB - diabetes_v10i1e75672_app3.docx ]

Multimedia Appendix 4
Hemoglobin A1C change for participants who completed the program. A total of 27 participants completed the program, and 25 had hemoglobin A1C lab values available.
[DOCX File, 46 KB - diabetes_v10i1e75672_app4.docx ]

Multimedia Appendix 5
Total number of prescriptions for program completers, baseline to 24 weeks.
[DOCX File, 147 KB - diabetes_v10i1e75672_app5.docx ]

Multimedia Appendix 6
Change in total daily dose of insulin among program enrollees and program completers.
[DOCX File, 18 KB - diabetes_v10i1e75672_app6.docx ]

Multimedia Appendix 7
Medications for participants with hemoglobin of <6.5% at 24-week follow-up (n=6).
[DOCX File, 17 KB - diabetes_v10i1e75672_app7.docx ]

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## Abbreviations

**CGM:** continuous glucose monitoring
**CPP:** clinical pharmacy practitioner
**DPP-4:** dipeptidyl peptidase-4
**EHR:** electronic health record
**GLP-1 RA:** glucagon-like peptide-1 receptor agonists
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**HDL:** High-density lipoprotein
**LC:** low carbohydrate
**LC-CGM:** low carbohydrate nutrition counseling guided by continuous glucose monitoring
**LDL:** low-density lipoprotein
**QI:** quality improvement
**RD:** registered dietitian
**SGLT2:** sodium glucose cotransporter-2
**T2D:** type 2 diabetes mellitus
**TDD:** total daily dosage
**VA:** Veteran Affairs
**VHA:** Veterans Health Administration
**VLC:** very low-carbohydrate
**VVC:** VA Video Connect platform


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# Correlation Between Technology and Improved Outcomes in Youth With Type 1 Diabetes Mellitus: Prospective Study Examining Outcomes for Patients With Depression and Those With Public Insurance

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## Abstract

**Background:** Adherence to type 1 diabetes mellitus (T1DM) treatment regimens decreases during adolescence. While comorbid depression and health insurance disparities are individually known to potentiate this risk, technological devices for T1DM appear to be protective.

**Objective:** We examined whether technology use impacted the association between depression and poorer health outcomes in T1DM. Given established insurance-based disparities based on technology access, we also studied whether the protective effects of T1DM technology differed among publicly and privately insured youth.

**Methods:** Data were prospectively collected from pediatric patients with T1DM across 3 California medical centers. We used linear and negative binomial regression analyses to examine whether technology use was related to diabetes outcomes and whether this differed based on depression status (technology-by-depression interaction) and health insurance type (technology-by-insurance interaction).

**Results:** Across 1573 patients aged 12 to 25 years (mean age 15.9, SD 2.9 years; n=1050, 66.4%, non-Hispanic White; n=745, 47.0% female), those with a depression diagnosis had higher hemoglobin $A_{1c}$ ($HbA_{1c}$; mean 9.1%, SD 2.1% vs 10.1%, SD 2.2%) and more frequent diabetic ketoacidosis (DKA) events per year (mean 0.10, SD 0.36 vs 0.24, SD 0.66) than those without ($P$=.003). Patients using both a continuous glucose monitor (CGM) and pump had lower $HbA_{1c}$ levels and fewer DKA events per year (mean $HbA_{1c}$ 8.2%, SE 0.1%; mean DKA events per year 0.05, SE 0.01) than those using one device (mean $HbA_{1c}$ 9.0%, SE 0.1%; mean DKA events 0.08, SE 0.1%) or none (mean $HbA_{1c}$ 10.0%, SE 0.1%; mean DKA events 0.19, SE 0.1%; $P$<.001). While youth with public insurance had significantly higher $HbA_{1c}$ levels than those with commercial insurance (mean 9.3%, SD 2.1% vs 9.0%, SD 2.0%, $P$<.001), those using a CGM had no reliable decrease in $HbA_{1c}$ compared to their commercially insured peers ($P$=.35).

**Conclusions:** Technology use in pediatric T1DM appears protective for both youth with a history of depression and those who are publicly insured. These data underscore the importance of universal access to technology to mitigate disparities based on comorbid mental health issues and differential access to care.

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**KEYWORDS**

adolescence; depression; health insurance; continuous glucose monitor; pump; adherence; type 1 diabetes mellitus; T1DM



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## Introduction

The incidence of pediatric type 1 diabetes mellitus (T1DM) is increasing wordwide 3% per year [1]. In the United States, the cost of diagnosed diabetes was estimated to be in the US $400 billion range in 2022 [2], much of this cost being related to complications of suboptimal adherence to treatment. Consistent glucose control is vital to avoiding long-term complications of T1DM, such as retinopathy, nephropathy, and cardiovascular disease [3,4]. Current guidelines suggest keeping hemoglobin $A_{1c}$ ($HbA_{1c}$), the traditional gold standard metric for T1DM control, to below 7% in both children [5] and adults [6]. Another important clinical outcome in diabetes care is the prevention of diabetic ketoacidosis (DKA), a life-threatening complication of diabetes that continues to be the most common cause of hospitalization and death in children with T1DM [7,8].

The advent of insulin pumps and continuous glucose monitors (CGMs) has significantly advanced T1DM management in recent years. Children who use CGMs [9] and pumps [10] are more likely to attain $HbA_{1c}$ levels below 7%, irrespective of socioeconomic status, insulin regimen, or duration of diabetes [9]. Despite these advancements, adherence to T1DM regimens (eg, consistent insulin administration, regular glucose monitoring, and appropriate compliance with dietary recommendations) continues to be suboptimal. The transition from childhood to adolescence has been established as a strong risk factor for poorer adherence and blood glucose control [11,12]. This developmental transition is characterized by shifting responsibilities from parents to patient, feelings of increased social pressure from peers, and fatigue from chronic illness management [13], factors that have been shown to further complicate this period and to be linked to comorbid depression. Depression is common in adolescence and has been linked to reduced adherence [14] and higher $HbA_{1c}$ levels [15] via its negative impact on motivation, cognitive functioning, and self-efficacy.

Health insurance type is known to influence access to T1DM care and supplies [16]. Despite growing evidence that generous insurance coverage of diabetes technology improves outcomes [17], there continue to be significant barriers for youth with public insurance related to strict prior authorization requirements, high copays, and lack of access to specialized health care for both pumps and CGMs [16].

The aim of this study was to investigate whether diabetes technology use moderated the negative effects of teenage depression across 3 large health care systems in California. We also examined whether technology use mitigated the previously demonstrated disparities in glycemic control associated with public insurance. We hypothesized that having a history of depression and being publicly insured would predict higher $HbA_{1c}$ levels and more frequent episodes of DKA, and that these effects would be reduced by the use of technology.

## Methods

### Participants

Data were prospectively collected from patients aged 12 to 25 years with T1DM who were seen for outpatient care at 1 of 3 University of California (UC)–affiliated health system pediatric endocrinology clinics between 2016 and 2021: UC Davis, UC Los Angeles, and UC San Diego.

### Ethical Considerations

The following work represents secondary analyses using existing clinical data with primary consent. All data were anonymized prior to analysis. The original consent for clinical care within the respective medical institutions covers secondary analyses without additional consent and therefore IRB approval was not required for this study.

### Data Collection

Health care providers were asked to complete flow sheets that were synchronized by the 3 pediatric endocrinology clinics to collect similar information at each clinical appointment. For patients with multiple time points, data associated with the most recent visit were used. The flow sheets contained demographic and medical data, such as age, sex, race/ethnicity, health insurance type (public [MediCal, California Children's Services] versus commercial [health maintenance organization, preferred provider organization]), diabetes technology use (pump, CGM, neither, or both), number of DKA events in the past year, most recent $HbA_{1c}$ level, and depression diagnosis. While some centers established a depression diagnosis based on a standard depression screener (eg, the Patient Health Questionnaire 9), other patients were asked to self-report an existing depression diagnosis.

### Statistical Analysis

Demographic differences between patients with and without a depression diagnosis were assessed using the Welch *t* test and a $\chi^2$ analysis. Multivariable associations of technology use and depression on $HbA_{1c}$ levels and number of DKA events were assessed using linear and negative binomial regression models, respectively. Models were adjusted for age, sex, and insurance status (public vs private). To test for differential impacts of technology use on patients with and without depression, interactions terms for technology-by-depression were introduced into these models. Analyses were conducted in R (version 4.1.3; R Project for Statistical Computing) and Stata (version 17; StataCorp).

## Results

### Overview

There were 15,284 flow sheets for the patients, aggregated to a person-year level. Of these, 35.50% (n=5426) were missing information on depression, 6635 (43.41%) were missing information on $HbA_{1c}$ level or DKA events, 112 (0.73%) were missing CGM or pump use information, and none were missing covariate information (age, sex, and insurance status). Our final analytic sample size was 2896 person-years from 1573 patients



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(average 1.8 years, SD 0.99 contributed per person). Of the contributed person-years, 2089 (72.1%) were from UC San Diego, 567 (19.6%) were from UC Davis, and 240 (8.3%) were from UC Los Angeles. The average age of all patients was 15.9 (SD 2.9) years, and patients were evenly split by sex and public versus private insurance (Table 1). There were no significant differences in health outcomes by age (mean difference 0.3, SD 3.0 years; *P*=.27) or sex (n=1426, 52.84% vs n=95, 48.22% for boys; *P*=.24). As has been previously reported, patients who identified as Hispanic and Black had higher $HbA_{1c}$ and more frequent DKA events (Table 1).

**Table .** Demographic characteristics of study participants stratified by depression status. Significant *P* values are shown in italics.

| Variables | | Not depressed (n=2699, 93%) | Depressed (n=197, 7%) | *P* value |
|---|---|---|---|---|
| **Sex, n (%)** | | | | .24 |
| | Female | 1269 (47.03) | 102 (51.78) | |
| | Male | 1426 (52.84) | 95 (48.22) | |
| Age (years), mean (SD) | | 16.0 (2.9) | 15.7 (3.0) | .27 |
| **Insurance type, n (%)** | | | | .51 |
| | Private | 1348 (49.96) | 94 (47.72) | |
| | Public | 1347 (49.92) | 103 (52.28) | |
| Hemoglobin $A_{1C}$ (%), mean (SD) | | 9.10 (2.05) | 10.11 (2.22) | *<.001* |
| Diabetic ketoacidosis events per year per patient, mean (SD) | | 0.104 (0.364) | 0.244 (0.658) | *.003* |
| **Race/ethnicity, n (%)** | | | | *.02* |
| | Asian | 90 (3.34) | 2 (1.02) | |
| | Black non-Hispanic | 144 (5.34) | 7 (3.55) | |
| | Hispanic | 806 (29.88) | 80 (40.61) | |
| | Other | 284 (10.52) | 22 (11.17) | |
| | White non-Hispanic | 1320 (48.91) | 82 (41.62) | |
| | Unknown | 51 (1.89) | 4 (2.03) | |
| | CGM[a] use (yes) | 1270 (47.07) | 75 (38.07) | *.01* |
| | Pump use (yes) | 1125 (41.70) | 73 (37.06) | .19 |
| **Technology use, n (%)** | | | | .06 |
| | No technology | 1033 (38.26) | 89 (45.18) | |
| | 1 technology (CGM or pump) | 929 (34.45) | 68 (34.52) | |
| | 2 technologies (CGM and pump) | 733 (27.16) | 40 (20.30) | |

[a]CGM: continuous glucose monitor.

## Technology Use

Use of either CGM (dichotomized as yes/no; mean $HbA_{1c}$ level 8.5%, SD 1.7% vs 9.8%, SD 2.2%) or pump (dichotomized as yes/no; mean $HbA_{1c}$ level 8.6%, SD 1.6% vs 9.6%, SD 2.3%) technology was associated with lower $HbA_{1c}$ levels (*P*<.001). When comparing use of 0, 1, or 2 forms of technology, use of *both* CGM and a pump was associated with more significant reductions in $HbA_{1c}$ than either technology alone (mean $HbA_{1c}$ level 8.2%, SD 1.4% vs. 9.1%, SD 2.1%; *P*<.001). A similar pattern was found for DKA events (mean DKA events 0.07, SD 0.25 vs 0.15, SD 0.48 for CGM technology; mean DKA events 0.05, SD 0.27 vs 0.15, SD 0.45 for pump technology, mean DKA events 0.05, SD 0.23 vs 0.08, SD 0.31 for one compared to both technologies; *P*<.001).

## Technology Use and Depression

Patients with depression had significantly higher $HbA_{1c}$ and more DKA events relative to nondepressed patients (Table 1). There was a main effect of technology use across diabetic outcomes for both patients with depression and those without, such that youth with depression who used a CGM, pump, or both had lower $HbA_{1c}$ and fewer DKA events than youth with depression who used no technology (*P*<.01 for all comparisons; Multimedia Appendix 1). The same pattern was found in patients without a history of depression (*P*<.001 for all comparisons; Multimedia Appendix 1).

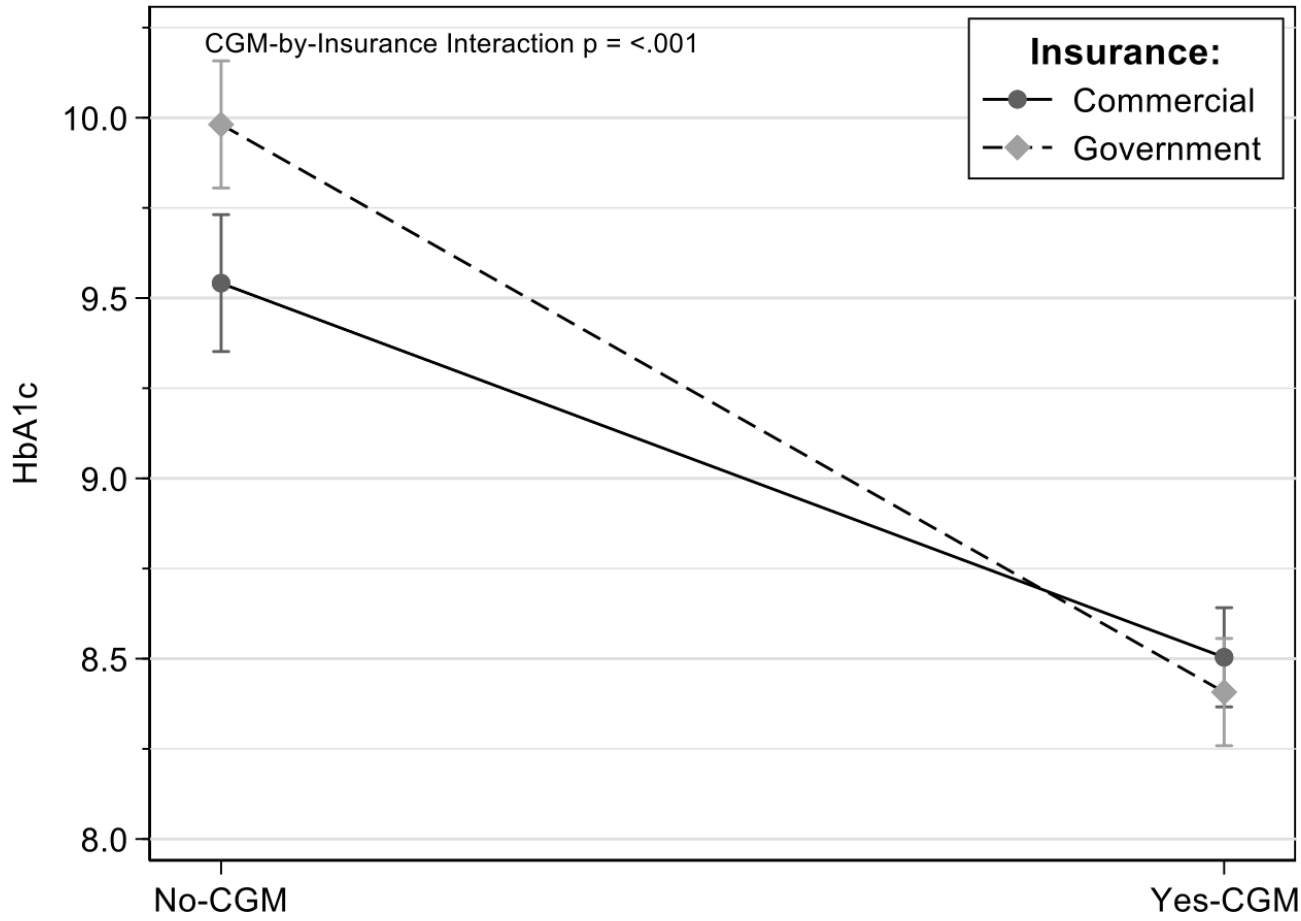


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### Technology Use and Insurance Type

There were significant differences in diabetic outcomes based on insurance type. Youth with public insurance had higher $HbA_{1c}$ levels than those with commercial health insurance (*P*<.001). Youth with public insurance who used a CGM had similar mean $HbA_{1c}$ levels as youth with commercial insurance who used a CGM, effectively reversing the disparity in health outcomes associated with public insurance (interaction: *P*<.001; Figure 1). Using a pump was also associated with significantly lower $HbA_{1c}$ levels for both commercially and publicly insured youth, though the pump-by-insurance type interaction was not significant (*P*=.30). The relationship between technology use and insurance type was not significant for DKA events (*P*<.05; Multimedia Appendix 2).

**Figure 1.** Hemoglobin $A_{1C}$ ($HbA_{1C}$) levels for youth with and without use of a continuous glucose monitor along insurance types.




## Discussion

We found that use of diabetes technology was associated with improved glycemic control, attenuating the negative impact of depression and mitigating outcome disparities related to public insurance. Diabetes technology use was predictive of better glycemic control through both lower $HbA_{1c}$ levels and fewer DKA events. While having a reported depression diagnosis was associated with higher $HbA_{1c}$ levels and more DKA events, technology use attenuated this risk in an additive manner. These findings support the strategy of offering diabetes technology to all youth, regardless of comorbid mental health issues. However, providing an insulin pump to youth with depression has historically been considered risky given the potential for self-harm via exogenous insulin administration. Given the benefits of technology use in youth with depression, clinicians who continue to be hesitant to prescribe a pump to due to fears of "suicide by insulin" should consider using tailored screening of suicide risk rather than a broader depression or mood measure. The Columbia-Suicide Severity Rating Scale [18] appears to identify twice the number of T1DM patients at risk for self-harm than its more general depression counterpart, the Patient Health Questionnaire 9 [19], which was used in this study [20]. Our results also underline the importance of screening for depression in pediatric settings in order to minimize its impact on the health of individuals with T1DM. In fact, research shows that both pharmacological and psychotherapeutic treatments for depression are associated with improvements in glycemic control [21].

Although not examined in this study, it is also worthwhile to consider whether comorbid depression impacts regularity and consistency of technology use. In general, youth who perceive more barriers to technology use are less likely to use it [22]. In youth with T1DM, commonly reported barriers to consistent technology use include cost and insurance issues and wear-related concerns [22]. While depression does not appear to predict discontinuation of CGM use [23], more research is needed to confirm this finding. Data on technology use collected for this study reflect a dichotomous variable and therefore cannot be used to inform the larger literature on health outcomes as it



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relates to technology consistency and discontinuation. What is known in regards to CGM is that users consistently report more engagement in diabetes self-care and a better quality of life, likely because they feel more efficacious in day-to-day disease management [24]. Given that helplessness is central to the development and maintenance of depression [25], encouraging CGM use may present one way to help youth feel more in control of their health.

With regard to insurance type, our study demonstrates that outcome disparities between publicly and commercially insured youth are mitigated by both CGM and pump use. Prior studies of publicly insured pediatric patients with T1DM indicate that interruptions in the use of CGM were largely due to insurance gaps and were predictive of poorer outcomes [26]. Countries that have facilitated technology access have seen improved clinical outcomes in youth with T1DM. For instance, after Australia changed its national health policy to universally subsidize CGM use in youth with T1DM, both $HbA_{1c}$ levels and DKA hospitalizations significantly decreased in youth [27]. There have also been documented differences in countries with and without universal health care. A large-scale examination of T1DM outcomes in American versus German youth found that disparities between socioeconomic status and $HbA_{1c}$ were evident in both groups but that technology access was a significant covariate only in the American sample [28].

At the time of data collection in California (2016-2021), public insurance companies mandated that patients document 4 fingerstick blood glucose tests every day for at least 1 month to qualify for a CGM [16]. Even 1 instance of a missed test could disqualify families. Many other state Medicaid programs have had the same requirement [16]. Fortunately, as of 2021, pharmacy benefits for publicly insured patients in California have expanded, making it easier to obtain diabetes technology for publicly insured patients [29]. Our data support expanding pharmacy benefits to other states that have not yet made them publicly available.

Besides improved clinical outcomes, prior research has shown that facilitating universal access to CGM and pump use is associated with significant cost savings. While the cost of a CGM is estimated to be US $15.20/day (extrapolated to approximately US $5000/year) [30], 1 admission for DKA in the United States costs upward of $30,000 [31]. In fact, the cost-effectiveness ratio of CGMs in pediatric T1DM is well established, demonstrating not only short-term improvements but significant reductions in costs related to long-term complications [32], emergency room visits, and hospitalizations [33].

There are several limitations in our current study. First and foremost, as this was a retrospective, nonrandomized cohort, causality cannot be inferred from our results. Patients who use diabetes technology were self-selected to some degree, and thus may have had differences in motivation, self-efficacy, and other important variables that could contribute to improved outcomes. Patients and families more motivated to attain optimal diabetes control may be more likely to pursue technology, suggesting that social support is also likely at play. Therefore, future studies evaluating social determinants of health may be helpful to clarify the impact of social support on the benefits of diabetes technology. As laid out in the introduction, publicly insured youth with CGM may have had to document daily adherence to blood glucose monitoring in order to qualify for the device. As such, we cannot exclude the possibility that $HbA_{1c}$ levels for this group are attributable to better overall adherence rather than solely contingent on subsequent CGM use.

Depression was collected as a binary variable, and so degree of depression and status of treatment were not known. Patients with milder or better-controlled depression might be more likely to agree to diabetes technology than those with more severe symptomatology (due to increased feelings of hopelessnes and helplessness). Furthermore, the depression diagnosis data were not collected uniformly, which could have impacted the validity of results. It is also possible that some patients in the sample may have had undiagnosed depression, while others may have said they had depression without having a formal diagnosis. Future research should seek to replicate these results using a uniform method of depression screening. Thankfully, the utility of universal depression screening in pediatric patients with T1DM is gaining momentum [34]. It is also worth considering preliminary data on the use of medical record mining algorithms that can effectively predict patients at higher risk of depression in pediatric settings, where adolescents may be likely to underreport difficulties due to stigma, socially desirable responding, and the desire to be autonomous in their health management [35]. The integration of mental health care providers in clinical settings can also be a value-added service that removes the burden of mental health screening from endocrinologists [36].

To conclude, this is the first study to examine the interplay between socioeconomic, psychological, and medical factors in elucidating differential outcomes for adolescents with T1DM. It also represents a large sample of youth across 3 major health systems from one of the most populous states, allowing for the examination of these complex variables at the state level. Future studies should aim to replicate the above model with a national sample to determine how insurance status interacts with sociocultural variables such as parent education, income, race/ethnicity, and health literacy, especially given established disparities in technology acceptance based on cultural factors [37]. Our study also supports universal depression screening of adolescents in pediatric settings to ensure that mental health issues are treated promptly and are less likely to impact medical trajectories. Finally, given the concerning trend that socioeconomic status–based disparities appear to be increasing in American youth with T1DM [28], we cannot overstress the importance of facilitating universal coverage of diabetes technology. Such efforts are vital in our fight to provide equitable care that will facilitate improved clinical outcomes across demographic groups.



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## Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Adjusted effects of technology use on hemoglobin $A_{1c}$ levels and diabetic ketoacidosis events for youth with and without depression.
[DOCX File, 18 KB - diabetes_v10i1e70380_app1.docx ]

Multimedia Appendix 2
Adjusted effects of insurance type on hemoglobin $A_{1c}$ levels and diabetic ketoacidosis events by technology use.
[DOCX File, 35 KB - diabetes_v10i1e70380_app2.docx ]

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## Abbreviations

**CGM:** continuous glucose monitor
**DKA:** diabetic ketoacidosis
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**T1DM:** type 1 diabetes mellitus
**UC:** University of California

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# Diabetes Medical Group Visits and Type 2 Diabetes Outcomes: Mediation Analysis of Diabetes Distress

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## Abstract

**Background:** Group-based diabetes care, both technology-enabled and in-person, can improve diabetes outcomes in low-income minority women, but the mechanism remains unclear.

**Objective:** We tested whether diabetes group medical visits (GMVs) reduced hemoglobin $A_{1c}$ ($HbA_{1c}$) by mitigating diabetes distress (DD), an emotional response affecting nearly half of adults with type 2 diabetes in community settings.

**Methods:** We conducted a mediation and moderation analysis of data from the Women in Control 2.0 comparative effectiveness study, which showed that both technology-enabled and in-person diabetes GMVs improve $HbA_{1c}$. We tested whether DD mediated the relationship between diabetes GMV engagement and reductions in $HbA_{1c}$. We also tested whether this relationship was moderated by depressive symptoms and social support. Participants were 309 low-income and minority women. Diabetes GMV engagement was measured using the Group Climate Questionnaire. The mediator, DD, was measured using the Diabetes Distress Screening Scale. The outcome was the 6-month change in $HbA_{1c}$. Social support was measured using the Medical Outcomes Study Social Support Survey.

**Results:** DD mediated the relationship between engagement and 6-month $HbA_{1c}$. Specifically, group engagement affected $HbA_{1c}$ by reducing distress associated with the regimen of diabetes self-management ($P$=.04), and possibly the emotional burden of diabetes ($P$=.09). The relationship between engagement and 6-month $HbA_{1c}$ was moderated by depressive symptoms ($P$=.02), and possibly social support ($P$=.08).

**Conclusions:** Engagement in diabetes GMVs improved $HbA_{1c}$ because it helped reduce diabetes-related distress, especially related to the regimen of diabetes management and possibly related to its emotional burden, and especially for women without depressive symptoms and possibly for women who lacked social support.

**Trial Registration:** ClinicalTrials.gov NCT02726425; https://clinicaltrials.gov/study/NCT02726425

***(JMIR Diabetes 2025;10:e57526)*** doi:10.2196/57526

**KEYWORDS**

diabetes; diabetic; diabetes mellitus; DM; type 1 diabetes; type 2 diabetes; diabetes mellitus type 2; diabetes outcomes; diabetes medical group visit; DMGVs; psychosocial functioning; psychosocial; glycemic control; glycemic; shared medical appointments; self-management; mediation analysis; social support; minority women; minority

## Introduction

Over 37 million people in the United States live with type 2 diabetes mellitus (T2DM), accounting for 7.8 million hospitalizations and over US $327 billion in health care costs annually, with persistent disparities in diabetes outcomes among low-income and minority adults being attributable to underlying health inequities [1-7]. Unmet social needs, such as housing, job, and food insecurity and structural barriers to health care, among them inadequate access, affordability, and quality make it difficult for underserved communities to access the medical care and support needed to effectively manage diabetes, increasing the burden of living with chronic disease for this segment of the population [8].

The overwhelming stress of diabetes self-management can produce an emotional response characterized as diabetes distress (DD). A distinct psychological consequence of living with T2DM, DD is more common than comorbid depression and



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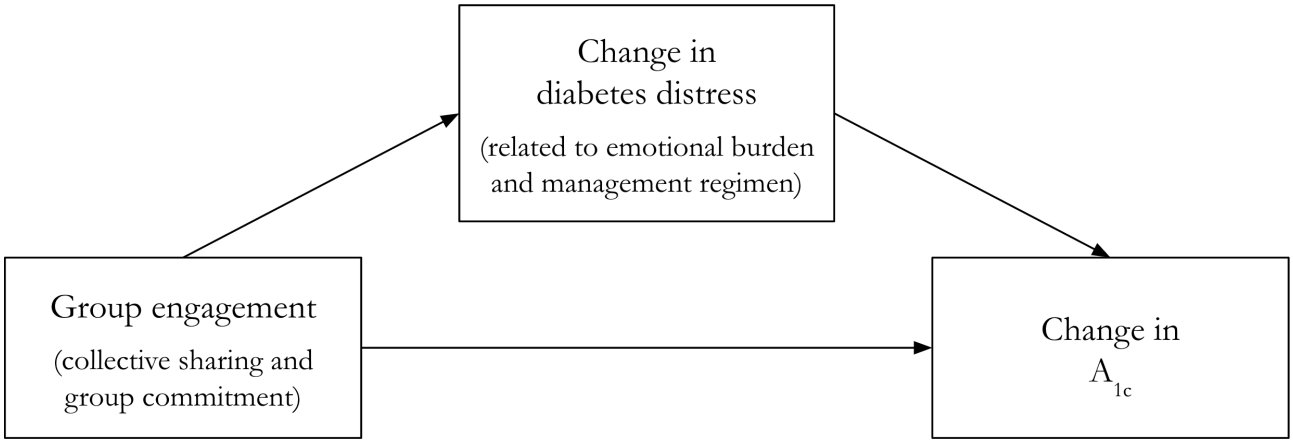
anxiety, with prevalence estimates ranging from 36% to 45% [9-11]. It has been linked to poor glycemic control, self-management, and self-efficacy among adult patients [12-15]. DD is a treatable barrier to effective diabetes self-management that is gaining increasing attention in primary and specialty care. A 2017 position paper from the American Diabetes Association recommended routine screening and integration of psychosocial care, considering emotional status and presence of a social support network, to improve the treatment course of those living with T2DM [9,16].

Identifying scalable approaches that address both the physical and mental health needs of those living with diabetes is a high priority. Emerging research has shown that group-based diabetes care can lead to positive health outcomes. Group-based education is often promoted as an effective approach to managing type 2 diabetes, with the potential to enhance self-management skills and improve health outcomes [17]. An alternative to individual clinical encounters, diabetes group medical visits (GMVs) convene groups of patients to receive peer support, diabetes self-management education, and a clinical consult within the context of a 2-hour shared appointment [18,19]. There is substantial published evidence demonstrating the clinical effectiveness of standard, in-person diabetes GMVs (or shared medical appointments) compared to usual care for adults living with diabetes. Four systematic reviews conclude that diabetes GMVs are clinically supported for improving glycemic control [18-21]. This GMV model of care has been associated with improved self-management mastery, quality of life, and mental health [18,19]. It can also reduce health disparities by fostering more equitable patient-provider relationships, creating relationships of care between patients, and improving health literacy [22]. However, implementing group-based care is not without challenges given heterogeneity of implementation across busy clinical practices, particularly those serving low-income and diverse communities and limited reporting [17,21,23].

Health technologies may bridge gaps in access to effective models of diabetes care, such as diabetes GMVs, but research on the effectiveness and scalability of existing applications is limited. In the Women in Control 2.0 (WIC2) study, our team tested the effectiveness of virtual, technology-enabled diabetes GMVs versus in-person GMVs for low-income, English- and Spanish-speaking minority women with uncontrolled diabetes [24]. Our findings showed that GMVs, whether in-person or technology-enabled, improved not only 6-month hemoglobin $A_{1c}$ ($HbA_{1c}$), but also 6-month DD. For this reason, we hypothesized that DD may mediate the effect of GMVs on glucose control. We further hypothesized that group-based care reduced DD by cultivating a sense of belonging, an opportunity to feel connected, heard, and understood by other participants with lived experience managing diabetes. The intervention, methods, and main results from the WIC2 study are reported elsewhere [24-26].

To test this conceptual model, we conducted a mediation analysis substudy of clinical trial data from the WIC2 study to determine whether participants' self-reported engagement with other group members affected glucose control by reducing DD or its subcomponents (Figure 1). We also aimed to test whether baseline characteristics moderated the relationship between engagement and $HbA_{1c}$.

**Figure 1.** Conceptual model. $A_{1c}$: hemoglobin $A_{1c}$.




## Methods

### Study Design

The WIC2 noninferiority, randomized controlled trial compared over-time changes in $HbA_{1c}$ among 309 women randomly assigned to attend either in-person or technology-enabled GMVs, both led by a prescribing clinician and a trained facilitator for 8 weeks and delivered in English or Spanish, depending on participants' language preferences at baseline. All participants then entered a 16-week maintenance period during which no GMVs took place, but participants were instructed to self-monitor nutrition and physical activity. Of 309 randomized participants, 207 (67%) met per-protocol criteria by attending 6 of 8 sessions. Noninferior improvements were detected in mean $HbA_{1c}$ from baseline to 6 months in both groups: $HbA_{1c}$ declined by −0.7% (SD 1.8%) among participants attending in-person GMV and by −0.5% (SD 1.6%) among participants attending virtual world GMV ($P$<.001) [23,24].

This WIC2 secondary analysis tested whether the improvements in $HbA_{1c}$ observed in the WIC2 study were associated with group engagement, whether this occurred through lowering DD, and whether that relationship was conditional on the following



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moderators measured at baseline: language, health literacy, depressive symptoms, anxiety, patient activation, $HbA_{1c}$, and social support. These analyses included all participants, irrespective of meeting per-protocol criteria by attending at least 6 sessions.

### Mediation

The explanatory variable, group engagement, was measured using the group engagement subscale of the Group Climate Questionnaire (GCQ-S)—a validated survey completed at baseline, 9 weeks, and 6 months assessing group cohesion [27]. Group cohesion has been conceptualized as 2 domains: affective, which is associated with the individual's attraction to the group or its members and ability to collectively share positive, as well as negative, emotional experiences; and behavioral, a domain associated with the individual's sense of commitment to the group [28,29]. The engagement subscale of group cohesion captures both these collective sharing and group commitment domains.

Each question from the GCQ-S was scored from 0 ("not at all") to 6 ("extremely"). A total score was determined by calculating the mean response to questions from the 5 items of the group engagement subscale, shown in Table S1 in Multimedia Appendix 1.

The potential mediators, self-reported DD and its subcomponents, were collected using the Diabetes Distress Screening Scale (DDS-17) at baseline, 9 weeks, and 6 months [10,30]. The subscales for the DDS-17 assess the emotional burden of diabetes, regimen of diabetes management, perceived quality of diabetes care from a physician, and interpersonal support from family and friends. We hypothesized that group engagement influenced $HbA_{1c}$ primarily by reducing distress associated with the emotional burden and regimen of diabetes management, because these were most directly targeted by the peer support and self-management components of the WIC2 curriculum in GMVs. We did not expect that GMVs would directly impact DD related to care from a physician and interpersonal support from family and friends.

Each question on the DDS-17 was scored from 1 ("not a problem") to 6 ("a very serious problem") and is listed in Table S1 in Multimedia Appendix 1. The total DD and subscale scores were calculated by taking the mean of all scale and subscale scores.

### Moderation

We also tested whether baseline social support, Spanish as a primary language, health literacy, depressive symptoms, anxiety, patient activation, or $HbA_{1c}$ moderated the relationship between group engagement and the 6-month change in $HbA_{1c}$.

Because the GMVs were group-based, we expected that they would be particularly helpful for participants who did not already enjoy supportive social networks. To measure social support, we used the Medical Outcomes Study Social Support Survey, a 19-item instrument developed for a 2-year study of patients with chronic conditions. The instrument has 4 subscales capturing emotional or informational, tangible, affectionate, and positive social interaction-related social support [31] (see Table S1 in Multimedia Appendix 1).

We also expected health literacy and patient activation to magnify the effect of group engagement by helping participants take fuller advantage of the WIC2 curriculum. High baseline anxiety or depressive symptoms may dampen the effect of group engagement by compounding the emotional or regimen-related burden of DD. Low baseline $HbA_{1c}$ may produce ceiling effects. Finally, we checked for differences across the culturally equivalent Spanish- and English-language WIC2 curricula.

### Statistical Analyses

To identify potential confounders, participants with low group engagement (≤median score) versus high engagement (>median score) were compared on baseline characteristics of the sample with means and SDs or percentages.

To summarize the main outcome variables and potential mediators, we took baseline and 6-month means and SDs as well as mean changes over time with SDs. We performed paired *t* tests on baseline versus 6-month values.

We tested whether the relationship between group engagement and $HbA_{1c}$ was mediated by DD or its subscores in two ways. First, we performed a series of ordinary least squares (OLS) regressions. We regressed the primary outcome (6 mo change in $HbA_{1c}$) on the explanatory variable (group engagement), the outcome (6 mo change in $HbA_{1c}$) on the potential mediators (DD and each of its subscales), and the potential mediators (DD and each of its subscales) on the explanatory variable (group engagement). For each, we ran both a bivariate regression and a multivariate regression that included cohort fixed effects and controlled for study arm.

Second, we performed mediation by simulation, using the *mediation* package for R (R Foundation) [32,33]. Using this method, we estimated the average causal mediation effect. As this is a secondary analysis that was not originally powered with causal mediation in mind, we expect this method to underestimate any true mediated effect.

Finally, we used OLS regression to determine whether Spanish as a primary language, health literacy, depressive symptoms, anxiety, patient activation, baseline $HbA_{1c}$, or social support and its subscores moderated the relationship between group engagement and 6-month change in $HbA_{1c}$. We regressed the 6-month change in $HbA_{1c}$ on group engagement interacted with each potential moderator. As with mediation by simulation, due to sample size, we expect this to be a conservative estimate of moderated effects.

### Ethical Considerations

Informed consent and approval by the Boston University or Boston Medical Center Institutional Review Board (H-34220) are documented in the WIC2 study [24]. All eligible and interested participants were consented and enrolled abiding by the principles of the Belmont Report and the Declaration of Helsinki. The informed consent process included a teach-back approach by which participants' understanding of this study's procedures, risk or benefits, and voluntary nature was confirmed.



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Enrolled participants self-reported their answers to research surveys about their health and lived experience with diabetes. All research data were stored in password-protected, HIPAA (Health Insurance Portability and Accountability Act)-compliant systems and linked with a study-generated identifier to protect confidentiality.

## Results

### Description of the Sample

A full description of the WIC2 study population was previously published [24]. In brief, participants' mean age was 56 (SD 10.4) years and mean $HbA_{1c}$ was 9.93% (SD 1.74%). All participants were female (n=309), 63.1% (195/309) self-identified as Black or African American, while 23.6% (73/309) were Spanish-speaking. A majority of participants (70.9%, 219/309) reported Medicaid, Medicare, or both as their insurance provider. Fifteen percent (47/309) of participants reported an anxiety disorder, and 25.2% (78/309) of participants reported a depressive disorder, including depression, major depression, dysthymia, or minor depression. Mean total DD was 2.27 (maximum score of 6; SD 1.04). See Table 1 for the mean DD subscales. No apparent differences were detected between low-engagement and high-engagement participants on observed characteristics. Remaining characteristics are summarized in Table 1.



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**Table .** Baseline sample characteristics for all participants and participants with above versus below median group engagement.

| Characteristics | | Total (N=309) | Engage[a] ≤ median (3.8; n=123) | Engage >median (3.8; n=114) |
|---|---|---|---|---|
| Spanish-speaking, n (%) | | 73 (24) | 30 (24) | 29 (25) |
| Low health literacy, n (%) | | 87 (28) | 36 (29) | 33 (29) |
| Anxiety disorder, n (%) | | 47 (15) | 16 (13) | 19 (17) |
| Depressive disorder[b], n (%) | | 78 (25) | 29 (24) | 32 (28) |
| PAM-13[c], mean (SD) | | 66.12 (20.56) | 66.1 (19.47) | 69.31 (19.05) |
| **Social support[d], mean (SD)** | | | | |
| | Overall | 3.78 (1.06) | 3.68 (1.09) | 3.9 (1.02) |
| | Affectionate | 4.05 (1.11) | 3.93 (1.16) | 4.17 (1.06) |
| | Emotional or informational | 3.82 (1.11) | 3.71 (1.16) | 3.96 (1.06) |
| | Positive social interaction | 3.80 (1.2) | 3.75 (1.2) | 3.91 (1.18) |
| | Tangible | 3.51 (1.26) | 3.43 (1.23) | 3.58 (1.3) |
| **Diabetes distress[e], mean (SD)** | | | | |
| | Total DD[f] | 2.27 (1.04) | 2.22 (1.08) | 2.36 (1.03) |
| | Regimen DD | 2.64 (1.33) | 2.56 (1.36) | 2.82 (1.34) |
| | Emotional burden DD | 2.69 (1.44) | 2.61 (1.47) | 2.81 (1.5) |
| | Physician DD | 1.53 (0.99) | 1.45 (0.94) | 1.56 (1.02) |
| | Interpersonal DD | 1.97 (1.28) | 2.05 (1.45) | 1.89 (1.12) |
| $HbA_{1c}$[g], mean (SD) | | 9.93 (1.74) | 9.74 (1.65) | 10.05 (1.86) |
| Age, mean (SD) | | 55.62 (10.4) | 56.17 (10.1) | 53.94 (10.55) |
| **Race, n (%)** | | | | |
| | Black or African American | 195 (63) | 81 (66) | 76 (67) |
| | White | 26 (8) | 12 (10) | 11 (10) |
| | Other race | 78 (25) | 30 (24) | 27 (24) |
| **Hispanic, n (%)** | | | | |
| | Yes | 105 (35) | 41 (33) | 40 (35) |
| | No | 195 (65) | 82 (66) | 74 (65) |
| **Insurance, n (%)** | | | | |
| | Commercial | 69 (22) | 28 (23) | 29 (25) |
| | Medicare or Medicaid | 219 (71) | 88 (72) | 82 (72) |
| **Education, n (%)** | | | | |
| | High school graduate or less | 152 (49) | 63 (51) | 54 (47) |
| | Any college, vocational, or trade school | 132 (43) | 53 (43) | 53 (46) |
| | Any postgraduate | 14 (5) | 6 (5) | 7 (6) |
| **Employment status, n (%)** | | | | |
| | Full-time | 75 (24) | 28 (23) | 35 (31) |
| | Part-time | 44 (14) | 19 (15) | 16 (14) |
| | Not employed | 156 (50) | 68 (55) | 51 (45) |
| **Household income, n (%)** | | | | |
| | ≤US $29,999 | 140 (45) | 51 (41) | 56 (49) |



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| Characteristics | | Total (N=309) | Engage[a] ≤ median (3.8; n=123) | Engage >median (3.8; n=114) |
|---|---|---|---|---|
| | ≥US $30,000 | 59 (19) | 25 (20) | 23 (21) |
| | Refused, do not know, or none | 101 (33) | 47 (38) | 35 (31) |

[a]Assessed using the engagement subscale of the Group Climate Questionnaire (GCQ-S).

[b]Including depression, major depression, dysthymia, or minor depression.

[c]PAM-13: Patient Activation Measure.

[d]Assessed using the Medical Outcomes Study Social Support Survey.

[e]Assessed using the Diabetes Distress Screening Scale (DDS-17).

[f]DD: diabetes distress.

[g]$HbA_{1c}$: hemoglobin $A_{1c}$.

## Results of Main Relationships

The outcome, $HbA_{1c}$, decreased from 9.9% (SD 1.7) at baseline to 9.3% at 6 months (SD 2) on average ($P$<.001, via paired 2-tailed $t$ test). The potential mediators—total DD score and each DD subscore—also decreased from baseline to 6 months ($P$<.001 for all DD scores except the physician subscore [$P$=.095, via paired $t$ test]). The magnitude of this decrease was greatest for the regimen (−0.6, SD 1.2) and emotional burden subscores (−0.6, SD 1.2; Table 2).

**Table .** Summary of main outcome variables and potential mediators (all participants).

| | Baseline, mean (SD) | 6 Months, mean (SD) | Change, mean (SD) | $P$ value[a] |
|---|---|---|---|---|
| Group engagement[b] | N/A[c] | 3.6 (1.3) | N/A | N/A |
| Diabetes distress[d] | 2.3 (1) | 1.9 (1) | −0.4 (0.9) | <.001 |
| DD[e] regimen | 2.6 (1.3) | 2.1 (1.2) | −0.6 (1.2) | <.001 |
| DD emotional burden | 2.7 (1.4) | 2.2 (1.3) | −0.6 (1.2) | <.001 |
| DD physician | 1.5 (1) | 1.4 (0.9) | −0.1 (1) | .095 |
| DD interpersonal | 2 (1.3) | 1.7 (1.2) | −0.3 (1.2) | <.001 |
| Hemoglobin $A_{1c}$ | 9.9 (1.7) | 9.3 (2) | −0.6 (1.7) | <.001 |

[a]$P$ value from a paired 2-tailed $t$ test.

[b]Assessed using the engagement subscale of the Group Climate Questionnaire (GCQ-S).

[c]N/A: not applicable.

[d]Assessed using the Diabetes Distress Screening Scale (DDS-17).

[e]DD: diabetes distress.

Table 3 summarizes the individual associations between the outcome, mediators, and independent variable, and Figure 2 maps those associations to our conceptual model.



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**Table .** Main relationships between outcome, explanatory variables, and mediators.

| | Bivariate[a] | | Fixed effects[b] | |
|---|---|---|---|---|
| | Coefficient (SE) | *P* value | Coefficient (SE) | *P* value |
| $HbA_{1c}$[c] on engagement[d] | −0.21 (0.08) | .01[d] | −0.25 (0.08) | .004[d] |
| Distress (total)[e] on engagement | −0.1 (0.04) | .03[d] | −0.1 (0.05) | .03[d] |
| Distress (regimen) on engagement | −0.14 (0.06) | .02[d] | −0.16 (0.06) | .01[d] |
| Distress (emotional burden) on engagement | −0.12 (0.06) | .04[d] | −0.12 (0.06) | .04[d] |
| Distress (physician) on engagement | −0.1 (0.05) | .04[d] | −0.08 (0.05) | .011[d] |
| Distress (interpersonal) on engagement | 0 (0.06) | .94 | 0.01 (0.06) | .90 |
| $HbA_{1c}$ on distress (total) | 0.24 (0.12) | .048[d] | 0.24 (0.12) | .04 |
| $HbA_{1c}$ on distress (regimen) | 0.27 (0.09) | .002 | 0.26 (0.09) | .004 |
| $HbA_{1c}$ on distress (emotional burden) | 0.22 (0.09) | .02[d] | 0.2 (0.09) | .03[d] |
| $HbA_{1c}$ on distress (physician) | 0 (0.11) | .996 | 0.04 (0.11) | .74 |
| $HbA_{1c}$ on distress (interpersonal) | −0.02 (0.09) | .84 | 0 (0.09) | .98 |

[a]Ordinary least square regression, described in left-hand column.

[b]Ordinary least square regression, controlling for study arm and with cohort fixed effects, described in left-hand column.

[c]$HbA_{1c}$: hemoglobin $A_{1c}$.

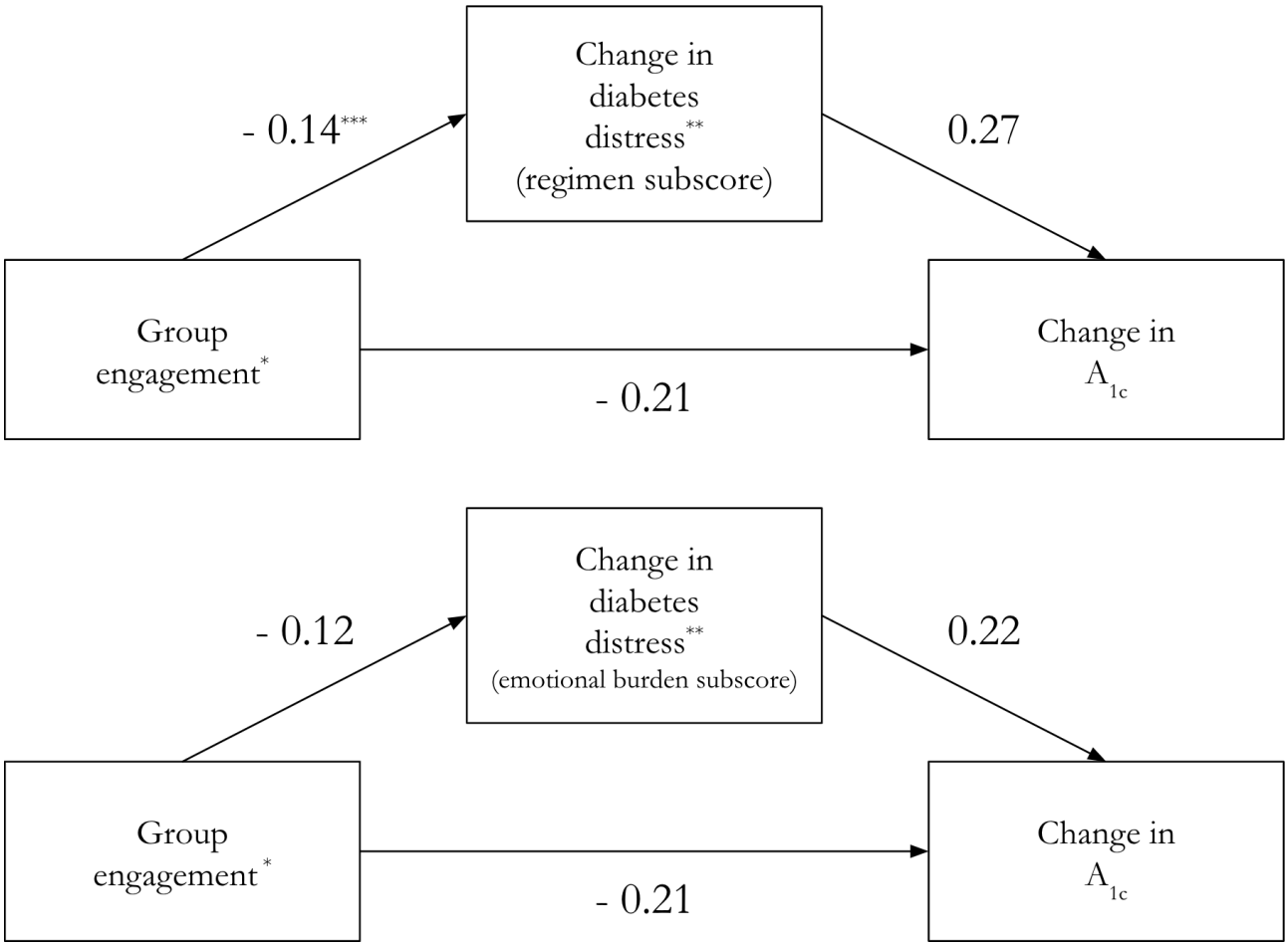
[d]Assessed using the engagement subscale of the Group Climate Questionnaire (GCQ-S).

[e]Assessed using the Diabetes Distress Screening Scale (DDS-17).



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**Figure 2.** Coefficients on mediator relationships of interest from OLS regressions * Assessed using the engagement subscale of the Group Climate Questionnaire (GCQ-S). ** Assessed using regimen and emotional burden subscales of the Diabetes Distress Screening Scale (DDS-17). *** Coefficients and *P* value thresholds derived from Table 3 OLS regressions. DDS-17: Diabetes Distress Screening Scale; GCQ-S: Group Climate Questionnaire; OLS: ordinary least square.




We detected a negative relationship between group engagement score and 6-month change in $HbA_{1c}$. A one-point increase in group engagement score was associated with, on average, a 0.21 greater decrease in $HbA_{1c}$ from baseline to 6 months. This was true both without (*P*=.01) and with (*P*=.004) cohort fixed effects and controlling for study arm.

In Table 3, we also detected a negative relationship between group engagement and all DD mediators, except for the interpersonal subscore. A one-point increase in group engagement score was associated with, on average, a 0.1 greater decrease in total DD score from baseline to 6 months (*P*=.03), a 0.14 greater decrease in regimen subscore (*P*=.02), a 0.12 greater decrease in emotional burden subscore (*P*=.04), and a 0.1 greater decrease in physician subscore (*P*=.04). The results were similar with and without cohort fixed effects and controlling for study arm.

Finally, we detected a positive relationship between 3 mediators and 6-month change in $HbA_{1c}$: total DD, and the regimen and emotional burden subscores. A one-point decrease in the regimen subscore was associated with, on average, a 0.27% greater decrease in $HbA_{1c}$ from baseline to 6 months, again both without (*P*=.002) and with (*P*=.004) cohort fixed effects and controlling for study arm. A one-point decrease in the emotional burden subscore was associated with, on average, a 0.22% greater decrease in the change in $HbA_{1c}$ from baseline to 6 months, both without (*P*= .02) and with (*P*=.03) cohort fixed effects and controlling for study arm.

## Results of Mediator Analysis

Table 4 lists the total effect of engagement on the 6-month change in $HbA_{1c}$, the average causal mediation effect (the proportion of the total effect that runs through the mediator), and the average direct effect (the remaining proportion of the total effect that does not run through the mediator), calculated by simulation, for each of five possible mediators: DD and each of its 4 subscores.



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**Table .** Mediator analysis[a].

| Mediator | Total effect | *P* value | ADE[b] | *P* value | ACME[c] | *P* value |
|---|---|---|---|---|---|---|
| Diabetes distress (total)[d] | −0.2 | .02[a] | −0.18 | .026[a] | −0.02 | .20 |
| Distress (regimen) | −0.2 | .02[a] | −0.16 | .048[a] | −0.04 | .04[a] |
| Distress (emotional burden) | −0.2 | .02[a] | −0.18 | .042[a] | −0.02 | .09 |
| Distress (physician) | −0.2 | .01[a] | −0.2 | .014[a] | 0 | .798 |
| Distress (interpersonal) | −0.2 | .02[a] | −0.2 | .02[a] | 0 | .92 |

[a]Mediation by simulation performed using *mediate* package in R.

[b]ADE: average direct effect.

[c]ACME: average causally mediated effect.

[d]Assessed using the Diabetes Distress Screening Scale (DDS-17).

An average causally mediated effect of group engagement on 6-month change in $HbA_{1c}$ was detected that runs through the regimen (*P*=.04) of DD. An average causally mediated effect of group engagement on 6-month change in $HbA_{1c}$ may also run through the emotional burden of DD (*P*=.094).

There was no evidence that total DD mediated the relationship between group engagement and 6-month change in $HbA_{1c}$ (*P*=.20). There was also no evidence that the physician (*P*=.798) or interpersonal (*P*=.92) DD subscores mediated this relationship.

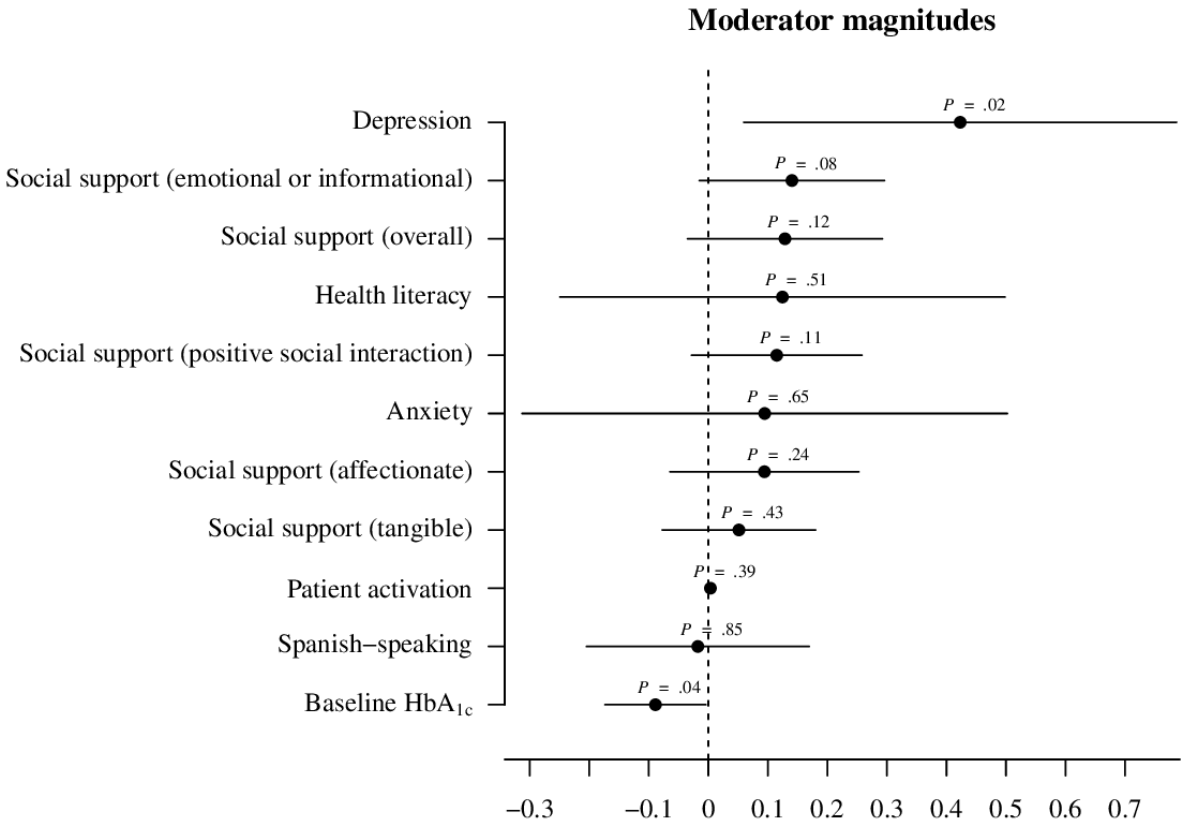
### Results of Moderator Analyses

Figure 3 plots coefficients with 95% CIs from the interaction terms of each OLS model regressing 6-month change in $HbA_{1c}$ on engagement interacted with the potential moderators. Baseline depressive symptoms, emotional or informationally based social support, and baseline $HbA_{1c}$ were found to moderate the relationship between group engagement and 6-month change in $HbA_{1c}$. Participants that did not report depression, major depression, dysthymia, or minor depressive symptoms at baseline saw their $HbA_{1c}$ decline by an additional 0.42% for each one-point increase in group engagement score (*P*=.02). For each lower point of self-reported emotional or informationally based social support, participants saw their $HbA_{1c}$ decline by an additional 0.14% for each one-point increase in group engagement score (*P*=.08), though a larger sample size is needed to confirm this result. For each additional percentage point of baseline $HbA_{1c}$, participants saw their 6-month $HbA_{1c}$ decline by an additional 0.09% with each one-point increase in group engagement score (*P*=.04).



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**Figure 3.** Moderator effects are plotted as coefficients on OLS model interaction terms with 95% CIs. *P* values are for each OLS model interaction term. Social support and subscores were assessed using the Medical Outcomes Study Social Support Survey. Health literacy was assessed with the yes or no question "Do you usually ask someone to help you read materials you receive from the hospital?" Patient activation was assessed using PAM-13. Depression includes depression, major depression, dysthymia, or minor depression. OLS: ordinary least square; PAM-13: Patient Activation Measure.




## Discussion

### Summary of Findings

While GMVs are associated with improved glucose control, the underlying mechanism of how group-based care is linked to improved outcomes has been unclear. This analysis of mediators provides evidence that engaging in GMVs (either in-person or technology-enabled) works to lower $HbA_{1c}$, in part, by reducing the components of DD associated with the management regimen of diabetes, and possibly also the emotional burden of diabetes management.

Specifically, we found that while the regimen and possibly the emotional burden components of DD mediated the effect of GMVs, the physician or interpersonal (with family or friends) components of DD did not. The mediated effect for total DD, measured as a summary score from the DDS-17, was not significant (*P*=.20), and was likely diluted by the components of total DD making up the physician and interpersonal subscores.

These findings are consistent with our hypothesis that GMVs target a participant's ability to self-manage diabetes and, possibly, cultivate a sense of belonging and shared understanding by relating to others within the group. In particular, GMVs may improve regimen-related DD by alleviating the stigma of failing in self-management behaviors, fostering peer-supported adherence to treatment, and improving health literacy. GMVs likely target emotional burden-related DD by building psychological safety, providing social acceptance, and mitigating feelings of powerlessness. This is also consistent with findings from the DDS-17 developers that the regimen and emotional burden distress subscales contribute most significantly to the total DD [34].

These findings also suggest that GMVs may be less relevant for how participants relate to their broader social networks outside the group, such as friends, family, and physicians. Support from peers specifically within the GMVs may be key to the relationship between GMV engagement, improved DD, and improved glycemic control, as previous studies have also found that peer-to-peer social, emotional and informational support, both with and without technology supplement, can improve glycemic control and reduce DD among minority groups [35-38].

Our moderation analysis showed that engagement in group visits was most strongly associated with decline in $HbA_{1c}$ for participants with higher baseline $HbA_{1c}$, without depressive symptoms at baseline, and, possibly, who reported little emotional or informationally based social support.

Participants that reported low emotional and informational social support may have especially benefited from GMVs that offered an empathetic social setting that they may have otherwise



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lacked, though a larger sample size is required to confirm this result.

In contrast, participants with comorbid depressive symptoms may have struggled with practicing the self-management behaviors prescribed in the GMVs. Existing research has also found that depressive symptoms can inhibit self-management mastery and undermine treatment focused on diabetes empowerment [39,40]. Individuals who feel they have little control over their T2DM and are unable to reach treatment goals report less motivation to manage their condition [41]. In light of studies showing that DD, but not depressive symptoms by themselves, have a concurrent and longitudinal association with $HbA_{1c}$ levels, these findings suggest that comorbid depressive symptoms may negatively influence $HbA_{1c}$ primarily by rendering diabetes self-management education and support less effective [12].

### Limitations

First, these analyses tested mediators of group engagement, rather than a direct measure of the intervention. Testing for a mediator of the study arm was not possible because these data were generated by a noninferiority trial that, by design, randomized participants to 2 interventions that both improved $HbA_{1c}$. As technology-enabled GMVs were noninferior to their in-person counterparts, the study arm by itself does not generate meaningful variation on the explanatory variable. Furthermore, testing for an effect of intervention adherence sacrifices sample size, as few participants had substantially low attendance. Engagement offered the variation on the explanatory variable while still representing a meaningful measure of participation in GMVs. In the absence of validated standalone measures of engagement for group interventions, we used the engagement subcomponent of the GCQ-S. Nevertheless, we did replicate our mediation analysis using the study arm, and these results are summarized in Table S2 in Multimedia Appendix 1.

Second, this was a secondary analysis of data from the existing, published WIC2 study, which was not originally powered to detect mediation or moderation. This biases us toward type II error (false negatives), or against detecting a mediated or moderated effect even where one may exist. In practice, our sample size can support the simple OLS regressions we use in our first mediation analysis (Table 3 and Figure 2), but may be too small for more complex analysis such as mediation by simulation (Table 4) and interaction effects (Figure 3). For this reason, in addition to reporting findings where $P<.05$, we also report findings for $P$ values lower than 0.1 and interpret them as suggestive of relationships that we might detect given a larger sample. In particular, our analyses may underestimate the role of the emotional burden of DD as a mediator; while our mediation analysis using regression did detect a mediation effect for the emotional burden of DD in models both with and without controls and cohort fixed effects, our mediation analysis using simulation can only suggest this at $P=.09$.

Third, while this study detected an average causally mediated effect of regimen-related and emotional burden-related DD, it also estimated an average direct effect that runs through other mediators. Specifically, regimen-related and emotional burden-related DD were found to mediate 30% of the total effect of engagement on $HbA_{1c}$, leaving 70% of the effect, which runs through other mediators, to be explained in further research.

Finally, because group engagement was not randomly assigned, though no observed confounding was detected, this study cannot rule out unobserved confounding on the relationship between engagement and DD or on the relationship between DD and $HbA_{1c}$.

### Conclusions

Our findings showed that engagement in group-based diabetes care improved $HbA_{1c}$ by way of reducing diabetes-related distress, especially the components related to the regimen and possibly the emotional burden of living with T2DM. Strategies that encourage collective sharing and group commitment should be actively integrated in GMVs to positively influence diabetes outcomes such as DD and glucose control. Additionally, it is important to identify patients with comorbid depressive symptoms and, possibly, those lacking social support separate from the GMVs, as our findings confirmed previous research suggesting that untreated depressive symptoms may interfere with the positive effects of medical group-based care [39,40]. Future research should explore how care models can be more effective in specifically treating patients with depressive symptoms and other comorbid conditions.

## Acknowledgments

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## Conflicts of Interest

SM holds equity in See Yourself Health LLC, a digital health service provider.

Multimedia Appendix 1
Group cohesion, diabetes distress, and social support instruments; relationships with this study's treatment; full group cohesion measure; and moderator predicted values.
[DOCX File, 163 KB - diabetes_v10i1e57526_app1.docx ]

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## Abbreviations

**DD:** diabetes distress
**DDS-17:** Diabetes Distress Screening Scale
**GCQ-S:** Group Climate Questionnaire
**GMV:** group medical visit
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**HIPAA:** Health Insurance Portability and Accountability Act
**OLS:** ordinary least square
**T2DM:** type 2 diabetes mellitus
**WIC2:** Women in Control 2.0



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Original Paper

# Exploring Psychosocial Burdens of Diabetes in Pregnancy and the Feasibility of Technology-Based Support: Qualitative Study

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## Abstract

**Background:** Gestational diabetes mellitus and type 2 diabetes mellitus impose psychosocial burdens on pregnant individuals. As there is less evidence about the experience and management of psychosocial burdens of diabetes mellitus during pregnancy, we sought to identify these psychosocial burdens and understand how a novel smartphone app may alleviate them. The app was designed to provide supportive, educational, motivational, and logistical support content, delivered through interactive messages.

**Objective:** The study aimed to analyze the qualitative data generated in a feasibility randomized controlled trial of a novel mobile app designed to promote self-management skills, motivate healthy behaviors, and inform low-income pregnant individuals with diabetes.

**Methods:** Individuals receiving routine clinical care at a single, large academic medical center in Chicago, Illinois were randomized to use of the SweetMama app (n=30) or usual care (n=10) from diagnosis of diabetes until 6 weeks post partum. All individuals completed exit interviews at delivery about their experience of having diabetes during pregnancy. Interviews were guided by a semistructured interview guide and were conducted by a single interviewer extensively trained in empathic, culturally sensitive qualitative interviewing of pregnant and postpartum people. SweetMama users were also queried about their perspectives on the app. Interview data were audio-recorded and professionally transcribed. Data were analyzed by 2 researchers independently using grounded theory constant comparative techniques.

**Results:** Of the 40 participants, the majority had gestational diabetes mellitus (n=25, 63%), publicly funded prenatal care (n=33, 83%), and identified as non-Hispanic Black (n=25, 63%) or Hispanic (n=14, 35%). Participants identified multiple psychosocial burdens, including challenges taking action, negative affectivity regarding diagnosis, diet guilt, difficulties managing other responsibilities, and reluctance to use insulin. External factors, such as taking care of children or navigating the COVID-19 pandemic, affected participant self-perception and motivation to adhere to clinical recommendations. SweetMama participants largely agreed that the use of the app helped mitigate these burdens by enhancing self-efficacy, capitalizing on external motivation, validating efforts, maintaining medical nutrition therapy, extending clinical care, and building a sense of community. Participants expressed that SweetMama supported the goals they established with their clinical team and helped them harness motivating factors for self-care.

**Conclusions:** Psychosocial burdens of diabetes during pregnancy present challenges with diabetes self-management. Mobile health support may be an effective tool to provide motivation, behavioral cues, and access to educational and social network resources to alleviate psychosocial burdens during pregnancy. Future incorporation of machine learning and language processing



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models in the app may provide further personalization of recommendations and education for individuals with DM during pregnancy.

**Trial Registration:** ClinicalTrials.gov NCT03240874; https://clinicaltrials.gov/study/NCT03240874

***(JMIR Diabetes 2025;10:e53854)*** doi:10.2196/53854

**KEYWORDS**

digital health; mHealth; pregnancy; psychosocial; social determinants; technology; diabetes; burdens; qualitative analysis; mobile apps; feasibility

## Introduction

Gestational diabetes mellitus (GDM), defined by the World Health Organization as a condition of hyperglycemia in pregnancy with blood glucose measurements exceeding normal values but below values diagnostic of diabetes, and type 2 diabetes mellitus (T2DM) during pregnancy impose greater burdens and correlate with greater health risks including increased rates of maternal and neonatal morbidity than diabetes mellitus (DM) outside of pregnancy [1]. Antenatal DM management mitigates these risks [2]. Current DM intervention methods in the United States focus primarily on medical therapies, such as medication regimens, blood glucose maintenance, and medical nutrition therapy (MNT) [2]. Although evidence is clear that improved glycemic control during pregnancy results in improved perinatal outcomes, ample data suggest that social and structural determinants of health can preclude full achievement of DM goals in this critical life period [3-5].

However, there is less evidence about the experience and management of potential psychosocial burdens of DM during pregnancy. Psychosocial factors related to DM diagnoses encompass the environmental, social, behavioral, and emotional elements that can affect long-term care. These factors, which include diabetes-related distress (ie, treatment burden and fear of uncertain future health outcomes), economic distress, and mental well-being challenges can impact adequate provision of self-care and adherence to medical treatment plans [6]. For example, pregnant individuals with DM display more depressive symptoms, with prenatal stress and depression serving as a predictor for postpartum stress and depression [7,8]. In addition, the intersectionality of psychosocial stress with other social determinants of health, such as poverty and limited education, may compound the challenges of being pregnant with DM. For instance, Muhwava et al [9] identified greater levels of anxiety and stress in low-income pregnant women with GDM in South Africa and Yee et al [3] qualitatively characterized how the interplay of socioeconomic, psychological, and epistemic factors serves as a barrier to DM self-management during pregnancy. Psychosocial consequences of navigating GDM or diabetes in pregnancy have been characterized in the literature. A systematic review on women's experiences with a diagnosis of GDM found several qualitative studies revealing that individuals felt isolation, abandonment, and guilt after an initial GDM diagnosis, along with frustration with GDM management and financial burden of following treatment regimens [10-12]. Similar themes of diabetes-related distress, fear, and exhaustion were observed in recent studies examining the experiences of individuals with pre-existing diabetes in pregnancy [13,14]. Identifying potential psychosocial burdens, as a part of a multilevel understanding of social determinants of DM-related health during pregnancy, is thus crucial in the management of pregnant people with DM, as it may influence not only their perinatal outcomes, but long-term health outcomes as well.

Given this need for a comprehensive resource for individuals with DM in pregnancy, our team developed a novel mobile app for education and mitigating DM. Digital health technology, such as health-related smartphone apps, has proliferated in recent years in clinical, research, and public consumer spheres to help individuals with DM adjust to lifestyle interventions and maintain health care engagement [15]. SweetMama, a smartphone app leveraging the potential of digital health technology to improve health outcomes, was created to support DM management among low-income pregnant people [16]. In this secondary analysis of data from SweetMama participants, we aimed to identify the psychosocial burdens of having DM during pregnancy and sought to understand how a smartphone app may help alleviate such burdens.

## Methods

### Overview

This qualitative study evaluated data collected during a feasibility randomized controlled trial conducted among low-income, English-speaking pregnant people aged 18 years or older, who had a diagnosis of GDM or T2DM. Individuals with type 1 DM were not eligible for inclusion, given their greater use of continuous glucose monitors and insulin pumps. In this feasibility trial, individuals were randomized to use the SweetMama app (n=30) or usual care (n=10) from the diagnosis of DM during pregnancy through 6 weeks post partum. Unbalanced randomization was intentional since this is a feasibility study, and it was desirable to have greater exposure of the participants to SweetMama use. Results from the primary trial are currently under analysis. Participants received routine clinical care at a single, large academic medical center in Chicago, Illinois.

The SweetMama app was designed to provide supportive, educational, motivational, and logistical support content, delivered through interactive messages via the app, tailored to participants' treatment, reminders for appointments, and featured a library of trusted contents, that were received 3 times a week. This educational content included recipes, documents from clinicians, trusted educational websites, clinic information, SweetMama instructional videos, and videos on how to take insulin and safely dispose of needles. Participants also set goals



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for their DM management with their clinical team and would receive customized reminders weekly in the SweetMama app to monitor their progress in achieving their goals. SweetMama was not designed as a glucose-logging app, but rather served to provide diverse, low health literacy, user-friendly education and tips, alongside a repository of recipes, local resources, and trustworthy educational material. Further details about SweetMama have been previously described [17,18].

All participants completed in-depth, qualitative exit interviews after delivery about their experience of having DM during pregnancy. SweetMama users were also queried about their perspectives on the app. Interviews were guided by a semistructured interview guide and were conducted by a single interviewer [JJ; refer Acknowledgments section] with extensive training in empathic, culturally sensitive qualitative interviewing of pregnant and postpartum people. The interviewer identified as a Black woman researcher. The interview guide was designed by the investigator team based on extensive previous experience providing clinical care for and interviewing pregnant people on these topics, including during earlier usability phases of investigation before the development of this version of SweetMama [16-19]. The interview guide also adapted concepts from the Technology Acceptance Model, and it was cognitively tested on nonparticipants before its deployment in the study [20]. Interviews were approximately 40 to 60 minutes in length and were conducted in-person in a private location. These interviews were audio-recorded and professionally transcribed verbatim.

Interview data were analyzed using a grounded theory constant comparative technique [21,22]. This method of thematic analysis consists of line-by-line readings of interview transcripts which are coded for concept patterns, termed as subthemes, and then collapsed as overarching themes through review and discussion by research coders. Two researchers [LL and ES] conducted this thematic analysis of interview content to identify emergent themes related to the psychosocial burdens of living with DM during pregnancy and the potential role of the app in mitigating those burdens, if any.

### Ethical Considerations

Written consent was provided by all participants, and this study was approved by the Northwestern University institutional review board (IRB study number: STU00205409). The original consent form allowed for secondary analysis of participant data without additional consent. Study data were deidentified for researchers conducting the qualitative thematic analysis of the interview transcripts. Participants received compensation in the form of gift cards (US $100) for their participation in the trial.

## Results

### Overview

From January 14, 2020, to October 10, 2020, a total of 40 participants enrolled in the parent randomized controlled trial, of whom 30 participants were randomized to use SweetMama. Of the 30 SweetMama users, 18 had GDM and 12 had T2DM. Majority of those participants identified as non-Hispanic Black or African American (n=17, 57%) or Hispanic (n=12, 40%). Most SweetMama users (n=21, 70%) had completed at least some college or technical school education. All 40 participants met study criteria for low-income status, and a majority (n=33, 83%) had publicly funded prenatal care (Table 1).



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**Table 1.** SweetMama participant demographics.

| Variable of interest and groups | Usual care (n=10) | SweetMama (n=30) |
|---|---|---|
| Age (years), mean (SD) | 31.3 (6.9) | 31.4 (4.7) |
| **Race and ethnicity, n (%)** | | |
| Non-Hispanic Black or African American | 8 (80) | 17 (56.7) |
| Hispanic | 2 (20) | 12 (40) |
| Non-Hispanic White | 0 (0) | 1 (3.3) |
| Medicaid or Medicare, n (%) | 8 (80) | 25 (83.3) |
| **Education, n (%)** | | |
| Some high school or less | 0 (0) | 3 (10) |
| High school graduate | 5 (50) | 6 (20) |
| Some college or technical school | 3 (30) | 9 (30) |
| College or technical school graduate | 2 (20) | 12 (40) |
| **Relationship status, n (%)** | | |
| Married | 3 (30) | 14 (46.7) |
| Single | 5 (50) | 7 (23.3) |
| Other | 2 (20) | 9 (30) |
| Nulliparous, n (%) | 2 (20) | 6 (20) |
| **Current work status, n (%)** | | |
| Work full-time | 5 (50) | 11 (36.7) |
| Work part-time | 1 (10) | 8 (26.7) |
| Unemployed | 2 (20) | 4 (13.3) |
| Other | 2 (20) | 7 (23.3) |
| BMI at first prenatal visit ($kg/m^2$), mean (SD) | 36.7 (9) | 42.9 (12.4) |
| **Diabetes diagnosis, n (%)** | | |
| GDM[a] | 7 (70) | 18 (60) |
| T2DM[b] | 3 (30) | 12 (40) |

[a]GDM: gestational diabetes mellitus.

[b]T2DM: type 2 diabetes mellitus.

Thematic analysis of participant interview data focused on the psychosocial burdens of DM during pregnancy identified 5 major themes, namely challenges of taking action, negative affectivity regarding diagnosis, diet guilt, difficulties managing other roles and responsibilities, and reluctance to use insulin (Table 2). In addition, our analysis yielded findings on how the SweetMama smartphone app helped mitigate these burdens in each of these domains. The themes regarding mobile health (mHealth) support mechanisms included: enhancing self-efficacy, capitalizing on external motivation, validating user efforts, maintaining medical nutrition therapy, extending clinical care, and building a sense of community (Table 3). Each theme, with exemplary quotations, is discussed below.



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**Table 2.** Psychosocial burdens of diabetes diagnosis during pregnancy.

| Theme | Exemplary quotation |
|---|---|
| Challenges of taking action | • "Well, like I knew what I needed to do… The challenge is actually doing it and going about it. So not so much of the knowledge part. More of the action part to me." |
| Negative affectivity regarding diagnosis | • "I was not even like, because like I said at first I was in no way, shape or form okay with being gestational diabetes, ya know?" |
| Diet guilt | • "You know, sometimes it's hard...you have to be really strong willed. Because if you're, not that I ate bad or I had an unhealthy diet, but...whenever I feel like I'm told you can't do something that's when you...most want it. So that's like the most difficult part...I found. It's just hard staying away from food." |
| Difficulty managing other roles and responsibilities | • "I'm pregnant, I'm a full-time student...it was a little bit overwhelming to be able to maybe put a little bit more energy...due to COVID and just not being able to really go out to the stores...the way I typically would, that kinda discouraged me because it's like I wasn't really able to handle stuff the way I usually would outside. It's like as soon as I start using the app and stuff, what was going on with the virus and then you know stores were closed. It was just a lot going on at the time." |
| Reluctance to use insulin | • "I said I didn't want to be on insulin. I didn't want to take the medication at first, so that's how it was." |

**Table 3.** Role of a smartphone app in mitigating psychosocial burdens during pregnancy.

| Theme | Exemplary quotation |
|---|---|
| Enhancing self-efficacy | • "Probably the goals part again because when you're at like a certain level, like for example if you have diabetes and now you can do something about it, so if you see where you're at and where you need to reach that would motivate action." |
| Capitalizing on external motivation | • "Having more of a…even though you're doing this but this is what's helping you and this is what's helping your baby, a little bit more education on that track, it would make a new mother feel a little bit more secure in what they're doing." |
| Validating user efforts | • "Interviewer: So what you're saying is you know what to do but it's good to have that reminder. Why do you feel that way?"<br>• "Interviewee: Because it feels like you're doing right, I don't know. It's good to have some confirmation because I didn't have this before and sometimes I would think like or whether or not like I can eat something or I can go for a walk now or like after." |
| Maintaining medical nutrition therapy | • "I really want to adapt a better diet for myself. I know that, you know I can do it, because I've done it in the past, so I feel like that app will help me incorporate different things...eating the same thing can be boring, so the recipe portion of it was wonderful. Just seeing different things you can create out of stuff you already have in the house, as opposed to having to go buy expensive diet food all the time." |
| Extending clinical care | • "[Seeing videos of my providers in the app] showed that they cared. And to give patients more feedback on their health...It was like you took them home with you." |
| Building sense of community | • "I feel like it would be like a community of people to kinda come together as far as especially for people like me that never had diabetes before, to be a little bit more like educational help…with that process." |

## Psychosocial Burden Characterization

The first burden theme was the challenges of taking action. When asked about their experience with goal setting, participants reported struggling to act on the expectations to maintain their DM. Participants specified that they did not have difficulty understanding their goals, but rather they struggled with their motivation to be proactive and achieve their goals.

Second, negativity affectivity regarding diagnosis, in which participants experienced forms of denial of their diagnosis, emerged as a psychosocial burden, particularly for individuals with gestational, rather than pregestational, DM. Participants noted that they did not fully come to terms with their DM diagnosis:

> *I was really hesitant toward the beginning…like you know we just can't control our bodies and it's just a hormonal change.*

Others described having a highly negative affect toward the diagnosis, which hindered their ability to fully engage in DM-focused self-care, such as taking medication and following MNT.



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Next, many individuals reported experiencing diet guilt. Participants commonly reported that they struggled with transitioning their diets and described feeling guilty when they were nonadherent to recommendations. Participants noted they often wanted to "give up" by consuming food outside of their prescribed MNT plan:

> *I really got the taste for ice cream because I'm pregnant, my hormones are telling me ice cream.*

They specified that recommended foods "may not have been what [they] exactly wanted to eat." When participants "gave in" to their cravings for nonrecommended foods, participants experienced guilt, decreasing their motivation to continue with MNT. This cyclic effect of frustration and defeat was reported by several to be a challenge regardless of when their DM was diagnosed.

Fourth, participants described the difficulty of managing other roles and responsibilities. Participants felt overwhelmed by external circumstances, such as taking care of their children or the COVID-19 pandemic, which overlapped with this trial. Oftentimes, because of these circumstances, participants did not have time to or were unable to care for themselves. These responsibilities hindered participants' abilities to receive care and optimally manage their DM. Furthermore, participants demonstrated insight into the ways in which these competing priorities limited their ability to fully engage in care and expressed guilt for not being able to fully participate in recommended health care.

The final psychosocial burden theme was reluctance to take insulin. Participants reported hesitancy taking prescribed insulin due to uncertainty about how it will affect their health and their fetus:

> *To be honest I didn't want to [take insulin]...I don't know why I felt like when I had my daughter it was the reason she was colicky.*

This reluctance was often based on fear and uncertainty. Although participants did not typically disagree with medical recommendations, they did acknowledge concerns over what was unknown to them.

### mHealth Strategies to Reduce Psychosocial Burdens

SweetMama users offered feedback on the potential role of mHealth in alleviating the psychosocial burdens of DM in pregnancy (Table 3). Themes in this domain focused on how their use of the SweetMama app reduced the stresses of having DM, provided motivation, or validated behaviors.

The first facilitating theme was regarding enhancing self-efficacy. Participants reported that SweetMama empowered them to take action to manage their DM. SweetMama helped participants form beliefs that they were in control and had a choice in their DM treatment. Features such as recipes and access to resources helped maintain participants' sense of agency:

> *…if you need more information, you can click on that and they'll tell you more about what the subject was.*

Participants noted that as actions appeared easier to complete with the support of the tool, and that as tasks became easier, they were more motivated to complete them:

> *the simpler the recipes and the simpler the exercises…the easier things like you could apply it into your life, then the more likely the person will be willing to do it.*

Next, capitalizing on external motivation emerged as a benefit of SweetMama. Participants noted that SweetMama helped them harness their motivating factors, such as the health of their baby, to maintain their DM. For some participants, particularly when not intrinsically motivated for their own health, the attentiveness to the long-term goal of neonatal health was more motivating than the concept of promoting maternal health. When feeling a lack of motivation for self-care, participants were reminded that the health of their body reflected the health of their baby.

The theme validating user efforts was commonly endorsed. Participants felt SweetMama reassured them in their actions in managing DM, encouraging them to continue their efforts. This self-regulatory theme demonstrated the importance of feedback, even when it was not personalized; SweetMama, for example, did not provide customized feedback, but the generic supportive messaging and reassurance was seen as sufficiently beneficial. In addition, specific input from SweetMama, such as the reminders and messages tailored to treatment regimen and gestational age, provided validation to participants to quell uncertainties in their approach to DM management.

The fourth theme supporting the use of SweetMama was regarding maintaining medical nutrition therapy. Users identified that SweetMama aided in the maintenance of MNT by providing educational information, recipe ideas, and visual support. For some participants, the information provided by SweetMama on how to adopt a DM-focused diet during pregnancy helped them see the MNT goals as achievable rather than overwhelming and rigid. Participants favored the recipes on SweetMama to navigate their new diets. Participants especially noted that the variety of recipes allotted them creative freedom with food choices, fostering greater enthusiasm.

Fifth, SweetMama was lauded for its role in extending clinical care. Participants expressed that SweetMama added onto and supported the goals participants established with their clinical team. Unlike stand-alone apps that are unrelated to the health care team, SweetMama engaged the patient and her care team together in the process of goal setting. Even though SweetMama intentionally did not contain a direct patient-provider communication portal, the representation of the clinical team in the content helped participants feel connected to their clinical team, as participants were able to access support even when not physically with their medical providers.

Finally, participants noted that SweetMama served a therapeutic role by building a sense of community. SweetMama was effective in helping participants feel part of a community and did not have to navigate DM alone. Specific features in the educational curriculum, such as messages and reminders, dispelled feelings of isolation and worries.



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## Discussion

### Principal Findings

It has become widely understood that pregnancy serves as a window to improving long-term health [23]. Addressing challenges of DM during pregnancy may not only improve pregnancy outcomes but may also support long-term health benefits and health care engagement. We observed that psychosocial burdens present many challenges for DM self-management during pregnancy, particularly for low-income individuals who may experience greater challenges accessing resources. Here, we identified the use of a patient-centered mHealth tool like SweetMama is perceived by participants to effectively provide motivation, behavioral cues, and access to educational and social resources to alleviate these multilevel burdens of having DM during pregnancy. These broader benefits of SweetMama were previously explored in earlier developmental work as well [17].

A diagnosis of DM in pregnancy has been characterized in literature to spur a multitude of emotions, such as failure, despair, uncertainty, and fear [9,24]. This emotional complexity and depth were validated by our study with participant themes relating to guilt, challenges to action, and difficulty with managing responsibilities. These identified burdens are supported in a recent study conducted with Medicaid-enrolled pregnant individuals with T2DM, in which Fareed et al [25] identified themes among patient semistructured interviews, such as difficulty in "managing exhaustion" and "adherence to a new regimen," where fatigue and hardships in adopting lifestyle changes may exacerbate chronic conditions, like diabetes. Future work is required to understand if these emotional responses to diagnosis and management DM in pregnancy are associated with adverse perinatal outcomes and whether existing mental health issues undergird an increased risk to DM in pregnancy, potentially due to intersecting social, structural, and environmental influences [26]. Regardless, it is important to support individuals and prevent negative experiences during pregnancy, even in the absence of such causal relationships. Thus, understanding tools to alleviate these psychosocial burdens are critical to providing "whole person" care.

Regarding alleviation of psychosocial burdens in this study, participants reported the SweetMama intervention enhanced self-efficacy, capitalized on external motivation, provided positive reinforcement to maintain behaviors, extended clinical care, and built a sense of community. Giving specific attention to self-efficacy as an important quality of maintaining one's health with independence, we acknowledge that there are limited studies on DM management self-efficacy [27]. Self-efficacy is an important determinant in the success of and adherence to DM management. Increased self-efficacy may impact adherence to healthy behaviors, and it has been suggested that web-based curricula can also successfully increase DM management self-efficacy [27,28]. For instance, participants in a web-based education reported greater understanding of the elements of healthy eating and implementation of exercise [28]. However, this curriculum solely focused on managing aspects such as healthy lifestyle and diet. For this reason, we desired to examine and create a holistic, comprehensive curriculum that includes diet recommendations as well as appointment reminders, motivational messages, and other educational elements that inform DM self-management. Participants in this study stated a perceived enhancement of feeling empowered through the educational components of SweetMama, which in conjunction with the goal-oriented and appointment reminders, can facilitate adherence and engagement. Furthermore, previous literature examining GDM and mental health in minoritized populations has demonstrated increased risk of adverse mental health outcomes among individuals with GDM due to individual and structural burdens [29]. SweetMama, in contrast to other lifestyle interventions for people with GDM [30], has unique advantages as a comprehensive and accessible resource by touching upon components of GDM education, clinical engagement, and community building in 1 central hub. Furthermore, a qualitative meta-synthesis, which includes the initial SweetMama usability testing data, suggests that mHealth interventions are useful as a personalized and supportive tool for behavior change [31]. SweetMama's use of provider videos in its content library and user-friendly curricular messaging allowed for a more personal experience with the detailed educational content in contrast to similar apps that were also supportive in GDM and DM management in pregnancy but had added issues with technical usability which led to frustration [32].

### Strengths and Limitations

Strengths of this study include its in-depth, patient-centered focus on the patient experience, as well as its purposeful inclusion of an understudied population [17]. In addition, given that this study was performed among a multicultural sample, having an interviewer with training in culturally sensitive qualitative interviewing was an advantage to ensure conversations between the interviewer and participants were empathic and nonjudgemental. Limitations of the study include that the study's participants were from a single urban medical center with the majority identifying as non-Hispanic Black, limiting generalizability to other geographic regions or other types of health care settings. Second, since only English-speaking patients were included in the study, compounding burdens related to language and health literacy accessibility with a DM diagnosis may have been missed in the thematic analysis. A third limitation of the study is that the data presented are a secondary analysis of the primary SweetMama feasibility trial. Therefore, interview questions regarding psychosocial burdens of having diabetes in pregnancy were not directly probed, but were elicited by participants in their general feedback about their pregnancy experience and perceptions from using SweetMama. Fourth, as for any qualitative study, there is potential for bias during the process of constructing common thematic codes for unique and distinct responses from individual participants. Nonetheless, having 2 independent thematic coders as this study did helps to minimize individual research biases. Future work for SweetMama development includes greater linguistic and cultural adaptation for accessibility to a wider audience. Data from the primary feasibility trial of SweetMama are forthcoming, which will help elucidate whether a mHealth technology intervention such as SweetMama can improve perinatal outcomes among individuals



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with DM. Should the primary trial evidence support the clinical use of SweetMama, future work may include understanding how to integrate its use into health systems or individual clinics to promote the psychosocial well-being of pregnant people with diabetes.

### Comparison to Previous Work

Various mHealth technologies for individuals with diabetes in pregnancy have been assessed in the literature. These apps, such as MobiGuide for gestational diabetes by Peleg et al [33], Pregnant+ by Borgen et al [34], and Pears by Kennelly et al [35], focus predominantly on biometric data collection, with only a portion of the app dedicated to personalized goal setting and education [36]. Our findings from this secondary analysis, similar to previous studies investigating behavior change and self-management of DM in pregnancy, support that mHealth technologies provide an avenue for individuals to engage in personalized educational content aligned with clinical recommendations [37]. Studies described how pregnant individuals wished to obtain personalized recipes and exercise customization through mHealth apps [37,38], which are features that were already integrated in SweetMama and well received by participants. In addition, a similar app called "MySweetGestation," developed by Tumminia et al [39], was designed for women who have diabetes or are at risk of developing diabetes during pregnancy and also used interactive, app-based engagement strategies with the user to provide personalized information and monitoring, though it also did not incorporate a repository of recipe suggestions nor evaluated potential effects of using the app on psychosocial burdens of experiencing DM during pregnancy. As seen in our study, participant satisfaction with the use of mobile apps to support clinical care was very positive [40]. Previous published systematic reviews showed that internet-based self-monitoring interventions and technologies had some moderately positive effects on maternal outcomes, such as levels of glycated hemoglobin $A_{1c}$ and cesarean delivery rates, though discussion of psychosocial supports were seldom discussed [41-43].

Recent developments in digital health therapeutics include incorporating artificial intelligence, such as machine learning and natural language processing models. mHealth interventions, like wearable glucose monitoring devices, automated text messaging, and web-based health coaching have great opportunity to be integrated with these new advancements, which would allow for personalized health care support, though more work is required to understand the incorporation of machine learning into health care [44,45]. However, there are already existing applications for DM monitoring and management, in addition to broader digital health coaching applications such as the ProHealth eCoach prototype app by Chatterjee et al [46], that incorporate artificial intelligence, suggesting its potential for improving individual quality of life [47-50].

### Future Directions

Prioritization of user-centered design (UCD) that incorporates patient and provider perspectives in the development of DM-related mHealth technologies, especially among minoritized populations where mHealth may provide an avenue to bridge racial and ethnic health gaps, is of principal importance for health equity and cultural sensitivity [51-53]. UCD in mHealth interventions will allow DM support technologies to best promote timely health care engagement, intervention, and behavioral change in manners most acceptable to users. Qualitative data collection with mHealth stakeholders, such as pregnant people with DM and their health care providers, along with quantitative usability assessments, would allow for iterative feedback to improve mHealth implementation [5,16,17,54]. Incorporating an option to have a "social network" feature to add friends or family as a GDM mobile app used in a Nepalese hospital did, if desired, could potentially enhance individual sense of support through navigating DM in pregnancy [55]. Should an app like SweetMama enter the consumer space, UCD should play a predominant role in enabling effective and consistent user engagement. Moving forward, the SweetMama development team aims to incorporate missing perspectives from non–English-speaking patients and operationalize UCD principles to expand app accessibility, improve the user experience, and incorporate greater consideration of language diversity and the cultural preferences of users [56]. Our early-phase study of SweetMama contributes to the broader literature that demonstrates the promise of mHealth interventions for patients with DM during pregnancy, with potential for providing them with a greater sense of self-efficacy, community, and agency to preserve their physical and psychosocial health during pregnancy and in the long term.

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## Data Availability

Given the sensitive and individualized nature of qualitative data, these data will not be publicly available. Investigators wishing to access these data may contact the corresponding author; data may be made available upon reasonable request and with evidence of appropriate approvals.



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## Authors' Contributions

LMY, KL, and CMN contributed to conceptualization. LL, ES, KL, and LMY handled data curation. MVR, LL, ES, and LMY conducted formal analysis. LMY and CMN managed funding acquisition. LL, ES, KL, and LM handled investigation. LMY, LL, ES, and KL contributed to methodology. LMY, CMN, and KL handled project administration. LMY managed resources. LMY and CMN conducted supervision. KL, LL, ES, and LMY managed validation. MVR and LL contributed to visualization. MVR and LL wrote the original draft. MVR, LL, ES, KL, CMN, and LMY conducted review and editing.

## Conflicts of Interest

None declared.

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## Abbreviations

**DM:** diabetes mellitus
**GDM:** gestational diabetes mellitus
**mHealth:** mobile health
**MNT:** medical nutrition therapy
**T2DM:** type 2 diabetes mellitus
**UCD:** user-centered design

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Original Paper

# mHealth Social Support Versus Standard Support for Diabetes Management in Safety-Net Emergency Department Patients: Randomized Phase-III Trial

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## Abstract

**Background:** Mobile health (mHealth) is a low-cost method to improve health for patients with diabetes seeking care in safety-net emergency departments, resulting in improved medication adherence and self-management. Additions of social support to mHealth interventions could further enhance diabetes self-management by increasing the gains and the postintervention maintenance.

**Objective:** We assessed outcomes of an unblinded, parallel, equal-allocation randomized phase-III trial that tested a social support mHealth intervention to improve emergency department patients' diabetes self-management.

**Methods:** Patients with glycated hemoglobin ($HbA_{1c}$) levels of ≥8.5% mg/dL and a text-capable phone were recruited during their emergency department visit for any reason (diabetes related or not) at a US public hospital along with a friend or family member as a supporter. Patients received 6 months of the Trial to Examine Text Messaging in Emergency Department Patients With Diabetes self-management mHealth program. Supporters were randomized to receive either (1) an mHealth social support program (Family and Friends Network Support)—daily SMS text messages guiding supporters to provide diabetes-related social support—or (2) a non-mHealth social support program as an active control—pamphlet-augmented social support with Family and Friends Network Support content. Point-of-care $HbA_{1c}$ level, self-reported diabetes self-care activities, medication adherence, and safety events were collected. Mixed-effects linear regression models analyzed group differences at the end of the intervention (6 months) and the postintervention phase (12 months) for $HbA_{1c}$ level and behavioral outcomes.

**Results:** A total of 166 patients were randomized. In total, 8.4% (n=14) reported type 1 diabetes, 66.9% (n=111) reported type 2 diabetes, and 24.7% (n=41) did not know their diabetes type; 50% (n=83) reported using insulin for diabetes management. Trial follow-up was completed with 58.4% (n=97) of the patients at 6 months and 63.9% (n=106) of the patients at 12 months. Both groups showed significant $HbA_{1c}$ level improvements (combined group change=1.36%, SD 2.42% mg/dL; 95% CI 0.87-1.83; $P$<.001), with no group difference (group mean difference=0.14%, SD 4.88% mg/dL; 95% CI −1.11 to 0.83; $P$=.87) at 6 months. At 12 months, both groups maintained their improved $HbA_{1c}$ levels, with a combined mean change from 6 months of 0.06% (SD 1.89% mg/dL; 95% CI −0.34 to 0.47; $P$=.76) and no clinically meaningful difference between groups. No differences were



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observed in safety events. In subgroup analyses, patients recently diagnosed with diabetes in the mHealth social support group improved their glycemic control compared to the standard social support group (between-group difference of 1.96%, SD 9.59% mg/dL; 95% CI −3.81 to −0.125; *P*=.04).

**Conclusions:** A 6-month change in $HbA_{1c}$ level did not differ by mode of social support in persons using an existing patient-focused mHealth diabetes self-management program, but both groups improved in self-management and glycemic control. Newly diagnosed patients with diabetes benefited most from mHealth-augmented social support.

**Trial Registration:** ClinicalTrials.gov NCT03178773; https://clinicaltrials.gov/study/NCT03178773

**International Registered Report Identifier (IRRID):** RR2-10.1016/j.cct.2019.03.003

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**KEYWORDS**

social support; mobile health; mHealth; SMS text messaging; diabetes self-management

## Introduction

### Background

Social support interventions using family members and peers to provide emotional and informational support for patients with diabetes have shown improvements in patient motivation, healthy behaviors, and glycemic control [1-3]. However, typical social support interventions require (1) in-person training of family and friends, (2) coordination of schedules and physical location between the patient and their supporter, and (3) the cost of providing physical space and personnel to train these supporters. Because training and support usually occur face-to-face, social supporters are often limited to people who are proximate to the patient and have time available to be trained, rather than being the most influential person in the patient's life. Mobile health (mHealth) can overcome these transportation and time commitment obstacles and increase the scalability of social support interventions.

mHealth-based social support interventions may increase the efficacy and effectiveness of patient-focused mHealth interventions for diabetes self-management. mHealth for diabetes self-management is effective. Improvements in medication adherence and self-care activities have resulted in glycated hemoglobin ($HbA_{1c}$) level improvements of 0.3% to 0.8% [4]. Despite this, a digital divide persists, with less uptake in populations of a lower socioeconomic status and from minoritized backgrounds [5]. SMS text message–based mHealth strategies have successfully been used among vulnerable patient populations in the United States [6], such as CareMessage [7] in federally qualified health centers in Los Angeles County, California, and Rapid Education/Encouragement and Communications for Health among low-income, primary care clinic patients in Nashville, Tennessee [8]. Outside of primary care settings, the Trial to Examine Text Messaging in Emergency Department Patients With Diabetes (TExT-MED) intervention was tested in safety-net emergency department (ED) patients [9]. The original 6-month, fully automated, SMS text message–based TExT-MED curriculum is based on National Diabetes Education Program [10] messages adapted for SMS text message character limits and emphasizes education and behavior changes. Intervention participants improved their $HbA_{1c}$ levels by 0.4% compared to control participants [9]. Particularly in underresourced populations, patient-focused interventions could be strengthened by adding social support for diabetes modules for loved ones of people with diabetes. In addition, social support may be provided and received differently in different cultural contexts, with family and close friendships taking primacy for patients from a more collectivist cultural background [11]. Using mobile training, a patient can select anyone from their social support network regardless of physical location to be a Family and Friends Network Support (*FANS*) provider. Adding this mobile social support module, TExT-MED+FANS, builds on the success of the original TExT-MED intervention by adding an emotional and highly personal touch to enhance results.

### Objectives

Augmenting mHealth interventions with social support is a growing field of research and has the possibility of creating scalable, effective interventions that can translate into clinical care. Studying these interventions within a safety-net population characterized by inadequate disease control and significant constraints on time and travel can show the potential benefits for those facing barriers to accessing care. The ED provides a unique setting to reach patients and their social supporters during a health crisis, when they may be particularly receptive to adopting behavior changes. In this randomized controlled trial, we tested the effect of 2 approaches to social support to augment an existing patient-focused mHealth intervention. The intervention group received the social support curriculum via mHealth, whereas the control group received the social support curriculum via a paper-based format. The full details of the study design and procedures have been published previously [12] and are available at ClinicalTrials.gov (NCT03178773). This paper presents the trial outcomes.

## Methods

### Study Design

This was an unblinded, randomized, parallel, active controlled trial with a 1:1 allocation ratio. All patient participants received an SMS text message–based mHealth curriculum for diabetes self-management. At the patient level, supporters were randomized to receive (1) the FANS mHealth social support program or (2) the FANS non-mHealth social support program as an active control.



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## Ethical Considerations

Institutional review board approval for this study was obtained before study initiation from the University of Southern California Health Sciences Institutional Review Board (HS-17-00406). Patients were consented in the language of their choice (Spanish or English) using written consent documents. Patients repeated back understanding of the study purpose to confirm understanding. Supporters were verbally consented in the language of their choice. All participants had the opportunity to ask questions and obtain clarification on the study purpose. Study data were maintained on HIPAA (Health Insurance Portability and Accountability Act)–compliant servers. The mHealth platform used was HIPAA compliant. Patients were compensated with US $20 at enrollment, US $5 after the 3-month phone survey, US $50 at the 6-month follow-up, US $5 after the 9-month phone survey, and US $100 at the 12-month follow-up. Some patients also came for in-depth semistructured interviews (results reported separately) and received US $100. Supporters were not compensated at enrollment but received US $25 after the 6-month follow-up and US $100 if they came for in-depth semistructured interviews at the end of the study.

## Patient Screening, Eligibility Criteria, and Recruitment

Patients with diabetes were screened and enrolled by surveying the electronic patient tracking system from July 2017 to October 2018. Inclusion criteria were age of ≥18 years, $HbA_{1c}$ level of ≥8.5% mg/dL as measured using the Afinion point-of-care $HbA_{1c}$ analyzer, and ability to consent. Patients were excluded if they did not have stable ownership of a mobile phone for ≥30 days, were not able to send and receive SMS text messages, did not read English or Spanish, or could not identify a support person who could be contacted within 2 weeks to enroll. To identify a support person, patients were asked the following: *Do you have a support person you can count on?* (In Spanish: *¿Tiene una persona de apoyo con la que puede contar?*) Patients who reported type 1, type 2, or unknown type of diabetes were enrolled as prior work with this population has shown that up to 30% of patients are unsure of which type of diabetes they have [13]. Research assistants explained the purpose of the study and obtained consent while the patient was still in the ED. Patients were informed at enrollment that the designated supporter could receive multiple SMS text messages per day and would be prompted to offer increased support.

## Patient and Supporter Enrollment and Randomization

After consenting, patients were registered on the mHealth platform but were only eligible to complete study enrollment if a supporter agreed to participate as well. If a supporter was not enrolled within 2 weeks of patient consent, the patient still received the patient SMS text messaging program but was excluded from further participation in the study. Randomization to pamphlet- or mHealth-augmented social support took place after supporter enrollment.

Supporters were enrolled during the initial in-person enrollment of the patient if available in the ED, by telephone, or at a later time remotely. Support person enrollment consisted of verbal consent and confirmation of age of >18 years and ability to send and receive SMS text messages. Randomization group was assigned through sealed envelope allocation after supporter consent to participate; the randomization sequence was generated by the senior study biostatistician. Supporters then completed baseline survey instruments and were registered on the mHealth platform if randomized to the mHealth social support intervention arm or received a pamphlet if randomized to the active control standard support arm.

## Intervention

### *TExT-MED: Patient Intervention (Received by All Patients)*

The original 6-month, fully automated, SMS text message–based TExT-MED patient curriculum has been previously described [9]. TExT-MED was based on the National Diabetes Education Program [10] adapted for character limits (160 characters) and emphasized education and behavior changes. The program was designed to enhance knowledge, self-efficacy, and diabetes self-management. Patient messages, delivered twice daily, included (1) educational and motivational messages, (2) medication reminders, (3) trivia questions, and (4) healthy living challenges.

After the original TExT-MED study, Agile Health purchased, modified, and commercialized the program as MyAgileLife. This enhanced version delivered 3 daily messages with a greater focus on skills such as setting goals, enabling social support, and increasing engagement. To synchronize patient and supporter messages, we used a locally modified MyAgileLife version. All patients received the TExT-MED patient intervention.

### *FANS Curriculum: Supporter Intervention*

#### Overview

The development of the FANS support curriculum has been described separately [12]. In brief, the messages were developed based on National Diabetes Education Program and American Diabetes Association recommendations, synchronizing in content and time with 2 of the 3 daily patient messages. The FANS messages focused on (1) instrumental support (tangible goods and actions), (2) informational support (knowledge), and (3) emotional support [14]. Given the financial constraints of the patients and family members of this population, FANS messages emphasized nonfinancial forms of instrumental support. One FANS message per week was an active support challenge message that encouraged patient contact, emphasized a specific support care behavior, or challenged the FANS supporters to perform the same health behavior as the patient and communicate that to the patient. In total, the FANS curriculum consisted of 381 messages. All supporters received the FANS curriculum but were randomized to the treatment or active control group—FANS curriculum delivered via mHealth versus non-mHealth methods, respectively.

#### Treatment Condition: Supporters Randomized to FANS Curriculum via mHealth

Supporters in the intervention group received 2 to 3 SMS text messages daily, synchronized in content and time with the patient TExT-MED messages. Messages to supporters started on the same day as the patients' TExT-MED messages. Research



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assistants did not provide further guidance to supporters other than to read the messages and an information line to text or call if they had technical difficulties.

#### Active Control Condition: Supporters Randomized to FANS Curriculum via Non-mHealth Methods

Supporters randomized to the active control group received the FANS curriculum delivered through non-mHealth methods. Supporters received a paper pamphlet of the FANS curriculum, with each 2-page layout of the pamphlet corresponding to 1 week of TExT-MED patient messages. The pamphlet was provided directly by a research assistant if the supporter enrolled in person or mailed to the supporter's home if they enrolled remotely. Each supporter was instructed to start on week 1 of the pamphlet on the same day that their patient's messages would start (the dyad's *Healthy Start Date*). Research assistants did not provide further guidance to supporters on how to text or provide social support. An information telephone number was provided in case they had technical difficulties.

### Safety Monitoring

There was a potential risk of hypoglycemia as patients improved their medication adherence or physical activity, especially if patients were previously prescribed insulin or oral insulin secretagogues at increasing doses due to persistent hyperglycemia. Patient knowledge of symptoms of and treatment for hypoglycemia is low [13]; thus, hypoglycemia was the first focus of the educational messages sent to both supporters and patients. Upon enrollment, patients were instructed to report episodes of hypoglycemia to the research team and call their primary care team. If the patient did not have a regular primary care source, the research team instructed the patient to visit the urgent access center at the medical center where they were initially enrolled. We evaluated for a difference in patient-reported hypoglycemic events between the 2 groups at 6 and 12 months.

### Data Collection Procedures, Schedule, and Outcome Measures for Patients

Patient assessments took place at enrollment and 3, 6, 9, and 12 months for behavioral and psychosocial outcomes and at baseline and 6 and 12 months for clinical outcomes. Trained research assistants conducted in-person assessments at an office at the medical center using standardized protocols and equipment in the patient's preferred language. For assessments at 3 and 9 months, participants had the option of an in-person, mail, or phone appointment. Data were entered into a data management system maintained by the Southern California Clinical and Translational Science Institute [15].

At baseline, we collected self-reports of race and ethnicity, language preference, health literacy (3-item Brief Health Literacy Screen [16]), and mobile technology use measured using questions modeled after the Pew Hispanic Center survey [17].

At baseline and 6 and 12 months, we collected $HbA_{1c}$ using the Afinion AS100 capillary point-of-care machine, systolic blood pressure, weight, and abdominal circumference. We collected patient height only at baseline to calculate BMI.

Patient measures collected at baseline and 3, 6, 9, and 12 months were as follows: (1) the Summary of Diabetes Self-Care Activities [18] (each measure ranges from 0 to 7, indicating the number of days per week that the patient reports engaging in these behaviors), (2) the 3-item medication adherence scale by Wilson et al [19] (total score ranges from 0 to 100, with higher scores indicating better medication adherence), (3) self-efficacy (Diabetes Empowerment Scale–Short Form [20]; ranges from 8 to 40 points; a higher score indicates higher self-efficacy), (4) the Diabetes Distress Scale [21] (an average of 17 Likert-scale items; overall scores range from 1 to 6, with higher scores indicating higher levels of distress), (5) depression (Patient Health Questionnaire–9 [22]; a widely used scale for depression; higher levels indicate more depression symptoms), (6) the Diabetes Fatalism Scale [23] (sum of 3 subscales: emotional distress, religiosity, and coping and perceived self-efficacy; the total score ranges from 12 to 72, with higher scores indicating higher fatalism), (7) the World Health Organization–Five Well-Being Index [24] (a widely used measure of quality life validated in many languages that consists of only 5 items), (8) the Diabetes Family Behavior Checklist supportive and nonsupportive subscores [25] (the supportive subscore ranges from 4 to 45 [higher scores indicate more supportive behaviors]; the nonsupportive subscore ranges from 7 to 35 [higher scores indicate more nonsupportive behaviors]), (9) the Diabetes Care Profile Support Questions [26] (with subscores for support wanted, support received, and support attitudes; each subscore ranges from 5 to 30, with higher scores indicating higher desire for support and higher support received), and (10) the Norbeck Social Support Questionnaire Emotional and Tangible subscales [27] (the emotional subscore ranges from 0 to 16, with higher scores indicating higher perceived emotional support, and the tangible subscore ranges from 0 to 8, with higher scores indicating higher perceived tangible support).

Patient self-reported frequency of patient-supporter contact and proportion of communication about diabetes was also collected.

### Data Collection Procedures, Schedule, and Outcome Measures for Supporters

Supporter assessments took place at baseline and 6 and 12 months. Supporters had the option of an in-person, mail, or phone appointment. All assessments were with trained research assistants in the language of the participants' preference.

Self-report of age, race and ethnicity, language preference, health literacy [16], and mobile technology use [17] were collected at baseline. At baseline and 6 months, support people reported (1) frequency of patient-supporter contact and the proportion of the communication that was about diabetes and (2) supporter diabetes-related distress (Partner Distress Scale [28]).

### Primary and Secondary Outcomes

The primary outcome was change in $HbA_{1c}$ level from baseline to 6 months. The secondary outcomes were (1) 6- to 12-month postintervention change in $HbA_{1c}$ level, (2) baseline to 6-month change in BMI and blood pressure, and (3) baseline to 6-month change in diabetes self-management behaviors (measured using the Summary of Diabetes Self-Care Activities)



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## Data Analysis

### *Primary Outcome Analysis*

The primary outcome was the change in $HbA_{1c}$ level from baseline to 6 months between the mHealth social support and standard social support groups. Participants who completed the 12-month study provided 2 outcome measures of 6-month change: a 0- to 6-month measure of treatment efficacy and a 6- to 12-month measure of sustainability of treatment effect. The normality of the outcome variable (6-month change) was graphically evaluated. We used a mixed-effects linear regression model to account for correlated outcome data (0-6–month and 6-12–month changes) and loss to follow-up. Analyses were conducted using intention to treat, with participants analyzed according to their randomized intervention regardless of adherence. The linear mixed-effects model included a random intercept term for participants. Fixed effects included treatment allocation, initial level of $HbA_{1c}$ (0-month measure for treatment efficacy and 6-month measure for sustainability), and a covariate of study period (0-6 months and 6-12 months). We tested for group differences in the main effect of treatment over both periods of 0 to 6 months and 6 to 12 months. An interaction term of treatment by study period tested for differences in treatment effects by study period; treatment effects were estimated and tested for differences by study period in this interaction model. Model assumptions, including normality of model residuals and homogeneity of variance, were evaluated. All analyses were conducted in Stata (version 17; StataCorp) [29].

Due to the possibility of unequal groups, we planned to examine for potential confounding from candidate variables by the change in intervention efficacy estimation method, with a cutoff of 20% change [12]. Potential confounders examined were sex of the patient, sex of the supporter, patient age, race and ethnic group, language preference, health literacy, patient and supporter technological capacity, patient and supporter living at the same address, baseline family supportive behaviors, and supporter being immediately present for enrollment versus requiring multiple contact attempts.

After the regression model was built, predicted mean differences between the groups in $HbA_{1c}$ levels at 6 months were examined with the margins and contrast postestimation tools in Stata at the 6-month time point. A sensitivity analysis confined to adherent participants (those who had not opted out of messages and had received ≥75% of messages confirmed by the message delivery platform) was planned but was not possible due to limitations in most patients' cellular service provider platforms.

### *Secondary Outcome Analysis*

Secondary outcomes of the 6- to 12-month intervention efficacy of mHealth social support versus standard social support on $HbA_{1c}$ and 0- to 6-month intervention efficacy of mHealth social support versus standard social support on clinical outcomes and self-care behaviors were examined using the same mixed-effects models as for the primary outcome.

### *A Priori Subgroup Analysis*

To determine whether subgroups of participants were differentially affected by the intervention, secondary analyses evaluating intervention moderators were planned a priori [12]. For $HbA_{1c}$ and each of the secondary outcomes, interaction terms (randomized intervention-by-moderator product terms) were added to mixed-effects linear models similar to those described previously. Variables evaluated as moderators included patient and supporter sex, race and ethnicity in 4 categories, language preference, health literacy (low health literacy was defined as a Brief Health Literacy Score of <12), new diagnosis of diabetes (<12 months), baseline frequency of mobile technology use as high or low based on latent profiles previously described [30], and physical proximity to supporter. Intervention effects were estimated by levels of the moderator for significant moderators only at a *P* value of .05 for the interaction term between randomization group and moderator.

### *Post Hoc Subgroup Analysis*

During enrollment, substantial differences in baseline support and contact between patients and their selected supporters became evident as some supporters took up to 2 weeks to complete enrollment procedures. We conducted a subgroup analysis based on supporter immediate availability for enrollment versus delayed enrollment.

### *Sample Size and Effect Size Calculations*

We planned to enroll 166 patient-supporter dyads assuming a 30% loss to follow-up [31] to yield a planned sample size of 116 total dyads. Power of 0.80 and 2-sided α of .05 using an SD of the final $HbA_{1c}$ level of 1.6 (the value of our previous trials) provided the ability to detect a mean difference in change in $HbA_{1c}$ level of 0.84 between the 2 groups at the 6-month follow-up [32].

# Results

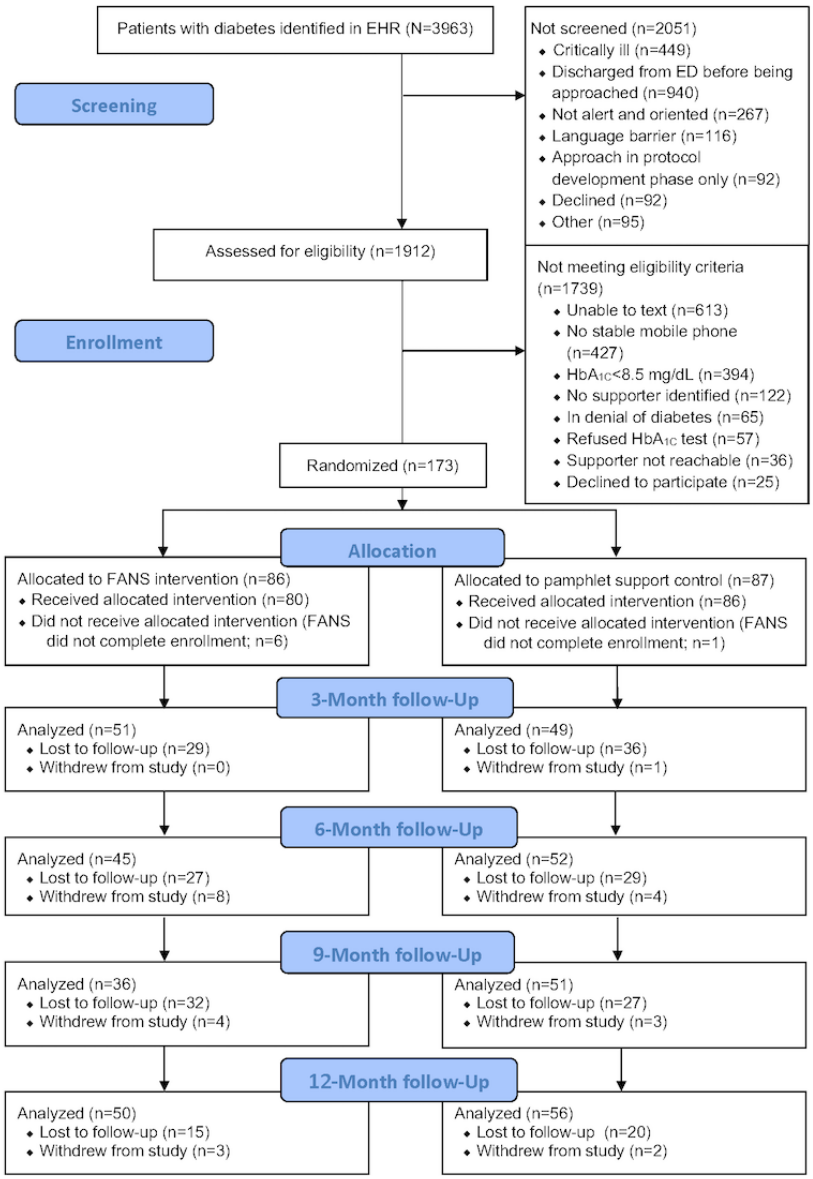
## Screening and Recruitment

Nearly 4000 patients with diabetes were identified during their ED visits in the electronic patient tracking system. Nearly half of these patients (1912) were screened for eligibility (see the CONSORT [Consolidated Standards of Reporting Trials] diagram in Figure 1). Of these 1912 patients, 209 (10.93%) were initially recruited, and 173 (8.63%) met the criteria and agreed to enroll. A total of 166 patients had a consenting support person identified and were randomized. The most common reason for ineligibility was not using SMS text messaging (613/1912, 32.06% of patients), followed by not having a stable mobile phone number (427/1912, 22.33% of patients). Less than 10% of patients (156/1912, 8/15%) were unable to identify an available supporter. After randomization, 4% (7/173) of the supporters failed to complete the initial process of enrollment in the study and were excluded. Recruitment ended once the final cohort of 166 patient-supporter dyads was randomized and fully enrolled in the intervention.



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**Figure 1.** Participant flow diagram. ED: emergency department; EHR: electronic health record; FANS: Family and Friends Network Support; $HbA_{1c}$: glycated hemoglobin.




## Participant Characteristics

The characteristics and baseline measurements of the patient cohort are shown in Table 1. The enrolled patient cohort was 51.2% (85/166) female, 69.9% (116/166) Spanish speaking, and 77.7% (129/166) born outside the United States, with a median age of 48.2 (IQR 40.7-55) years. Two-thirds (111/166, 66.9%) reported type 2 diabetes, and 50% (83/166) used insulin. Their mean $HbA_{1c}$ level was 10.8 (SD 1.7) mg/dL. Comorbidities were common. Mean systolic blood pressure was 134.6 (SD 24.6) mm Hg, mean BMI was 30.07 (SD 7.60) $kg/m^2$, and mean Patient Health Questionnaire–9 score was 9.16 (SD 6.63; mild depression). Medication adherence and diabetes self-care behaviors were low, with mean days of performing recommended daily diabetes self-care activities of 2.47 (SD 2.57) to 4.06 (SD 2.93) and a mean Wilson medication adherence score of 66.5 (SD 29.5). The mHealth social support intervention group consisted of more male individuals (45/80, 56% vs 37/86, 43%) and fewer Spanish speakers (52/80, 65% vs 64/86, 74%) than the standard support control group.



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**Table 1.** Patient baseline characteristics (N=166).

| | Total | Intervention (n=80) | Active control (n=86) |
|---|---|---|---|
| $HbA_{1c}$[a] level (%; mg/dL)[b], mean (SD) | 10.84 (1.69) | 10.90 (1.73) | 10.78 (1.67) |
| Reason for emergency visit was diabetes related, n (%) | 128 (77.1) | 60 (75) | 68 (79.1) |
| Insulin-dependent diabetes, n (%) | 83 (50) | 38 (47.5) | 45 (52.3) |
| BMI ($kg/m^2$)[b], mean (SD) | 30.07 (7.60) | 29.34 (7.18) | 30.78 (7.96) |
| Age (y), mean (SD) | 47.60 (10.43) | 46.91 (9.98) | 48.25 (10.85) |
| Systolic BP[c] (mm Hg)[b], mean (SD) | 134.6 (24.6) | 133.8 (25.9) | 135.4 (25.8) |
| Male sex, n (%) | 81 (48.8) | 45 (56.3) | 37 (43) |
| **Race and ethnicity, n (%)** | | | |
| American Indian or Alaska Native | 5 (3) | 3 (3.8) | 2 (2.3) |
| Asian or Pacific Islander | 2 (1.2) | 0 (0) | 2 (2.3) |
| Black | 9 (5.4) | 6 (7.5) | 3 (3.5) |
| Latino | 147 (88.6) | 68 (85) | 79 (91.9) |
| Non-Hispanic White | 3 (1.8) | 3 (3.8) | 0 (0) |
| Spanish language preferred, n (%) | 116 (69.9) | 52 (65) | 64 (74.4) |
| Foreign born (n=165), n (%) | 129 (77.7) | 56 (70) | 74 (86) |
| Acculturation (Short Acculturation Scale for Hispanics), mean (SD) | 2.01 (1.18) | 2.10 (1.21) | 1.92 (1.16) |
| Health literacy (Brief Health Literacy Screen)[d], mean (SD) | 4.60 (3.43) | 4.75 (3.54) | 4.45 (3.34) |
| Depression (PHQ-9[e])[b], mean (SD) | 9.16 (6.63) | 9.44 (6.31) | 8.90 (6.94) |
| Self-efficacy (Diabetes Empowerment Scale–Short Form)[b], mean (SD) | 3.85 (0.66) | 3.89 (0.62) | 3.81 (0.69) |
| Distress due to DM[f] (Diabetes Distress Scale)[b], mean (SD) | 2.48 (1.03) | 2.63 (1.11) | 2.34 (0.93) |
| Quality of life (WHO-5[g])[d], mean (SD) | 60.9 (28.00) | 58.0 (29.45) | 61.9 (26.59) |
| Fatalism (Diabetes Fatalism Scale)[b], mean (SD) | 34.94 (9.89) | 35.86 (9.85) | 34.09 (9.90) |
| Medication adherence (n=165; Wilson 3-item medication adherence scale)[d], mean (SD) | 66.5 (29.5) | 65.8 (28.2) | 67.29 (30.9) |
| **Summary of Diabetes Self-Care Activities (d), mean (SD)** | | | |
| General diet[d] | 3.23 (2.47) | 3.07 (2.51) | 3.38 (2.44) |
| Specific diet[d] | 3.87 (1.90) | 3.74 (1.89) | 3.98 (1.90) |
| Glucose monitoring[d] | 2.65 (2.92) | 2.76 (3.06) | 2.55 (2.79) |
| Foot care[d] | 4.06 (2.93) | 4.11 (2.86) | 4.01 (3.00) |
| Carbohydrate spacing[d] | 2.89 (2.56) | 3.00 (2.46) | 2.78 (2.65) |
| Exercise[d] | 2.47 (2.57) | 2.43 (2.53) | 2.51 (2.62) |
| **Support measures, mean (SD)** | | | |
| Supportive diabetes family behaviors[d,h] | 23.90 (8.87) | 24.46 (8.99) | 23.37 (8.78) |
| Nonsupportive diabetes family behaviors[b,h] | 18.23 (6.61) | 18.70 (6.69) | 17.78 (6.54) |
| Diabetes support needs[b,i] | 23.61 (7.52) | 24.04 (7.55) | 23.22 (7.51) |
| Diabetes support received[d,i] | 18.54 (8.90) | 19.16 (9.06) | 17.98 (8.77) |
| Diabetes support attitudes[d,i] | 6.45 (5.17) | 6.39 (4.68) | 6.51 (5.62) |
| General emotional support (n=152)[d,j] | 13.84 (3.23) | 13.7 (3.15) | 14.0 (3.32) |



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| | Total | Intervention (n=80) | Active control (n=86) |
|---|---|---|---|
| General tangible support (n=152)[d,j] | 6.99 (1.68) | 7.15 (1.57) | 6.83 (1.77) |

[a]$HbA_{1c}$: glycated hemoglobin.

[b]Higher value indicates clinically worse value.

[c]BP: blood pressure.

[d]Lower value indicates clinically worse value.

[e]PHQ-9: Patient Health Questionnaire–9.

[f]DM: diabetes mellitus.

[g]WHO-5: World Health Organization–Five Well-Being Index.

[h]Diabetes Family Behavior Checklist.

[i]Diabetes Care Profile.

[j]Norbeck Social Support Questionnaire.

## Supporter Characteristics and Baseline Support

The supporters were 70.5% (117/166) female and 57.2% (95/166) Spanish speaking, with 65.7% (109/166) of supporters being born outside the United States (Table 2). Their mean age was 43.69 (SD 14.54) years. A total of 27.7% (46/166) of patient-supporter dyads were language discordant in the language they preferred to receive SMS text messages. Of the supporters, 20.5% (34/166) also had diabetes, 68% (23/34) with type 2 diabetes, 6% (2/34) with type 1 diabetes, and 24% (8/34) who did not know the type of diabetes they had. The supporters were predominantly family members—30.7% (51/166) were spouses, 14.5% (24/166) were siblings, 23.5% (39/166) were adult children of the patients, 16.9% (28/166) were other relatives, 12% (20/166) were friends, and 2.4% (4/166) of the patients did not wish to disclose the nature of their relationship with their supporter.

**Table 2.** Supporter baseline characteristics (N=166).

| | Total | Intervention (n=80) | Active control (n=86) |
|---|---|---|---|
| Supporter has diabetes, n (%) | 34 (20.5) | 16 (20) | 18 (20.9) |
| Age (y), mean (SD) | 43.69 (14.54) | 42.89 (13.79) | 44.45 (15.26) |
| Male sex, n (%) | 49 (29.5) | 21 (26.3) | 28 (32.6) |
| Spanish speaking, n (%) | 95 (57.2) | 48 (60) | 46 (53.5) |
| Foreign born, n (%) | 109 (65.7) | 52 (65) | 57 (66.3) |
| Supporter enrollment delayed (not the same day), n (%) | 67 (40.4) | 34 (42.5) | 33 (38.4) |

## Study Follow-Up

We obtained measures of our primary outcome, $HbA_{1c}$ level at 6 months, from 52% (42/80) of the mHealth support intervention group and 60% (52/86) of the active control standard support group. In the intervention group, 10% (8/80) of the patients dropped out, and 34% (27/80) were lost to follow-up. In the active control group, 6% (5/86) of the patients dropped out, and 34% (29/86) were lost to follow-up. At 12 months, after a maintenance phase with no SMS text messages, we obtained $HbA_{1c}$ measurements for 62% (50/80) of the patients in the intervention group and 65% (56/86) of the patients in the active control group. In the intervention group, 9% (7/80) of the patients withdrew during the maintenance phase, but 6% (5/80) of the patients followed up who were not available at 6 months. In the active control group, 6% (5/86) of the patients withdrew during the maintenance phase, but 5% (4/86) more followed up who were not available at 6 months.

Comparison of the patients who completed or did not complete follow-up at 6 months showed that patients who did not complete the 6-month assessments reported more negative attitudes toward their baseline social support (Diabetes Care Profile support attitudes negative subscore=2.25, 95% CI 1.95-2.55 vs 1.56, 95% CI 1.36-1.76; group difference=−0.69, 95% CI −1.03 to −0.35). Patients unavailable for follow-up were substantially younger (mean age 45.78 y, SD 10.79; 95% CI 43.13-48.43 vs 48.80 y, SD 10.06; 95% CI 46.80-50.80) and more acculturated (Short Acculturation Scale for Hispanics=mean 2.17, SD 1.27; 95% CI 1.86-2.49 vs mean 1.90, SD 1.11; 95% CI 1.68-2.12), although these differences were not significantly different (Multimedia Appendix 1).

## Primary Outcome: 6-Month Change in $HbA_{1c}$ Level

The mHealth support intervention and non-mHealth standard support active control condition were similarly efficacious in improving glycemic control ($HbA_{1c}$), with no clinically meaningful difference between groups (group mean difference=0.14% mg/dL, SD 4.88% mg/dL; 95% CI −1.11 to 0.83; Table 3). Patients in the active control arm had a mean decrease in $HbA_{1c}$ level of 1.42% mg/dL (SD 2.18% mg/dL; 95% CI 0.82-2.02), whereas patients in the intervention arm had a mean decrease in $HbA_{1c}$ level of 1.28% mg/dL (SD 2.70% mg/dL; 95% CI 0.48-2.09), with a combined sample change of 1.36% mg/dL (SD 2.42% mg/dL; 95% CI 0.87-1.83). We found no confounders of the intervention effect in a mixed-effects



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model with individual participants with random intercepts and controlling for baseline $HbA_{1c}$.

**Table 3.** The 6-month change in outcome measures (6 months minus baseline).

| | Active control, mean change (SD; 95% CI) | Intervention, mean change (SD; 95% CI) | Group difference, mean change (SD; 95% CI) | Combined group, mean change (SD; 95% CI) |
|---|---|---|---|---|
| $HbA_{1c}$[a,b] | −1.42 (2.18; −2.02 to −0.82) | −1.28 (2.70; −2.09 to −0.48) | −0.14 (4.88; −1.11 to 0.83) | −1.36 (2.42; −1.83 to −0.87) |
| BMI[a] | 7.91 (33.80; −1.70 to 17.52) | 3.84 (22.94; −2.97 to 10.65) | 4.07 (58.27; −7.74 to 15.88) | 5.96 (29.03; 0.08 to 11.84) |
| Systolic BP[a,c] | 6.14 (30.45; 1.14 to 13.44) | 10.06 (36.34; 0.72 to 20.83) | −3.91 (66.85; −16.56 to 8.74) | 8.02 (33.28; 1.72 to 14.32) |
| Medication adherence[a] | 15.73 (30.87; 7.13 to 24.32) | 12.39 (31.11; 3.15 to 21.63) | 3.34 (62.09; −9.11 to 15.78) | 14.16 (30.87; 7.97 to 20.35) |
| SDSCA[d]—general diet[a] | 1.55 (2.91; 0.74 to 2.36) | 0.17 (2.69; −0.38 to 1.97) | 0.37 (5.63; −0.75 to 1.50) | 1.37 (2.80; 0.81 to 1.93) |
| SDSCA—specific diet[a] | 0.42 (2.12; –0.17 to 1.01) | 0.78 (1.93; 0.21 to 1.35) | −0.36 (1.68; −1.18 to 0.46) | 0.60 (2.03; 0.10 to 0.18) |
| SDSCA—glucose monitoring[a] | 0.91 (3.00; 0.08 to 1.75) | 0.10 (2.84; −0.75 to 0.94) | 0.82 (5.87; −0.36 to 1.99) | 0.53 (2.94; −0.06 to 1.12) |
| SDSCA—foot care[a] | 1.25 (2.96; 0.42 to 2.08) | 1.36 (2.69; 0.56 to 2.16) | −0.11 (5.69; −1.25 to 1.03) | 1.30 (2.83; 0.73 to 1.87) |
| SDSCA—carbohydrate spacing[a] | 0.71 (4.34; −0.50 to 1.92) | 0.20 (3.31; −0.80 to 1.20) | 0.51 (7.82; −1.06 to 2.09) | 0.47 (3.89; −0.31 to 1.26) |
| SDSCA—exercise[a] | 0.39 (2.99; −0.44 to 1.23) | 0.90 (3.14; −0.31 to 1.84) | −0.51 (6.13; −1.74 to 0.72) | 0.63 (3.06; –0.02 to 1.25) |
| Self-efficacy[a] | 0.17 (0.63; 0.00 to 0.35) | 0.05 (0.69; −0.16 to 0.25) | 0.12 (1.32; −0.14 to 0.39) | 0.11 (0.66; −0.02 to 0.25) |
| DM[e] distress score[a] | −0.65 (0.97; −0.92 to 0.38) | −0.60 (1.15; −0.94 to −0.26) | −0.05 (2.13; −0.48 to 0.37) | −0.63 (1.06; −0.84 to −0.42) |
| Depression (PHQ-9[f])[a] | −3.86 (6.19; −5.60 to −2.12) | −2.33 (6.20; −4.17 to −0.49) | −1.54 (12.40; −4.04 to 0.96) | −3.13 (6.21; −4.39 to −1.88) |
| Quality of life[a] | 9.70 (34.02; 0.93 to 18.45) | 4.96 (29.90; −3.91 to 13.83) | 4.74 (61.57; −7.61 to 17.08) | 7.47 (32.16; 1.32 to 13.62) |
| Fatalism score[a] | 1.44 (9.47; −1.25 to 4.13) | −0.58 (10.61; −3.73 to 2.57) | 2.02 (20.07; −2.05 to 6.09) | 0.47 (10.03; −1.56 to 2.50) |
| Supportive family behaviors[a] | −0.58 (7.99; −2.80 to 1.65) | −0.12 (9.08; −2.81 to 2.58) | −0.46 (17.07; −3.88 to 2.96) | −0.36 (8.48; −2.06 to 1.34) |
| Nonsupportive family behaviors[g] | −0.58 (6.25; −2.32 to 1.16) | −0.56 (6.86; −2.60 to 1.48) | −0.02 (13.11; −2.65 to 2.61) | −0.57 (6.51;−1.87 to 0.74) |
| DCP[h] support needs[g] | −4.44 (10.79; −7.45 to −1.44) | −5.80 (9.05; −8.49 to −3.11) | 1.36 (20.07; −2.66 to 5.39) | −5.08 (9.99; −7.08 to −3.08) |
| DCP support received[a] | 0.08 (9.68; −2.62 to 2.77) | 3.65 (9.10; 0.95 to 6.36) | −1.91 (18.87; −7.36 to 0.21) | 1.76 (9.54; −0.16 to 3.67) |
| DCP support attitudes[a] | −0.96 (6.51; −2.77 to 0.85) | 0.87 (5.73; −0.83 to 2.57) | −1.83 (12.34; −4.31 to 0.64) | −0.10 (6.20; −1.34 to 1.14) |
| Emotional support[a] | −0.64 (4.03; −1.82 to 0.54) | 0.22 (4.01; −1.17 to 1.61) | −0.86 (8.43; −2.64 to 0.93) | −0.24 (4.04; −1.13 to 0.65) |
| Tangible support[a] | −0.06 (1.99; −0.65 to 0.52) | 0.29 (2.02; −0.34 to 0.93) | −0.36 (4.02; −1.21 to 0.50) | 0.10 (2.00; −0.32 to 0.53) |
| Supporter diabetes-related distress[g] | −0.45 (0.83; −0.66 to −0.24) | −0.28 (0.95; −0.54 to −0.02) | −0.17 (1.77; −0.50 to 0.15) | −0.37 (0.89; −0.54 to −0.21) |

[a]Higher value indicates clinically worse value.

[b]$HbA_{1c}$: glycated hemoglobin.

[c]BP: blood pressure.

[d]SDSCA: Summary of Diabetes Self-Care Activities.

[e]DM: diabetes mellitus.

[f]PHQ-9: Patient Health Questionnaire–9.

[g]Lower value indicates clinically worse value.

[h]DCP: Diabetes Care Profile.



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### Secondary Outcome: 6- to 12-Month Maintenance of $HbA_{1c}$ Level

Overall, the intervention and active control arms maintained improved $HbA_{1c}$ levels, with a combined mean change of 0.06% mg/dL (SD 1.89% mg/dL; 95% CI −0.34 to 0.47) from the 6- to 12-month postintervention maintenance phase. There was no clinically meaningful difference between groups, with a mean increase in $HbA_{1c}$ level of 0.36% mg/dL (SD 1.97% mg/dL; 95% CI −0.22 to 0.93) in the active control arm compared to a decrease of 0.29% mg/dL (SD 1.74; 95% CI −0.85 to 0.27) in the intervention arm (Table 4).

**Table 4.** The 12-month change in outcome measures (12 months minus 6 months).

| | Active control, mean change (SD; 95% CI) | Intervention, mean change (SD; 95% CI) | Group difference, mean change (SD; 95% CI) | Combined group, mean change (SD; 95% CI) |
|---|---|---|---|---|
| $HbA_{1c}$[a,b] | 0.36 (1.97; −0.22 to 0.93) | −0.29 (1.74; −0.85 to 0.27) | 0.65 (3.76; −0.16 to 1.45) | 0.06 (1.89; −0.34 to 0.47) |
| BMI[b] | 3.38 (22.51; −3.38 to 10.14) | −4.02 (24.88; −12.31 to 4.28) | 7.40 (47.44;−3.03 to 17.82) | 0.44 (23.74; −5.17 to 5.26) |
| Systolic BP[b,c] | 4.95 (31.81; −5.09 to 14.99) | −2.09 (37.46; −14.96 to 10.78) | 7.04 (69.26; −8.79 to 22.87) | 1.71 (34.47; −6.17 to 9.59) |
| Medication adherence[b] | −1.74 (18.92; −7.36 to 3.88) | −3.22 (22.89; −10.54 to 4.10) | 1.48 (41.81; −7.48 to 10.45) | −2.43 (20..75; −6.88 to 2.02) |
| SDSCA[d]—general diet[b] | −0.23 (2.50; −0.97 to 0.50) | −0.96 (2.74; −1.84 to −0.09) | 0.73 (5.25; −0.39 to 1.84) | −0.57 (2.62; −1.13 to −0.01) |
| SDSCA—specific diet[b] | −0.29 (1.85; −0.83 to 0.26) | −0.45 (1.85; −1.04 to 0.14) | 0.16 (3.71; −0.63 to 0.95) | −0.36 (1.84; −0.75 to 0.03) |
| SDSCA—glucose monitoring[b] | 0.66 (3.19; −0.28 to 1.60) | 0.18 (2.40; −0.59 to 0.94) | 0.48 (5.72; −0.73 to 1.70) | 0.43 (2.84; −1.70 to 1.04) |
| SDSCA—foot care[b] | 0.81 (2.64; 0.03 to 1.59) | −0.01 (1.93; −0.63 to 0.61) | 0.82 (4.70; −0.18 to 1.82) | 0.43 (2.36; −0.07 to 0.93) |
| SDSCA—carbohydrate spacing[b] | −0.11 (4.51; −1.43 to 1.21) | −0.31 (3.89; −1.57 to 0.95) | 0.20 (8.52; −1.63 to 2.03) | −0.20 (4.22; −1.10 to 0.71) |
| SDSCA—exercise[b] | −0.11 (2.57; −0.98 to 0.77) | −0.81 (2.88; −1.73 to 0.11) | 0.71 (5.88; −0.55 to 1.96) | −0.43 (2.94; −1.06 to 0.19) |
| Self-efficacy[b] | −0.13 (0.49; −0.27 to 0.02) | 0.03 (0.54; −0.14 to 0.21) | −0.16 (1.03; −0.38 to 0.06) | −0.05 (0.53; −0.16 to 0.06) |
| DM[e] distress score[b] | −0.06 (0.92; −0.33 to 0.21) | 0.01 (0.71; −0.22 to 0.23) | −0.07 (1.67; −0.42 to 0.29) | −0.03 (0.83; −0.21 to 0.15) |
| Depression (PHQ-9[f])[b] | 0.18 (6.86; −1.88 to 2.24) | 0.13 (5.17; −1.53 to 1.78) | 0.05 (12.27; −2.59 to 2.70) | 0.15 (6.09; −1.16 to 1.47) |
| Quality of life[b] | −0.09 (31.47; −10.07 to 9.90) | −6.30 (29.86; −15.86 to 3.26) | 6.21 (64.60; −7.56 to 19.99) | −2.94 (30.66; −9.80 to 3.91) |
| Fatalism score[b] | 1.30 (8.97; −1.43 to 4.02) | 1.20 (8.51; −4.00 to 1.59) | −0.10 (17.56; −3.96 to 3.76) | −1.26 (8.70; −3.17 to 0.66) |
| Supportive family behaviors[b] | −0.70 (7.87; −3.02 to 1.61) | −0.98 (9.32; −2.01 to 3.96) | −0.27 (7.19; −3.94 to 3.39) | 0.83 (8.52; −0.99 to 2.64) |
| Nonsupportive family behaviors[g] | 0.85 (6.10; −0.94 to 2.64) | 1.13 (6.93; −1.09 to 3.35) | −0.28 (13.03; −3.06 to 2.50) | 0.98 (6.46; −0.40 to 2.36) |
| DCP[h] support needs[g] | 0.39 (8.17; −2.01 to 2.78) | −0.40 (10.31; −3.70 to 2.90) | 0.78 (18.48; −3.16 to 4.72) | 0.02 (9.17; −1.93 to 1.98) |
| DCP support received[b] | 1.38 (7.54; −0.83 to 3.60) | −2.70 (8.17; −5.31 to −0.09) | 4.08 (15.73; 0.73 to 7.4) | −0.49 (8.16; −2.21 to 1.22) |
| DCP support attitudes[b] | 0.77 (4.56; −0.57 to 2.11) | −0.08 (4.01; −1.36 to 1.21) | 0.84 (8.67; −1.01 to 2.69) | 0.38 (4.31; −0.54 to 1.30) |
| Emotional support[b] | 0.48 (4.02; −0.72 to 1.68) | −0.69 (4.41; −1.99 to 0.61) | 1.17 (8.07; −0.57 to 2.91) | −0.06 (4.20; −0.93 to 0.81) |
| Tangible support[b] | 0.36 (2.17; −0.28 to 0.10) | −0.48 (2.08; −1.14 to 0.19) | 0.84 (4.27; −0.07 to 1.75) | −0.02 (2.16;−0.48 to 0.44) |

[a]$HbA_{1c}$: glycated hemoglobin.

[b]Lower value indicates clinically worse value.

[c]BP: blood pressure.

[d]SDSCA: Summary of Diabetes Self-Care Activities.

[e]DM: diabetes mellitus.

[f]PHQ-9: Patient Health Questionnaire–9.

[g]Higher value indicates clinically worse value.

[h]DCP: Diabetes Care Profile.



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### Secondary Outcome: Diabetes Self-Care Behaviors

The intervention and active control conditions were similarly efficacious in improving self-care behaviors. The 2 groups had similar changes in all self-care measures (Tables 3 and 4). We examined diabetes self-care behavior outcomes using the mixed-effects modeling described previously, allowing for random intercepts by individual patient. We found patient language preference to be a substantial confounder of intervention effect on general diet plan adherence and on disease-specific diet plan adherence, but controlling for this in a regression model did not change the group difference in intervention efficacy on self-care behaviors in the mHealth support arm versus the active control arm.

### Subgroup Analyses of Primary Outcome: 0- to 6-Month Efficacy of mHealth Support Intervention Versus Non-mHealth Standard Social Support on $HbA_{1c}$ Level

Among patients with a new diagnosis of diabetes, intervention group patients improved their $HbA_{1c}$ level to a greater degree than patients in the active control arm (mean between-group difference=1.96% mg/dL, SD 9.59% mg/dL; 95% CI −3.81 to −0.125; *P*=.04). We found no differences in intervention effects at 0 to 6 months based on subgroups of sex, race and ethnicity, language preference, health literacy, baseline frequency of mobile technology use, physical proximity to supporters, or baseline social support.

### Subgroup Analyses of Secondary Outcome: 6- to 12-Month Maintenance of $HbA_{1c}$ Level

In the same prespecified subgroup analysis as that of the 0- to 6-month time frame, we found that, among patients with a new diagnosis of diabetes, intervention group patients improved their $HbA_{1c}$ level to a greater degree than patients in the active control arm, with a predicted between-group difference of 2.4% mg/dL (SD 10.15% mg/dL; 95% CI −4.33 to −0.47; *P*=.002) at 12 months. We also found that patients who preferred SMS text messages in English maintained a better glycemic control through the mHealth social support intervention compared to the active control arm, with a predicted between-group difference of 2.53% mg/dL (SD 8.50% mg/dL; 95% CI −4.15 to −0.91; *P*=.02) at 12 months. We found no differences in $HbA_{1c}$ level at 6 to 12 months based on sex, race and ethnicity, health literacy, baseline frequency of mobile technology use, physical proximity to supporters, and baseline social support.

### Safety

The study group had a low adverse event profile. One patient's death due to urosepsis in the intervention arm during the postintervention maintenance phase was determined to be unrelated to the intervention after review by the local institutional review board. Severe hypoglycemic events (blood glucose of <70 mg/dL) at 6 months were self-reported in 20% (9/46) of intervention arm patients reporting at least one episode during the intervention phase and 37% (19/52) of active control arm patients reporting at least one hypoglycemic event during the intervention phase (*P*=.05).

## Discussion

### Principal Findings

In this study of augmenting existing social support via mHealth for the improvement in diabetes of safety-net ED patients, we found that all patients improved their glycemic control and self-management behaviors to a clinically significant degree. In the overall between-group analysis, we did not find that the mHealth social support intervention provided additional benefit over an active control condition of a pamphlet-based support curriculum sent to supporters. Both groups showed significant $HbA_{1c}$ level improvements (combined group change=1.36% mg/dL, SD 2.42% mg/dL; 95% CI 0.87-1.83), with no group difference (group mean difference=0.14% mg/dL, SD 4.88; 95% CI −1.11 to 0.83) at 6 months. At 12 months, both groups maintained their improved $HbA_{1c}$ levels, with a combined mean change from 6 months of 0.06% mg/dL (SD 1.89% mg/dL; 95% CI −0.34 to 0.47) and no clinically meaningful difference between groups. No differences were observed in safety events. In subgroup analyses, patients recently diagnosed with diabetes in the mHealth social support group improved their glycemic control to a greater degree compared to the standard social support group (between-group difference of 1.96% mg/dL, SD 9.59% mg/dL; 95% CI −3.81 to −0.125; *P*=.04)

### Comparison to Previous Literature

In previous studies, we found similar improvements in glycemic control, self-management behaviors, psychological outcomes, and social support measures to those found between the intervention and active control groups in our study. A previous pooled analyses of mHealth interventions to improve diabetes self-management showed mean $HbA_{1c}$ level improvements of 0.5% across types of diabetes and mHealth modalities [33], whereas a previous meta-analysis of 9 traditional social support interventions for diabetes self-management showed an improvement in $HbA_{1c}$ level of 0.25% at 3 months (95% CI −0.40 to −0.11) [34]. There is not sufficient literature to generate pooled estimates of mHealth-/eHealth-based social support for diabetes self-management [35]. As there was no placebo or sham message control group in this trial, the potential benefit of the patient-focused TExT-MED plus FANS social support augmentation via mHealth may be subject to a floor effect, with minimal improvement possible after the patient-focused intervention. In this study, we found a combined group $HbA_{1c}$ level improvement of 1.36% mg/dL (SD 2.42% mg/dL; 95% CI 0.87-1.83) and maintenance of that improvement at 12 months with a washout period change of 0.06% (SD 1.89% mg/dL; 95% CI −0.47 to 0.34). The larger improvement in $HbA_{1c}$ levels found in this study compared with previous literature is encouraging, suggesting that the addition of social supporters to an mHealth diabetes program, either via mHealth or standard methods, has the potential to improve the long-term health outcomes of socially vulnerable patients. In addition, we found that the intervention group reported fewer instances of hypoglycemia, an important safety outcome. mHealth social support augmentation has high potential to be translated to a system-wide intervention given the possibility of remote



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self-enrollment by patients and supporters, automated delivery, and minimal provider time required.

Patients who benefitted the most from the mHealth-augmented social support from the FANS intervention over the active control non-mHealth support were patients who were diagnosed with diabetes in the year before enrollment, highlighting the importance of activating social support when establishing strong self-management behaviors early in a diagnosis. Diabetes and other chronic medical conditions require complex lifestyle changes for the patient and their family members. Patients and family members may be largely unfamiliar with the best self-management practices [36-38]. A Cochrane Review analysis of a diabetes self-management education intervention versus standard care for patients with newly diagnosed diabetes showed mean differences in $HbA_{1c}$ levels (−0.21%, 95% CI −0.38 to −0.04) 12 months after the initial intervention that consisted of educational materials [39]. National and international guidelines recommend that diabetes self-management education and support be provided to patients with diabetes upon their initial diagnosis, and this benefit is covered by many medical insurers [40,41]. However, <10% of patients receive this training internationally, with even lower rates in the United States and in underresourced environments [42-44]. In addition, there are disparities in barriers to attendance to these trainings by type of medical insurance, socioeconomic status, language, and mental health conditions [42,45,46]. Educational interventions for those with newly diagnosed diabetes need to reach patients and their families at the critical time when their health behaviors require drastic change. mHealth-based training that incorporates family members and close friends, such as TExT-MED+FANS, can overcome these barriers.

Despite our efforts to specifically address the needs of a predominantly Spanish-speaking population at our ED, including careful translation of messages and extensive pretesting for cultural and linguistic congruency [12], patients who preferred SMS text messages in English maintained their improvements in glycemic control to a greater degree. This language disparity speaks to the continued obstacles that Spanish-speaking and other non–English-speaking patients experience in accessing providers who are culturally competent and able to speak their preferred language, resulting in poor health outcomes. Spanish speakers in the United States are disproportionately burdened by type 2 diabetes compared to their English-speaking counterparts and face increased barriers to self-management support, especially when they have a non–language-congruent primary health care provider [47-49]. However, Spanish-speaking groups have benefited from mHealth interventions—the Spanish-speaking and medically underserved patients who enrolled in the Vida Health Diabetes Management Program (a novel, culturally adapted, Spanish-language mHealth diabetes program for glycemic control based out of continuity care clinics) showed an impressive decrease in $HbA_{1c}$ levels of −1.23% at 1 year after enrollment [50]. Our initial TExT-MED patient-focused curriculum showed a 0.8% decrease in $HbA_{1c}$ levels among Spanish-speaking ED patients at 6 months after enrollment [9]. The critical link in addressing language and cultural barriers to adequate continuity of care for diabetes management may not be fully addressed in individual-level interventions such as SMS text messages; integration into patient-centered medical homes may be required to improve patient outcomes in linguistically underserved communities.

A relatively unique feature of this study is the requirement that all patients select a family member or friend to be a supporter. Several trials of social support have shown improvements in diabetes behaviors and glycemic control when a patient elects to enroll a supporter or informal caregiver compared to patients who do not select a supporter [51-53]. However, having higher baseline social support has been associated with improved diabetes control and self-management behaviors in cross-sectional studies [54-56]. One diabetes mHealth social support pilot intervention study for physical activity in a similar population also restricted enrollment to patients who had an available supporter and showed increased perceived social support for the social support arm but no difference in physical activity recorded by a pedometer [57]. By requiring a supporter for all patient participants, we can better understand how augmenting social support adds to patient-focused interventions rather than measuring possible confounding by having enough baseline support to be able to identify a supporter. In our context, we found a comparable benefit between the mHealth-augmented social support intervention and active control condition with a non-mHealth support curriculum when added to the patient-focused curriculum. Importantly, those patients who did not continue with the entire intervention and analysis phase held negative attitudes regarding their baseline social support compared to participants who completed the study. Improvements observed in both groups may reflect patients who most enjoyed having a family member involved, which might overestimate the intervention efficacy in either the mHealth-augmented or traditional social support arms. The method of including a social support person may only need well-designed educational mailing on how to best support a loved one with diabetes and be targeted to patients who have existing strong social support relationships to activate.

## Limitations

Despite the importance of this study in this high-need population, there are several limitations. First, there was no true control group with no activation of supporters, making it difficult to determine what improvements were solely due to the patient messages versus either the mHealth or standard method of social support activation. This would underestimate the overall effect of the TExT-MED+FANS intervention. Assessing the *dose* of messaging was also difficult as there were no messages that bounced back and participants used their own devices, limiting the ability to determine how many messages were actually read. This decision to use participants' own phones and universally compatible SMS text messaging was an important decision to maintain the pragmatic nature of this trial. We attempted a self-report measure of receipt of messages, but all patients and supporters received at least some messages and were not able to quantify the actual number. We are not able to stratify estimates of efficacy by intervention dose. In addition, we did not include a social desirability measure in baseline data, which may impact the self-reported behavior measures. However, given that there was no inactive control group, this likely had limited impact on estimates of between-group



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differences. Health behaviors were measured through self-report; the use of remote pill monitoring, mobile-connected pedometers, and extensive diet records was not possible and limited by the pragmatic nature of this trial. Studies with Wi-Fi-enabled pill counters and pedometers or photograph-captured food diaries would be more accurate but would have more limited data on effectiveness. The population of this study was constrained to ED patients with an $HbA_{1c}$ level of >8.5 mg/dL, which limits generalizability to primary care populations and patients with a more modest need for improvement in their diabetes management. Of note, of 4000 potentially eligible patients, only 166 (4.15%) were enrolled; patients with sufficient technological capacity to engage in mHealth and enough baseline social support to identify and enroll a supporter may have an advantage over the average source population patient. A potentially serious limitation is the significant loss to follow-up in this highly transient patient population. We attempted daily phone calls and SMS text messages, used alternate contact numbers, and also collected values for the primary outcome ($HbA_{1c}$ level) if available in the outcome time window. If the study had been limited to patients who had regular interaction with the health care system and more clinical data to draw from, we would have had a more complete dataset for endpoint measurements. However, we would miss the information from this highly vulnerable population with irregular access to care and infrequent $HbA_{1c}$ measurements. The higher-than-anticipated loss to follow-up rate may have impacted the study's power to detect a difference between the groups. However, the patients who completed the trial were generally similar to those who did not, with the exception that patients who left the study had more negative perceived attitudes toward social support than those who completed the study, potentially increasing the estimated effect of the FANS curriculum via the mHealth or standard approaches as those who stayed in the study may have had higher social support at baseline.

## Conclusions

In this randomized controlled trial of an mHealth-augmented social support curriculum added to an existing patient-focused mHealth program in ED patients with diabetes, engagement of family members via mHealth resulted in improved $HbA_{1c}$ levels, similar to the active control condition of the same patient-focused mHealth program using a pamphlet-based support curriculum sent to family members. The TExT-MED mHealth intervention for patients with or without an mHealth-augmented social support component has the potential to improve the long-term health outcomes of these vulnerable patients and has high potential to be translated to a system-wide intervention given the possibility of remote self-enrollment by patients. Patients who were newly diagnosed with diabetes may have benefited the most from mHealth-augmented social support, with greater and more persistent improvements in glycemic control. Our exploratory findings that the activation of social support through mHealth is most helpful in patients with newly diagnosed diabetes suggest that the first years of a diabetes diagnosis are the period when family members and friends are the most *activable* via mHealth delivery of support person training.

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## Data Availability

The datasets generated or analyzed during this study are not publicly available due institutional regulations but are available from the corresponding author on reasonable request.

## Authors' Contributions

EB was involved in conceptualization, data curation, formal analysis, funding acquisition, investigation, methodology, project administration, resources, supervision, writing—original draft, and writing—review and editing. DH was involved in investigation, resources, and writing—review and editing. MM was involved in conceptualization, funding acquisition, methodology, supervision, and writing—review and editing. WM was involved in data curation, formal analysis, supervision, and writing—review and editing. JM was involved in data curation, formal analysis, project administration, resources, supervision, and writing—review and editing. AA was involved in data curation, project administration, resources, supervision, and writing—review and editing. AHS was involved in methodology, data curation, project administration, resources, supervision, and writing—review and editing. SA was involved in conceptualization, funding acquisition, methodology, supervision, and writing—review and editing. SW was involved in conceptualization, funding acquisition, methodology, supervision, and writing—review and editing.



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## Conflicts of Interest

SA, MM, and EB have received compensation as consultants and on advisory boards from Agile Health on SMS text message–based interventions for patient self-care. No other authors have conflicts to declare.

Multimedia Appendix 1
Baseline characteristics—those lost to follow-up versus those who completed the 6-month assessment.
[DOCX File , 20 KB - diabetes_v10i1e56934_app1.docx ]

Multimedia Appendix 2
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 392 KB - diabetes_v10i1e56934_app2.pdf ]

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## Abbreviations

**ED:** emergency department
**FANS:** Family and Friends Network Support
**$HbA_{1c}$:** glycated hemoglobin
**HIPAA:** Health Insurance Portability and Accountability Act
**mHealth:** mobile health
**TExT-MED:** Trial to Examine Text Messaging in Emergency Department Patients With Diabetes



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# Trends in Mortality From Co-Occurring Diabetes Mellitus and Pneumonia in the United States (1999-2022): Retrospective Analysis of the Centers for Disease Control and Prevention Wide-ranging Online Data for Epidemiologic Research (CDC WONDER) Database

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## Abstract

**Background:** Pneumonia is the most common respiratory tract infection among patients with diabetes, affecting individuals across all age groups and sexes.

**Objective:** This study aims to examine demographic trends in mortality among patients diagnosed with both diabetes mellitus (DM) and pneumonia.

**Methods:** Deidentified death certificate data for DM- and pneumonia-related deaths in adults aged 25 years and older from 1999 to 2022 were obtained from the Centers for Disease Control and Prevention Wide-ranging Online Data for Epidemiologic Research (CDC WONDER) database. Age-adjusted mortality rates (AAMRs) per 1,000,000 population were calculated. The Joinpoint Regression Program was used to evaluate annual percentage changes (APCs) in mortality trends, with statistical significance set at $P<.05$. This study adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for reporting.

**Results:** Between 1999 and 2022, a total of 425,777 deaths were recorded from DM and pneumonia. The overall AAMR declined significantly ($P=.001$) from 98.73 in 1999 to 49.17 in 2016 (APC –4.68), and then surged to 97.66 by 2022 (APC 23.55). Men consistently experienced higher mortality than women throughout the study period. Male AAMR rose from 62.61 in 2016 to 127.05 in 2022 (APC 24.88), while female AAMR increased from 41.05 in 2017 to 75.25 in 2022 (APC 27.60). Race-based analysis demonstrated that American Indian or Alaska Native populations had the highest mortality rates among racial groups. Non-Hispanic White individuals exhibited a significant decline in AAMR ($P=.002$) from 89.76 in 1999 to 44.19 in 2017 (APC −4.58), followed by an increase to 83.11 by 2022 (APC 25.25). Adults aged 65 years or older bore the highest mortality burden, with rates declining steadily to 206.9 in 2017 (APC –5.15) before rising sharply to 371.3 in 2022 (APC 20.01). Nonmetropolitan areas consistently exhibited higher mortality than metropolitan areas, with particularly steep increases after 2018 (APC 64.42). Type-specific mortality revealed that type 1 DM AAMRs declined from 9.2 in 1999 to 1.4 in 2015 (APC –11.94) before rising again. By contrast, type 2 DM AAMRs surged drastically after 2017, peaking at 62.2 in 2020 (APC 58.74) before partially declining to 41.6 by 2022.



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**Conclusions:** DM is associated with an increased risk of mortality following pneumonia, particularly among men, older adults, and American Indian populations. Strengthening health care interventions and policies is essential to curb the rising mortality trend in these at-risk groups.

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**KEYWORDS**

Centers for Disease Control and Prevention Wide-ranging Online Data for Epidemiologic Research; CDC WONDER; diabetes mellitus; pneumonia; mortality trends; United States

## Introduction

Approximately 10% of the US population has diabetes mellitus (DM) [1]. Patients with DM are more susceptible to complications from infectious diseases and are reported to have a 4.4-fold higher risk of bacteremia than those without DM [2].

Among individuals with DM, pneumonia is the most common infection managed in hospitals and the third most common infection treated in emergency departments in the United States [1]. Individuals with diabetes are more prone to pneumonia due to various factors, including hyperglycemia-induced immune dysregulation, declining lung function, and coexisting comorbidities such as cerebrovascular events, cardiovascular disease (CVD), and chronic kidney disease (CKD), all of which adversely impact outcomes in pneumonia [3-5]. However, population-level data on mortality trends for co-occurring DM and pneumonia, particularly across demographic strata, remain limited [6,7]. Therefore, the objective of this study was to evaluate the demographic and regional differences in mortality patterns among patients with both pneumonia and DM.

## Methods

### Screening of Data

The Centers for Disease Control and Prevention Wide-ranging Online Data for Epidemiologic Research (CDC WONDER) database was used for this research. The CDC WONDER database comprises death certificates from all 50 US states and the District of Columbia. Patients with DM were identified using the International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) codes E10-E14, whereas patients with pneumonia were identified with the ICD-10 codes J09-J18. These ICD-10 codes have also been used in previous studies [8-10]. We used the Multiple Cause-of-Death Public Use Record death certificates to select records in which both DM and pneumonia were listed as either contributing or underlying causes of death [11]. Adults in our study were defined as individuals aged 25 years or older, consistent with prior CDC WONDER studies that use this threshold to define adulthood in the context of chronic disease mortality trends [12,13]. While this excludes younger populations, deaths in these age groups are rare and less likely to reflect long-term cardiometabolic complications.

### Ethics Considerations

The data provided in the database are deidentified by the government; therefore, our study is exempt from institutional review board approval. The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines were followed for reporting.

### Data Extraction

Data on deaths due to coexisting DM and pneumonia, including population size and location, were extracted for the period between January 1999 and December 2022. Demographic variables, such as gender/sex, race/ethnicity, age groups, urban-rural classification, and census regions, were analyzed for the same period. Based on previous analyses of the CDC WONDER database, race/ethnicity was categorized as Hispanic or Latino; Non-Hispanic (NH) American Indians or Alaska Natives (ANs); NH Asian or Pacific Islanders; NH Black or African Americans; and NH White individuals. This classification is based on data reported on death certificates in accordance with the US Office of Budget and Management Guidelines [14]. Census regions were divided into Northeast, Midwest, West, and South, based on US Census Bureau definitions. The National Center for Health Statistics Urban-Rural Classification Scheme was used to categorize the population into 2 groups, based on the 2013 US Census: metropolitan (large metropolitan area [population ≥1 million] and medium/small metropolitan area [population 50,000 - 999,999]) and nonmetropolitan (population <50,000). While the CDC WONDER database provides nationally representative data, it lacks individual-level clinical variables (eg, vital signs and treatment details), which are crucial for understanding the extent of disease.

### Data Analysis

The age-adjusted mortality rate (AAMR) per 1,000,000 people was calculated by standardizing DM- and pneumonia-related deaths to the US population in 2000 [15]. AAMRs for all demographic variables, including sex/gender, race/ethnicity, age groups, urbanization status, and census regions, were calculated, as the CDC WONDER database provides population sizes stratified by demographic and regional factors and age groups for each specific year [14].

The data for the urbanization group differed from all the other variables in that the AAMRs could only be calculated up to 2020. This is because standardized population data for 2021 and 2022 are not available in the CDC WONDER database. The database also provided 95% CIs for the AAMRs. Trends in AAMRs were analyzed using the Joinpoint Regression Program (version 5.0; National Cancer Institute), which calculates the annual percentage change (APC) [16]. This program uses log-linear regression models to detect temporal variations and identify significant changes in AAMRs over time. APCs with 95% CIs for AAMR were estimated at the identified



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line segments connecting the joinpoints, using the Monte Carlo permutation test. Based on the results of the 2-tailed *t* test, APCs were considered to have significantly increased or decreased only if the slope representing the change in mortality differed significantly from 0. The significance level was set at $P<.05$.

### Trend Analysis

Temporal trends in annual AAMRs from 1999 to 2022 were analyzed using the Joinpoint Regression Program (version 5.0; National Cancer Institute). Rates were log-transformed and modeled to identify inflection points in the trend. Joinpoint settings were as follows: minimum joinpoints=0 and maximum=4, with a minimum of 2 observations required before the first joinpoint, after the last joinpoint, and between joinpoints. Model selection used the weighted Bayesian information criterion (weighted BIC), with the permutation test seed set to 7160 and the empirical quantile seed set to 10,000 for reproducibility. For the overall data, the weighted BIC selected 2 joinpoints. Subgroup analyses by sex, age group, race/ethnicity, urban-rural classification, region, and diabetes type used identical settings; the weighted BIC also selected 2 joinpoints in each subgroup, facilitating consistent comparison of segment timing. APCs and 95% CIs were reported for each segment. Observed versus fitted rates were exported (Export.Data.txt); residuals on the log scale (Residual=ln[observed rate] − ln[fitted rate]) were computed. For the overall model, the Durbin-Watson statistic was 1.62, indicating mild positive autocorrelation. Basic visual inspection of residuals did not reveal extreme or systematic patterns. Formal residual autocorrelation tests and sensitivity analyses (eg, varying the minimum number of observations between joinpoints or the maximum number of joinpoints) were not performed for subgroups due to resource constraints. Nonetheless, we considered the assumption of independence to be approximately reasonable, while acknowledging this as a limitation.

### Ethical Considerations

This study utilized data from the CDC WONDER database, a publicly available dataset [17]. Therefore, institutional review board approval and informed consent are not applicable.

## Results

### Annual Trends for Overall Diabetes- and Pneumonia-Related Mortality

A total of 425,777 deaths related to DM and pneumonia occurred between 1999 and 2022. The overall AAMR for DM and pneumonia among individuals aged 25 years and above was 98.73 at the start of the study period in 1999, which decreased to 49.17 by 2016 (APC −4.68, 95% CI −9.06 to −2.04). From 2016 onward, there was a significant increase in the AAMR ($P$=.001), reaching 97.66 by 2022 (APC 23.55, 95% CI 11.59-55.40; Table 1, Figure 1).



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**Table .** Annual percent change in age-adjusted mortality rates per 1,000,000 for diabetes mellitus– and pneumonia-related deaths among older adults in the United States, 1999-2022.

| Year interval | Annual percent change (95% CI) |
|---|---|
| Overall | |
| 1999 - 2016 | −4.68[a] (−9.06 to −2.04) |
| 2016 - 2022 | 23.56[a] (11.60 to 55.41) |
| Men | |
| 1999 - 2016 | −4.78[a] (−9.47 to −1.93) |
| 2016 - 2022 | 24.89[a] (12.54 to 57.56) |
| Women | |
| 1999 - 2017 | −4.30[a] (−8.08 to −1.96) |
| 2017 - 2022 | 27.61[a] (11.63 to 68.61) |
| Young age | |
| 1999 - 2017 | 0.92 (−8.91 to 5.42) |
| 2017 - 2022 | 40.34[a] (15.99 to 124.26) |
| Middle age | |
| 1999 - 2016 | −2.34 (−10.49 to 2.44) |
| 2016 - 2022 | 35.78[a] (17.83 to 93.68) |
| Old age | |
| 1999 - 2016 | −5.16[a] (−8.76 to −2.95) |
| 2016 - 2022 | 20.01[a] (9.84 to 46.03) |
| NH[b] White | |
| 1999 - 2017 | −4.59[a] (−7.22 to −2.78) |
| 2017 - 2022 | 25.25[a] (12.68 to 53.96) |
| NH American Indian or Alaska Native | |
| 1999 - 2016 | −3.18 (−11.92 to 1.59) |
| 2016 - 2022 | 29.34[a] (13.82 to 72.43) |
| NH Black or African American | |
| 1999 - 2016 | −4.86[a] (−11.21 to −1.50) |
| 2016 - 2022 | 25.28[a] (10.59 to 64.76) |
| Hispanic or Latino | |
| 1999 - 2016 | −3.75 (−18.13 to 2.64) |
| 2016 - 2022 | 32.28[a] (11.98 to 96.77) |
| NH Asian or Pacific Islander | |
| 1999 - 2016 | −5.17[a] (−11.18 to −1.49) |
| 2016 - 2022 | 20.37[a] (8.38 to 52.55) |
| Nonmetropolitan areas | |
| 1999 - 2018 | −3.87[a] (−5.35 to −2.74) |
| 2018 - 2020 | 64.43[a] (32.82 to 83.88) |
| Metropolitan area | |

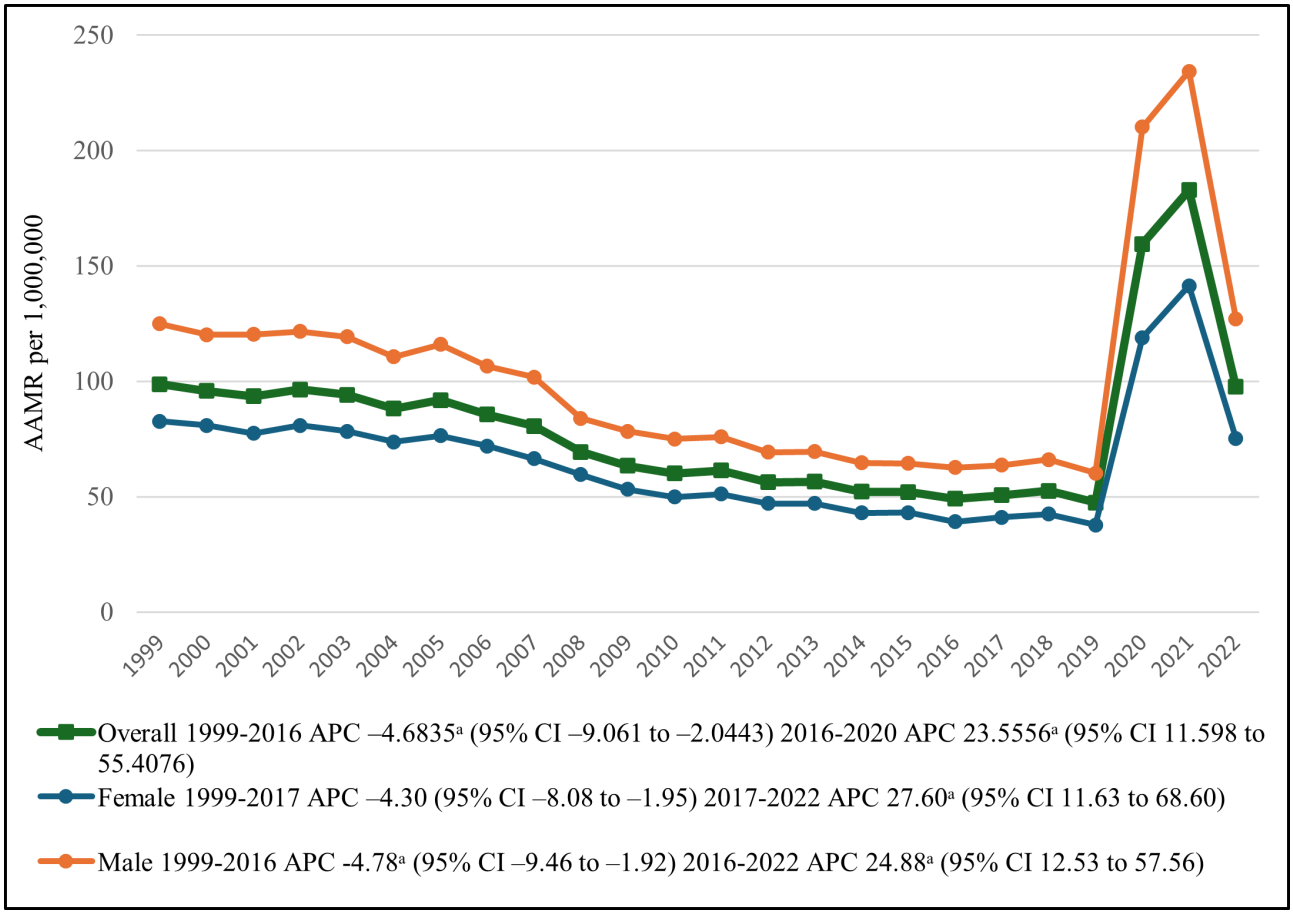


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| Year interval | Annual percent change (95% CI) |
|---|---|
| 1999 - 2018 | −4.64[a] (−6.50 to −3.28) |
| 2018 - 2020 | 85.94[a] (48.88 to 110.37) |

[a]Indicates that the APC is significantly different from zero at α=.05.
[b]NH: non-Hispanic.

**Figure 1.** Overall and sex-stratified diabetes mellitus– and pneumonia-related age-adjusted mortality rates (AAMRs) per 1,000,000 in the United States, 1999-2022. [a]The APC is significantly different from zero at α=.05. APC: annual percentage change.




## Annual Trends Stratified by Sex

Of the 425,777 deaths, 224,323 (52.69%) were men, and 201,454 (47.31%) were women. Overall, men consistently had higher AAMRs than women throughout the study period. Among men, the AAMR declined from 1999 to 2016 (APC –4.78, 95% CI –9.46 to –1.92), followed by a sharp increase from 62.61 in 2016 to 127.05 in 2022 (APC 24.88, 95% CI 12.53-57.56). By contrast, women's AAMR declined from 1999 to 2017 (APC −4.30, 95% CI−8.08 to −1.95), then rose markedly from 41.05 in 2017 to 75.25 in 2022 (APC 27.60, 95% CI 11.63-68.60; Tables 1 and 2, Figure 1).



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**Table .** Overall and sex - stratified diabetes mellitus– and pneumonia-related age-adjusted mortality rates per 1,000,000 in the United States, 1999-2022.

| Year | Men, age-adjusted rate (95% CI) | Women, age-adjusted rate (95% CI) | Overall, age-adjusted rate (95% CI) |
|---|---|---|---|
| 1999 | 124.94 (122.22 - 127.67) | 82.67 (80.95 - 84.39) | 98.73 (97.27 - 100.20) |
| 2000 | 120.21 (117.56 - 122.86) | 80.87 (79.18 - 82.56) | 95.82 (94.38 - 97.26) |
| 2001 | 120.32 (117.70 - 122.95) | 77.44 (75.79 - 79.09) | 93.53 (92.12 - 94.94) |
| 2002 | 121.61 (119.00 - 124.22) | 80.96 (79.28 - 82.63) | 96.51 (95.09 - 97.93) |
| 2003 | 119.27 (116.72 - 121.82) | 78.32 (76.68 - 79.95) | 94.13 (92.73 - 95.52) |
| 2004 | 110.65 (108.22 - 113.07) | 73.80 (72.22 - 75.38) | 88.18 (86.84 - 89.51) |
| 2005 | 115.99 (113.54 - 118.44) | 76.39 (74.79 - 77.99) | 91.90 (90.54 - 93.25) |
| 2006 | 106.52 (104.21 - 108.84) | 72.03 (70.48 - 73.57) | 85.61 (84.31 - 86.90) |
| 2007 | 101.81 (99.58 - 104.04) | 66.54 (65.06 - 68.01) | 80.63 (79.38 - 81.87) |
| 2008 | 83.98 (81.98 - 85.98) | 59.59 (58.21 - 60.97) | 69.43 (68.29 - 70.58) |
| 2009 | 78.34 (76.43 - 80.24) | 53.22 (51.91 - 54.52) | 63.39 (62.31 - 64.48) |
| 2010 | 75.05 (73.20 - 76.90) | 49.86 (48.61 - 51.11) | 60.15 (59.10 - 61.20) |
| 2011 | 75.95 (74.12 - 77.77) | 51.17 (49.92 - 52.42) | 61.39 (60.34 - 62.43) |
| 2012 | 69.24 (67.52 - 70.96) | 47.08 (45.89 - 48.28) | 56.22 (55.23 - 57.21) |
| 2013 | 69.54 (67.84 - 71.23) | 47.04 (45.85 - 48.22) | 56.54 (55.55 - 57.52) |
| 2014 | 64.72 (63.11 - 66.33) | 43.00 (41.88 - 44.13) | 52.16 (51.23 - 53.10) |
| 2015 | 64.43 (62.84 - 66.02) | 43.10 (41.99 - 44.21) | 52.09 (51.16 - 53.01) |
| 2016 | 62.61 (61.07 - 64.15) | 39.20 (38.15 - 40.26) | 49.17 (48.28 - 50.06) |
| 2017 | 63.63 (62.09 - 65.17) | 41.05 (39.98 - 42.12) | 50.61 (49.72 - 51.50) |
| 2018 | 66.07 (64.53 - 67.62) | 42.47 (41.39 - 43.55) | 52.59 (51.69 - 53.49) |
| 2019 | 60.20 (58.75 - 61.65) | 37.82 (36.81 - 38.83) | 47.53 (46.68 - 48.37) |
| 2020 | 210.24 (207.58 - 212.90) | 119.00 (117.20 - 120.79) | 159.52 (157.98 - 161.06) |
| 2021 | 234.26 (231.42 - 237.10) | 75.25 (73.83 - 76.66) | 182.84 (181.17 - 184.52) |
| 2022 | 127.05 (124.98 - 129.12) | 83.69 (83.01 - 84.38) | 97.66 (96.47 - 98.86) |
| Total | 99.43 (99.02 - 99.84) | 99.43 (99.02 - 99.84) | 80.65 (80.00 - 81.30) |

## Annual Trends Stratified by Race

Racial analysis revealed that the NH White population had the highest burden of deaths (287,507/425,777, 67.53%), followed by NH Black or African American (60,507/425,777, 14.21%), Hispanic or Latino (56,115/425,777, 13.18%), and NH Asian or Pacific Islander individuals (16744/425,777, 3.93%). NH AI or AN individuals had the lowest number of reported deaths (4904/425,777, 1.15%). After stratification by race/ethnicity, AAMRs were the highest among AI or AN individuals, followed by Hispanic or Latino, NH Black or African American, NH Asian or Pacific Islander, and NH White individuals. The AAMR of both NH Black or African American and NH Asian or Pacific Islander individuals decreased significantly ($P$=.04) from 1999 to 2016, followed by a significant steep increase ($P$=.04) through 2022. Hispanic or Latino and NH AI individuals differed in that their AAMRs did not show a significant decrease ($P$=.06) from 1999 to 2016; however, from 2016 onward, there was a significant increase ($P$=.001) until 2022. NH White individuals differed from all other racial groups in that their AAMR decreased significantly ($P$=.002) from 89.76 in 1999 to 44.19 in 2017 (APC –4.58, 95% CI −7.21 to −2.78), followed by a significant increase ($P$=.001), with the AAMR reaching 83.11 by 2022 (APC 25.25, 95% CI 12.67-53.96; Tables 1 and 3, Figure 2).



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**Table .** Diabetes mellitus– and pneumonia–related age-adjusted mortality rates per 1,000,000.

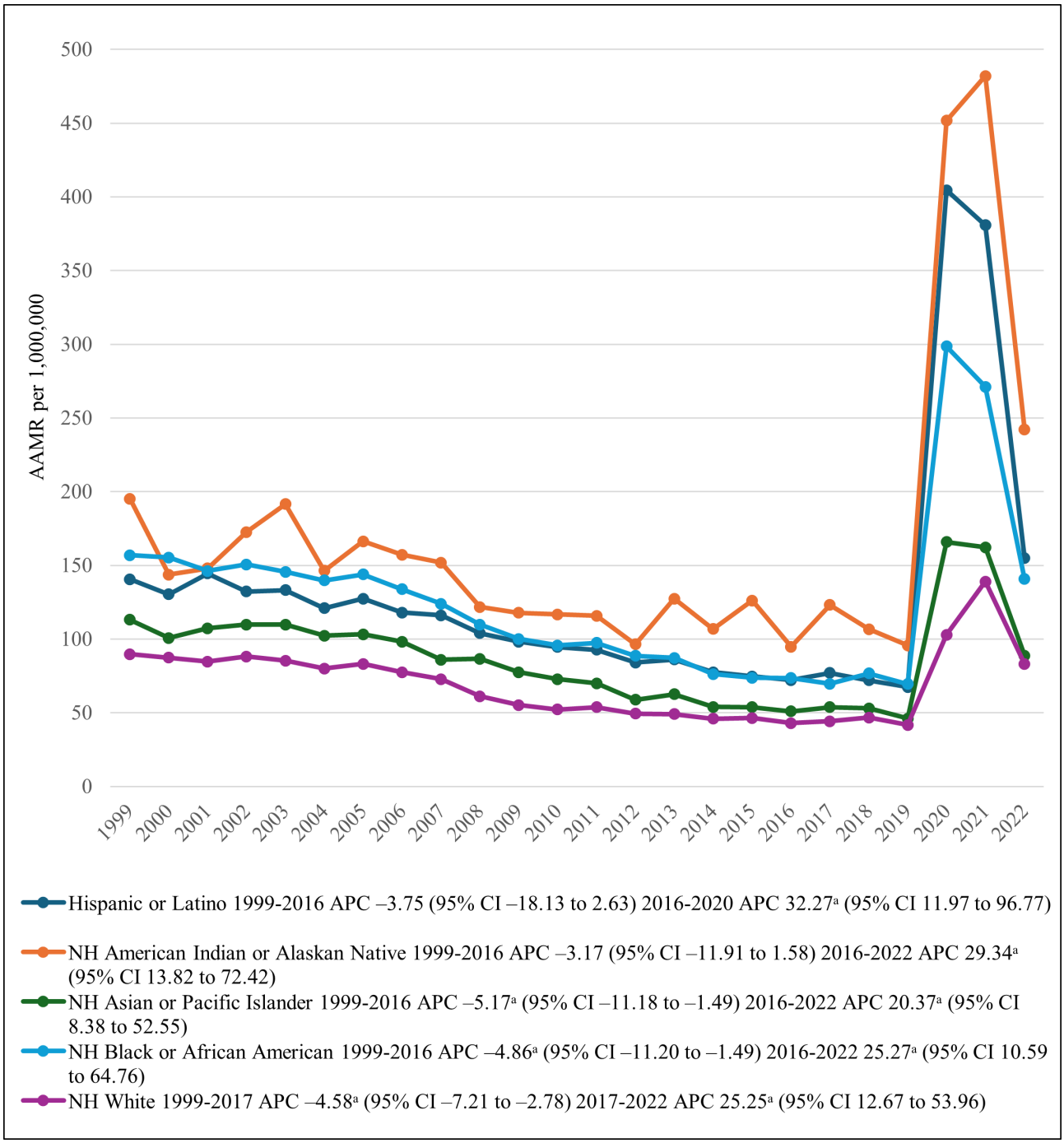
| Year | NH Asian or Pacific Islander, age-adjusted rate (95% CI) | NH[a] American Indian or Alaska Native, age-adjusted rate (95% CI) | NH Black or African American, age-adjusted rate (95% CI) | NH White, age-adjusted rate (95% CI) | Hispanic or Latino, age-adjusted rate (95% CI) |
|---|---|---|---|---|---|
| 1999 | 113.1 (101.59 - 124.62) | 195.13 (159.88 - 230.37) | 156.91 (150.42 - 163.41) | 89.76 (88.24 - 91.28) | 140.62 (132.13 - 149.11) |
| 2000 | 100.77 (90.30 - 111.24) | 143.76 (114.68 - 172.85) | 155.40 (148.96 - 161.84) | 87.43 (85.93 - 88.92) | 130.35 (122.40 - 138.30) |
| 2001 | 107.30 (96.94 - 117.65) | 148.00 (119.17 - 176.82) | 146.15 (139.95 - 152.35) | 84.66 (83.20 - 86.12) | 144.52 (136.35 - 152.69) |
| 2002 | 109.89 (99.79 - 120.00) | 172.57 (141.61 - 203.53) | 150.69 (144.42 - 156.96) | 88.13 (86.65 - 89.62) | 132.26 (124.66 - 139.86) |
| 2003 | 109.78 (100.00 - 119.57) | 191.5 (159.06 - 223.95) | 145.56 (139.43 - 151.68) | 85.43 (83.98 - 86.88) | 133.28 (125.88 - 140.69) |
| 2004 | 102.32 (93.13 - 111.52) | 146.36 (119.32 - 173.39) | 139.77 (133.83 - 145.72) | 80.00 (78.60 - 81.40) | 120.92 (114.04 - 127.80) |
| 2005 | 103.23 (94.38 - 112.09) | 166.35 (136.73 - 195.98) | 143.93 (138.00 - 149.86) | 83.14 (81.72 - 84.56) | 127.45 (120.62 - 134.28) |
| 2006 | 98.25 (89.87 - 106.64) | 157.21 (129.67 - 184.75) | 133.91 (128.23 - 139.58) | 77.48 (76.12 - 78.84) | 118.05 (111.62 - 124.48) |
| 2007 | 86.04 (78.42 - 93.67) | 151.92 (125.28 - 178.55) | 123.99 (118.60 - 129.39) | 72.87 (71.56 - 74.18) | 116.12 (109.91 - 122.33) |
| 2008 | 86.60 (79.18 - 94.01) | 121.77 (99.20 - 144.34) | 109.82 (104.82 - 114.82) | 61.26 (60.06 - 62.45) | 103.98 (98.28 - 109.68) |
| 2009 | 77.51 (70.76 - 84.27) | 117.82 (95.53 - 140.12) | 100.07 (95.36 - 104.78) | 55.31 (54.18 - 56.45) | 98.18 (92.89 - 103.48) |
| 2010 | 72.76 (66.35 - 79.17) | 116.68 (94.89 - 138.48) | 95.65 (91.08 - 100.22) | 52.31 (51.22 - 53.40) | 94.56 (89.39 - 99.72) |
| 2011 | 69.99 (63.99 - 76.00) | 115.75 (94.65 - 136.85) | 97.48 (92.94 - 102.01) | 53.76 (52.67 - 54.86) | 92.69 (87.78 - 97.59) |
| 2012 | 58.84 (53.49 - 64.19) | 96.50 (77.69 - 115.31) | 88.72 (84.48 - 92.95) | 49.47 (48.42 - 50.52) | 84.14 (79.62 - 88.67) |
| 2013 | 62.55 (57.25 - 67.85) | 127.44 (106.49 - 148.39) | 87.25 (83.13 - 91.38) | 49.14 (48.10 - 50.17) | 86.18 (81.73 - 90.62) |
| 2014 | 53.90 (49.18 - 58.62) | 106.82 (88.30 - 125.34) | 76.19 (72.41 - 79.97) | 45.98 (44.98 - 46.98) | 77.53 (73.45 - 81.60) |
| 2015 | 53.82 (49.26 - 58.39) | 126.13 (106.66 - 145.61) | 73.77 (70.11 - 77.43) | 46.40 (45.40 - 47.40) | 74.72 (70.83 - 78.62) |
| 2016 | 50.94 (46.63 - 55.25) | 94.76 (77.77 - 111.75) | 73.60 (70.00 - 77.20) | 42.98 (42.03 - 43.93) | 72.22 (68.49 - 75.96) |
| 2017 | 53.83 (49.53 - 58.13) | 123.20 (104.90 - 141.50) | 69.60 (66.17 - 73.03) | 44.19 (43.23 - 45.15) | 77.01 (73.28 - 80.74) |
| 2018 | 53.12 (48.98 - 57.25) | 106.65 (89.98 - 123.32) | 76.74 (73.19 - 80.29) | 46.68 (45.70 - 47.67) | 72.08 (68.55 - 75.62) |
| 2019 | 46.20 (42.46 - 49.95) | 95.65 (80.41 - 110.89) | 69.58 (66.25 - 72.91) | 41.71 (40.79 - 42.63) | 67.54 (64.20 - 70.88) |
| 2020 | 165.78 (158.90 - 172.67) | 451.73 (419.44 - 484.02) | 298.61 (291.87 - 305.35) | 102.85 (101.41 - 104.28) | 404.48 (396.66 - 412.31) |
| 2021 | 85.50 (80.60 - 90.41) | 482.03 (447.47 - 516.60) | 271.20 (264.75 - 277.64) | 138.97 (137.24 - 140.69) | 380.84 (373.36 - 388.32) |
| 2022 | 88.75 (83.82 - 93.68) | 242.20 (218.02 - 266.38) | 140.80 (136.19 - 145.41) | 83.11 (81.81 - 84.40) | 155.03 (150.24 - 159.82) |
| Total | 91.01 (89.48 - 92.54) | 168.31 (163.10 - 173.52) | 130.47 (129.39 - 131.55) | 67.42 (67.15 - 67.69) | 130.53 (129.26 - 131.80) |

[a]NH: non-Hispanic.



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**Figure 2.** Diabetes mellitus– and pneumonia-related age-adjusted mortality rates (AAMRs) per 1,000,000, stratified by race in the United States, 1999-2022. [a]The APC is significantly different from zero at α=.05. APC: annual percentage change; NH: non-Hispanic.




## Annual Trends Stratified by Age Groups

The older adult group (65 - 85+ years) accounted for a whopping 341,295 deaths (constituting 80.16% of all mortality; N=425,777), distantly followed by the middle-aged (45 - 64 years) and young adult groups (25 - 44 years), with 73,817 (17.34%) and 10,665 (2.50%) deaths, respectively. Overall, the older adult group (65 - 85+ years) had the highest AAMR, followed by the middle-aged group (45 - 64 years) and the young adult group (25 - 44 years). Starting in 1999, both young adult and middle-aged group AAMRs remained relatively stable until 2016, followed by a significant and dramatic increase (*P*=.001) through 2022. Older adults differed from the other 2 groups in that their AAMR steadily decreased from 440.9 in 1999 to 206.9 in 2017 (APC −5.15, 95% CI −8.76 to −2.94). From 2017 to 2022, the AAMR significantly increased (*P*=.001), reaching 371.3 (APC 20.01, 95% CI 9.84-46.02; Tables 1 and 4, Figure 3).



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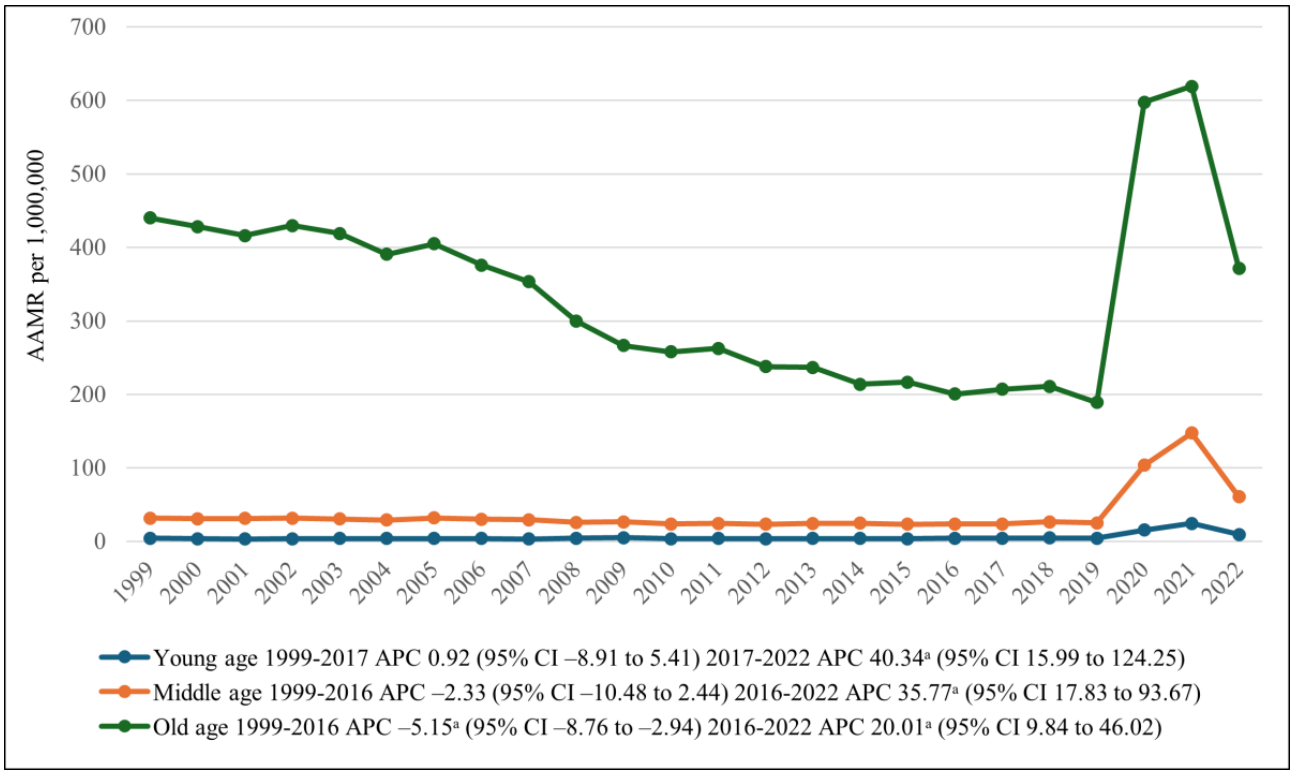
**Table .** Diabetes mellitus– and pneumonia-related age-adjusted mortality rates per 1,000,000, stratified by age groups in the United States, 1999-2022.

| Year | Young adults (25 - 44 years), age-adjusted rate (95% CI) | Middle aged (45 - 64 years), age-adjusted rate (95% CI) | Older adults (65 - 85+ years), age-adjusted rate (95% CI) |
|---|---|---|---|
| 1999 | 4.13 (3.69 - 4.56) | 31.50 (30.09 - 32.92) | 440.09 (433.08 - 447.10) |
| 2000 | 3.45 (3.06 - 3.85) | 30.74 (29.35 - 32.12) | 428.12 (421.24 - 434.99) |
| 2001 | 3.27 (2.88 - 3.66) | 31.16 (29.79 - 32.52) | 416.08 (409.35 - 422.81) |
| 2002 | 3.66 (3.25 - 4.08) | 31.64 (30.30 - 32.99) | 429.58 (422.78 - 436.38) |
| 2003 | 3.82 (3.39 - 4.24) | 30.52 (29.23 - 31.82) | 418.96 (412.29 - 425.63) |
| 2004 | 3.98 (3.55 - 4.42) | 29.07 (27.83 - 30.31) | 390.69 (384.28 - 397.10) |
| 2005 | 3.93 (3.49 - 4.36) | 31.95 (30.67 - 33.23) | 404.79 (398.32 - 411.26) |
| 2006 | 3.88 (3.45 - 4.31) | 30.06 (28.85 - 31.28) | 376.03 (369.85 - 382.22) |
| 2007 | 3.31 (2.91 - 3.71) | 29.37 (28.18 - 30.56) | 353.14 (347.19 - 359.08) |
| 2008 | 4.13 (3.68 - 4.58) | 26.02 (24.91 - 27.13) | 299.79 (294.37 - 305.21) |
| 2009 | 4.89 (4.40 - 5.38) | 26.45 (25.34 - 27.55) | 266.35 (261.28 - 271.42) |
| 2010 | 3.63 (3.20 - 4.05) | 23.55 (22.52 - 24.58) | 257.81 (252.86 - 262.76) |
| 2011 | 3.85 (3.41 - 4.28) | 24.24 (23.20 - 25.27) | 262.43 (257.50 - 267.36) |
| 2012 | 3.75 (3.32 - 4.18) | 23.36 (22.34 - 24.38) | 237.75 (233.11 - 242.39) |
| 2013 | 3.99 (3.55 - 4.43) | 24.45 (23.42 - 25.48) | 236.90 (232.33 - 241.47) |
| 2014 | 4.08 (3.63 - 4.53) | 24.81 (23.77 - 25.85) | 213.68 (209.38 - 217.97) |
| 2015 | 3.65 (3.23 - 4.08) | 23.39 (22.39 - 24.40) | 216.77 (212.50 - 221.04) |
| 2016 | 4.18 (3.73 - 4.63) | 23.51 (22.51 - 24.52) | 200.37 (196.31 - 204.43) |
| 2017 | 4.27 (3.82 - 4.73) | 23.86 (22.85 - 24.88) | 206.93 (202.87 - 211.00) |
| 2018 | 4.80 (4.32 - 5.28) | 26.74 (25.65 - 27.82) | 210.76 (206.72 - 214.81) |
| 2019 | 4.21 (3.76 - 4.66) | 25.15 (24.09 - 26.21) | 189.05 (185.28 - 192.82) |
| 2020 | 15.31 (14.46 - 16.16) | 103.79 (101.64 - 105.94) | 597.69 (591.07 - 604.30) |
| 2021 | 24.31 (23.23 - 25.38) | 147.52 (144.93 - 150.11) | 618.97 (612.14 - 625.79) |
| 2022 | 9.16 (8.51 - 9.82) | 60.75 (59.09 - 62.40) | 371.34 (366.18 - 376.49) |
| Total | 5.53 (5.41 - 5.65) | 34.09 (33.82 - 34.36) | 330.07 (329.01 - 331.13) |



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**Figure 3.** Diabetes mellitus– and pneumonia-related age-adjusted mortality rates (AAMRs) per 1,000,000, stratified by age group in the United States, 1999-2022. [a]The APC is significantly different from zero at α=.05. APC: annual percentage change.




## Annual Trends Stratified by Geographic Region

As data on urbanization status are available only up to 2020, a total of 351,840 deaths could be recorded, with 278,378 (79.12%) deaths occurring in metropolitan areas and 73,462 (20.88%) in nonmetropolitan areas. Overall, nonmetropolitan areas had higher AAMRs than metropolitan areas. The AAMR in metropolitan areas decreased from 1999 to 2018 (APC −4.64, 95% CI−6.49 to −3.27), followed by a significantly steeper increase (*P*=.002) through 2020 (APC 85.93, 95% CI 48.88 to −110.37). The AAMR in nonmetropolitan areas followed a similar trend, decreasing from 110 in 1999 to 67.61 in 2018 (APC −3.86, 95% CI −5.34 to −2.73). By 2020, the AAMR had significantly increased (*P*=.002) to 168.76 (APC 64.42, 95% CI 32.82-83.88; Tables 1 and 5, Figure 4).

The South region bore the greatest burden of deaths, with 159,187 out of 425,777 (37.39%) fatalities, followed by the West (104,971 deaths, 24.65%), Midwest (92,161 deaths, 21.65%), and Northeast (69,458 deaths, 16.31%) regions. Overall, the AAMR was highest in the West region, followed by the South, Midwest, and Northeast regions. The Northeast and South regions showed a significant decrease in AAMR (*P*=.002) from 1999 to 2016, followed by a significant increase (*P*=.001) through 2022. By contrast, the West and Midwest regions experienced a decrease in AAMR from 1999 to 2017, after which, similar to the other 2 regions, AAMRs increased through 2022 (Tables 1 and 6, Figure 5).



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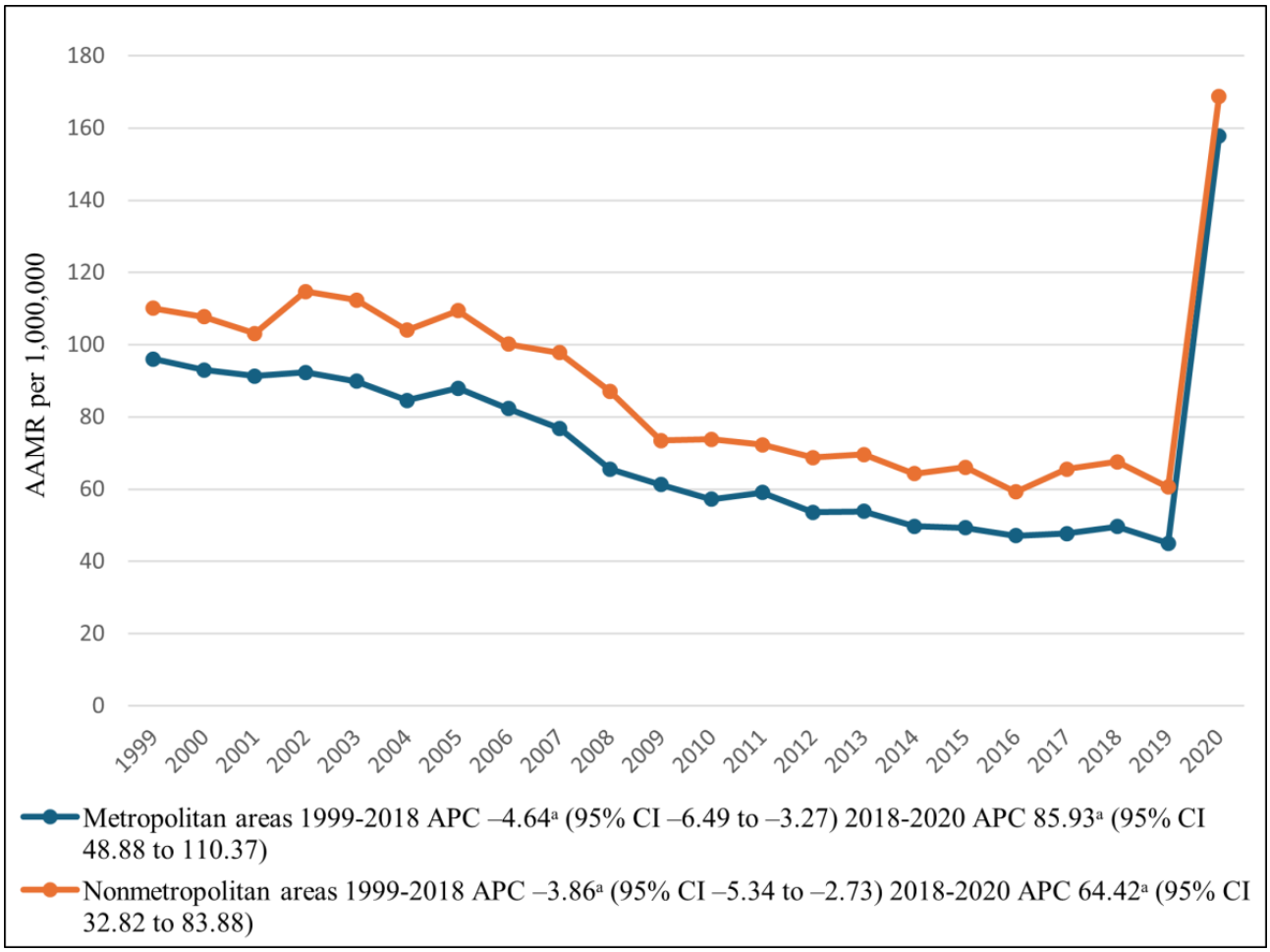
**Table .** Diabetes mellitus– and pneumonia–related age-adjusted mortality rates per 1,000,000, stratified by urban-rural classification in the United States, 1999-2022.

| Year | Metropolitan, age-adjusted rate (95% CI) | Nonmetropolitan, age-adjusted rate (95% CI) |
|---|---|---|
| 1999 | 96.03 (94.42 - 97.64) | 110.06 (106.51 - 113.60) |
| 2000 | 92.97 (91.39 - 94.54) | 107.76 (104.27 - 111.25) |
| 2001 | 91.32 (89.77 - 92.86) | 103.06 (99.66 - 106.47) |
| 2002 | 92.31 (90.76 - 93.85) | 114.75 (111.17 - 118.33) |
| 2003 | 89.87 (88.36 - 91.37) | 112.40 (108.87 - 115.93) |
| 2004 | 84.59 (83.14 - 86.04) | 103.99 (100.61 - 107.38) |
| 2005 | 87.91 (86.45 - 89.38) | 109.42 (105.97 - 112.88) |
| 2006 | 82.32 (80.92 - 83.73) | 100.17 (96.89 - 103.45) |
| 2007 | 76.80 (75.45 - 78.14) | 97.81 (94.58 - 101.03) |
| 2008 | 65.55 (64.32 - 66.78) | 87.08 (84.05 - 90.11) |
| 2009 | 61.24 (60.06 - 62.41) | 73.47 (70.68 - 76.25) |
| 2010 | 57.18 (56.05 - 58.30) | 73.81 (71.04 - 76.58) |
| 2011 | 59.06 (57.93 - 60.19) | 72.27 (69.55 - 74.99) |
| 2012 | 53.62 (52.56 - 54.69) | 68.73 (66.10 - 71.37) |
| 2013 | 53.85 (52.79 - 54.90) | 69.63 (66.99 - 72.27) |
| 2014 | 49.71 (48.71 - 50.71) | 64.27 (61.74 - 66.80) |
| 2015 | 49.30 (48.31 - 50.29) | 66.08 (63.53 - 68.62) |
| 2016 | 47.14 (46.19 - 48.09) | 59.28 (56.88 - 61.69) |
| 2017 | 47.69 (46.75 - 48.64) | 65.58 (63.06 - 68.10) |
| 2018 | 49.67 (48.71 - 50.62) | 67.61 (65.06 - 70.15) |
| 2019 | 45.04 (44.14 - 45.94) | 60.55 (58.17 - 62.94) |
| 2020 | 157.81 (156.14 - 159.48) | 168.76 (164.77 - 172.76) |
| Total | 72.91 (72.64 - 73.18) | 89.34 (88.67 - 90.01) |



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**Figure 4.** Diabetes mellitus– and pneumonia-related age-adjusted mortality rates (AAMRs) per 1,000,000, stratified by urbanization group in the United States, 1999-2020. [a]The APC is significantly different from zero at α=.05. APC: annual percentage change.






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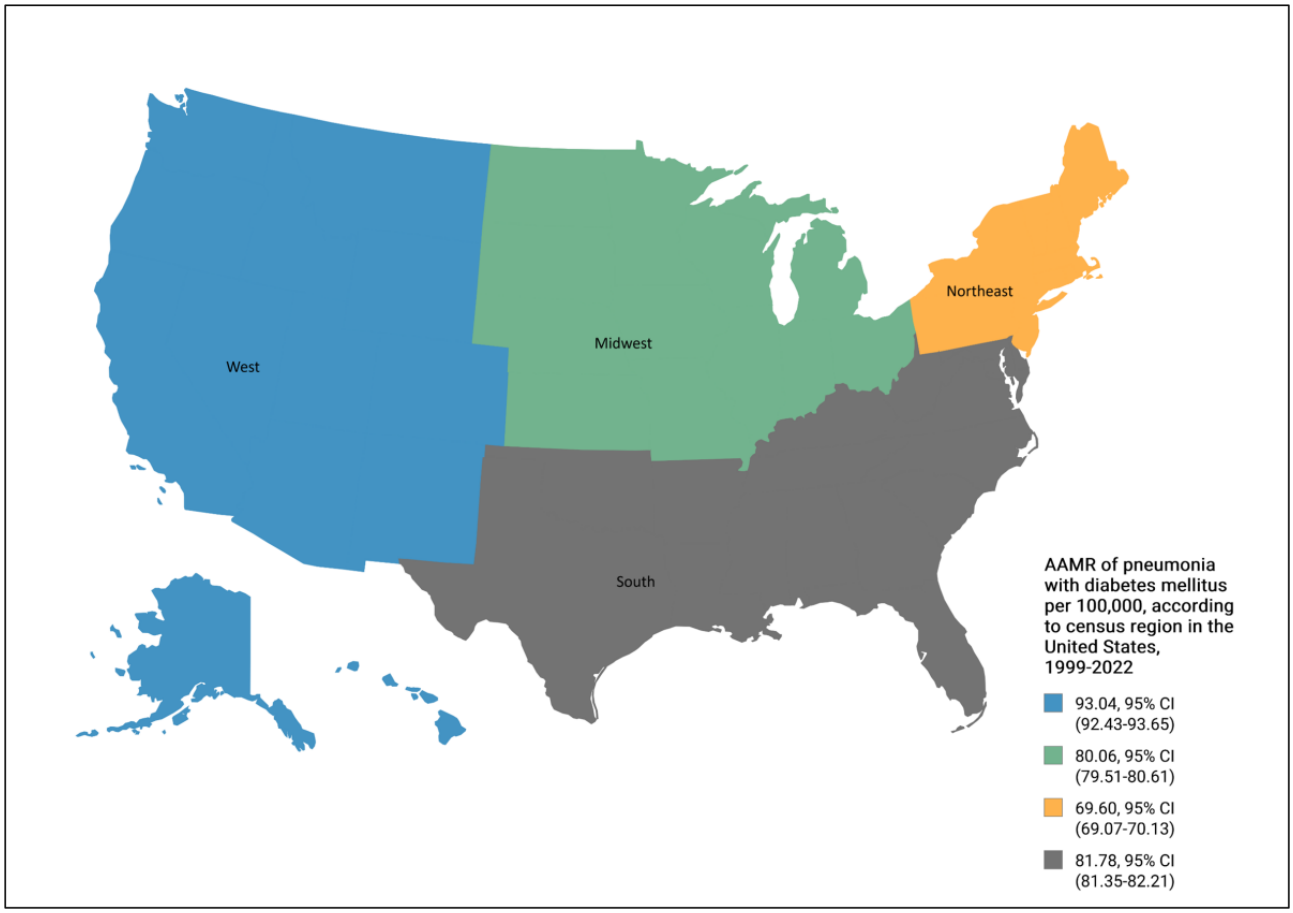
**Table .** Diabetes mellitus– and pneumonia-related age-adjusted mortality rates per 1,000,000, stratified by census region in the United States, 1999 to 2022.

| Year | Northeast, age-adjusted rate (95% CI) | Midwest, age-adjusted rate (95% CI) | South, age-adjusted rate (95% CI) | West, age-adjusted rate (95% CI) |
|---|---|---|---|---|
| 1999 | 90.91 (87.86 - 93.96) | 102.43 (99.38 - 105.47) | 92.78 (90.37 - 95.19) | 112.87 (109.33 - 116.41) |
| 2000 | 91.78 (88.73 - 94.83) | 94.04 (91.13 - 96.94) | 92.16 (89.78 - 94.54) | 108.30 (104.86 - 111.73) |
| 2001 | 85.79 (82.86 - 88.71) | 90.63 (87.79 - 93.46) | 90.67 (88.33 - 93.02) | 109.68 (106.27 - 113.09) |
| 2002 | 88.35 (85.40 - 91.31) | 96.13 (93.22 - 99.04) | 94.49 (92.11 - 96.87) | 108.47 (105.11 - 111.82) |
| 2003 | 84.25 (81.38 - 87.13) | 94.12 (91.26 - 96.98) | 90.91 (88.59 - 93.22) | 109.31 (105.98 - 112.63) |
| 2004 | 78.26 (75.50 - 81.02) | 90.11 (87.32 - 92.90) | 84.41 (82.21 - 86.62) | 102.05 (98.86 - 105.24) |
| 2005 | 79.82 (77.05 - 82.59) | 95.19 (92.34 - 98.04) | 87.53 (85.31 - 89.76) | 106.69 (103.48 - 109.90) |
| 2006 | 74.15 (71.50 - 76.81) | 87.82 (85.10 - 90.55) | 81.50 (79.38 - 83.62) | 100.67 (97.58 - 103.76) |
| 2007 | 68.48 (65.93 - 71.03) | 83.68 (81.05 - 86.31) | 78.02 (75.97 - 80.08) | 93.13 (90.20 - 96.06) |
| 2008 | 58.36 (56.03 - 60.70) | 71.57 (69.15 - 73.99) | 66.23 (64.36 - 68.11) | 82.67 (79.94 - 85.40) |
| 2009 | 52.10 (49.90 - 54.30) | 64.44 (62.16 - 66.73) | 61.98 (60.19 - 63.77) | 74.69 (72.13 - 77.25) |
| 2010 | 50.14 (48.00 - 52.29) | 58.43 (56.26 - 60.59) | 60.65 (58.89 - 62.40) | 69.96 (67.51 - 72.41) |
| 2011 | 53.66 (51.46 - 55.86) | 62.75 (60.52 - 64.98) | 57.56 (55.87 - 59.24) | 72.96 (70.49 - 75.42) |
| 2012 | 47.99 (45.92 - 50.05) | 55.36 (53.29 - 57.43) | 56.00 (54.36 - 57.64) | 64.31 (62.02 - 66.59) |
| 2013 | 48.51 (46.44 - 50.57) | 54.35 (52.31 - 56.40) | 56.96 (55.33 - 58.59) | 64.72 (62.47 - 66.98) |
| 2014 | 46.46 (44.44 - 48.48) | 50.81 (48.84 - 52.77) | 53.37 (51.81 - 54.92) | 55.97 (53.90 - 58.04) |
| 2015 | 46.78 (44.76 - 48.79) | 50.74 (48.79 - 52.68) | 52.42 (50.90 - 53.94) | 57.05 (54.99 - 59.11) |
| 2016 | 41.72 (39.83 - 43.61) | 46.14 (44.30 - 47.99) | 50.89 (49.41 - 52.38) | 55.31 (53.30 - 57.31) |
| 2017 | 41.19 (39.34 - 43.04) | 46.46 (44.63 - 48.30) | 52.08 (50.60 - 53.56) | 59.73 (57.68 - 61.78) |
| 2018 | 43.97 (42.06 - 45.87) | 49.82 (47.93 - 51.71) | 54.83 (53.32 - 56.33) | 58.20 (56.20 - 60.19) |
| 2019 | 41.30 (39.47 - 43.13) | 42.20 (40.48 - 43.92) | 50.40 (48.97 - 51.82) | 52.57 (50.69 - 54.45) |
| 2020 | 134.73 (131.42 - 138.04) | 146.56 (143.36 - 149.76) | 172.03 (169.44 - 174.62) | 169.59 (166.25 - 172.92) |
| 2021 | 96.86 (94.04 - 99.69) | 149.58 (146.27 - 152.88) | 215.70 (212.74 - 218.66) | 228.36 (224.42 - 232.31) |
| 2022 | 65.95 (63.66 - 68.23) | 88.47 (85.98 - 90.96) | 109.85 (107.80 - 111.91) | 111.59 (108.89 - 114.29) |
| Total | 69.60 (69.07 - 70.13) | 80.06 (79.51 - 80.61) | 81.78 (81.35 - 82.21) | 93.04 (92.43 - 93.65) |



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**Figure 5.** Diabetes mellitus– and pneumonia-related age-adjusted mortality rates (AAMRs) per 1,000,000, stratified by census regions in the United States, 1999-2022.



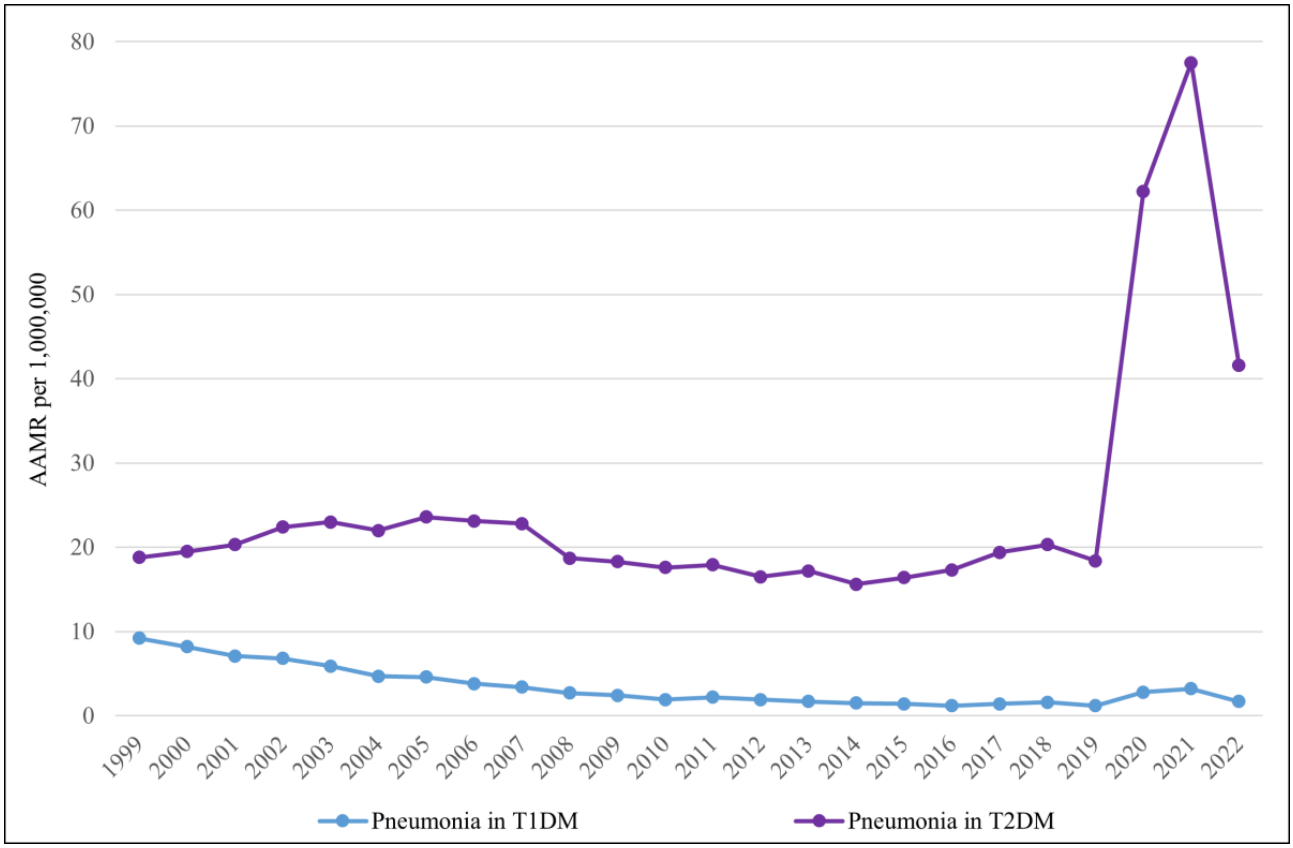

### Type 1 Diabetes Mellitus–, Type 2 Diabetes Mellitus–, and Pneumonia-Related Mortality

Based on the type of DM, diabetes- and pneumonia-related mortality exhibited a fascinating trend. The AAMR for type 1 DM and pneumonia-related mortality was 9.2 in 1999, dropping significantly (*P*=.04) to 1.4 by 2015 (APC −11.94, 95% CI −13.67 to −10.79). After 2015, the AAMR began increasing, reaching 3.2 by 2021; however, it dropped again to 1.7 in 2022. The overall trend from 2015 to 2022 was increasing in nature (APC 14.23, 95% CI 7.35-32.51). In terms of type 2 DM and pneumonia-related mortality, the AAMR remained relatively stable, from 18.8 in 1999 to 19.4 in 2017 (APC −2.09, 95% CI −6.27 to 2.42). From 2017, there was a drastic increase, and the AAMR reached a staggering 62.2 by 2020 (APC 58.74, 95% CI 10.56-81.43). After 2020, the AAMR began to decline, reaching 41.6, still higher than the previous baseline (APC −8.93, 95% CI −29.36 to 28.61; Figure 6).



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**Figure 6.** Diabetes mellitus– and pneumonia-related age-adjusted mortality rates (AAMRs) per 1,000,000 in the United States, 1999-2022, stratified by type of diabetes mellitus. T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus.




## Discussion

### Principal Findings

In this 2-decade analysis, we showed an overall decrease in mortality due to DM and pneumonia, which aligns with previous literature [18]. This decline can be attributed to factors such as better glycemic control in patients with diabetes, thereby preventing infections; improved management of fatal cardiovascular outcomes in such patients; and enhanced treatment protocols for pneumonia, including the use of antibiotics and vaccines [18-20]. Furthermore, all demographic and regional trends revealed significant differences in mortality rates. Men, AIs/ANs, individuals aged 65 - 86+ years, residents of nonmetropolitan areas, and those in the western region had higher mortality rates. In addition, a significant increase in mortality was observed during the COVID-19 pandemic.

### Gender Disparities

In our study, men were shown to have a higher mortality rate than women because of DM and pneumonia. This disparity can be attributed to sex differences in the prevalence of comorbidities such as CVD, smoking, and DM. Males are more inclined to engage in unfavorable lifestyle habits (eg, alcohol consumption, drug abuse, and smoking), which increases the risk for comorbidities such as hypertension, chronic obstructive pulmonary disease (COPD), DM, CKD, and CVD [20]. The increased frequency of DM in men is consistent with the literature and is primarily influenced by factors such as poor dietary practices, smoking, obesity, and alcoholism [21,22]. As these factors are more commonly observed in men than in women, they contribute to a higher risk of developing COPD and heart disease. COPD is also an independent risk factor for pneumonia in patients with DM [23]. In addition, men are more likely to experience occupational exposure to pathogens such as *Klebsiella*, *Streptococcus pneumoniae*, and *Chlamydia pneumophila* [24]. Furthermore, during COVID-19, when there was a significant increase in mortality rates among both sexes, this disparity persisted, with men accounting for a higher percentage of overall mortality. This may be because, compared with women, men are more likely to dismiss the risk of COVID-19 and, as a result, adopt fewer behavioral modifications, such as wearing masks or avoiding contact with people outside the home. It has also been reported that wearing masks is perceived by some men as a sign of “frailty” or “weakness” [25,26]. Notably, essential services, including transportation, law enforcement, emergency response, and industry, have a predominantly male workforce, resulting in a higher risk of exposure to the COVID-19 virus [27]. Furthermore, during hospitalization for COVID-19, poor diabetic control and compliance have been linked to severe pneumonia and poorer outcomes in patients with DM. Specifically, elevated plasma glucose levels are a predictor of fatal COVID-19 in men, but not in women [28]. Men also exhibit a greater inflammatory response in airways, due to increased accumulation of neutrophils and cytokines such as interleukin-8, interleukin-1β, and tumor necrosis factor-α, which likely contributes to the higher incidence and worse outcomes observed in men [29].

On the other hand, females have stronger immunity against viral infections, and this enhanced response can be attributed to



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increased antibody production driven by hormonal and genetic factors [30-32]. However, there is a more sincere counterpoint to these seemingly rosy figures for women. Compared with men, women with DM type 2 have a higher relative risk of CVD and mortality. Furthermore, young women with type 2 DM are less likely than men to receive the treatment and CVD risk reduction strategies recommended by current guidelines. These guidelines also lack information regarding gender-sensitive prevention and management approaches. Further research into the underlying mechanisms is essential to strengthen the evidence base and improve outcomes moving forward [33].

### Age Differences

The mortality trends by age stratification shown in our study differed significantly among older adults, middle-aged, and younger individuals. One possible explanation for this finding is that older adults with DM are at increased risk for CKD and CVD [34], both of which have been associated with higher mortality in patients with diabetes with pneumonia [35].

Evidence also suggests that multisystem geriatric syndromes are increasingly linked to DM [36]. These syndromes, including falls, functional decline, and delirium, are more common among older adults. They often contribute to disability and lower health-related quality of life, acting as barriers to regular check-ups and follow-ups, and potentially leading to poorer overall health care outcomes [37]. Furthermore, aging, increased levels of $HbA_{1c}$, and the accumulation of glycation end products may heighten susceptibility to infections in older individuals, as these factors are associated with diminished immune function and can contribute to increased morbidity and mortality [38].

DM is associated with a reduced health-related quality of life [38]. Contributing factors include the effects of polypharmacy, which can increase the risk of drug interactions, exacerbate geriatric syndromes, and even lead to death, as well as a greater risk of other chronic conditions and diabetes-specific complications. Additionally, the higher likelihood of older Americans having an annual income below the federal poverty level suggests that many seniors may have a limited capacity to manage DM and its consequences, due to socioeconomic constraints [3940].

### Racial/Ethnic Disparities

Racial trends in mortality due to DM and pneumonia show the highest mortality rates among NH AI/AN individuals, with Hispanics and NH African Americans occupying the second position at different points in time. A significant factor underlying this trend in NH AI/AN populations is the consistently higher prevalence of DM across all ages and both sexes [39]. This prevalence is nearly 3 times higher than that of US NH White individuals [4142]. Additionally, AI/AN populations with DM are significantly more prone to CVD, approximately 3-4 times more than those without DM [43]. These populations also tend to have a higher prevalence of multiple risk factors, including tobacco use, DM, hypertension, and dyslipidemia [44]. According to a previous study, 26.7% of AI/AN adults identified as smokers, making tobacco use a major public health concern in this group. Similarly, approximately 10% of individuals aged 12 years and older reported alcohol abuse, the highest rate among all the ethnic groups in the United States [45]. Public health care initiatives targeting these communities, especially those focused on smoking and alcohol use, could help raise awareness. Support groups and addiction clinics may also provide considerable benefit in addressing these issues.

Moreover, socioeconomic factors also contribute to this disparity. In 2010, 23% of AI/AN families had incomes below the poverty line, compared with 16% of the general population [46]. In addition, the environment faced by these individuals is often marked by lower educational attainment and higher stress levels. These factors make it more difficult for certain populations to access and afford health care services necessary to manage complex conditions involving the coexistence of DM and pneumonia [47,48]. Furthermore, a significant increase in mortality was observed among all racial groups during the COVID-19 pandemic, with the effect being particularly pronounced in the AI/AN population. This may be attributed to the greater social vulnerability and exposure to structural racism in these communities, which make them more susceptible to adverse health outcomes and mortality during public health emergencies, such as COVID-19 infections in patients with DM [49]. This situation is further compounded by widespread mistrust of medical institutions, which is more common among Black and AI/AN communities. During the COVID-19 era, this mistrust contributed to vaccine hesitancy, thereby increasing the burden of respiratory infections in these populations [50].

### Urban-Rural Differences

Our study revealed a greater increase in mortality rates in rural areas than in urban areas. This disparity can be attributed to the limited access rural residents have to the specialized health care required to manage DM and its complications [51]. The rural population in the United States also has a relatively high percentage of uninsured individuals [52]. Notably, only 11% of all physicians choose to practice in rural settings [53], leading to a shortage of emergency services, critical care resources, and subspecialty care [54]. To worsen matters, limited transportation options and longer travel times to health care facilities further contribute to the overall problem [55]. Telehealth and mobile health care services have the potential to address some of these deficiencies; we discuss these approaches in greater detail below. Furthermore, rural populations experience a higher prevalence of chronic conditions such as DM, largely due to increased rates of obesity and metabolic syndrome in these areas [56]. In addition, the concentration of unhealthy older individuals in rural communities further increases vulnerability to both DM and pneumonia [57].

Additionally, rural areas have a disproportionately large older adult population, comprising 22% of all older adults in the United States, despite only 15% of the overall US population residing in these regions [58]. As older individuals are at increased risk of developing DM and pneumonia, their growing presence in rural areas may help explain the observed mortality trends. Moreover, a high risk of pneumonia in rural areas has been linked to increased indoor and outdoor air pollution, as well as agricultural waste, which releases reactive nitrogen species and fine particulate matter, both of which adversely



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affect respiratory function [59]. Proximity to poultry farms and other agricultural settings has also been associated with an imbalance in the microbial composition of the respiratory tract, increasing susceptibility to pneumonia [60]. Finally, rural health systems were comparatively slower in responding to the COVID-19 pandemic. Public health measures such as mask wearing and lockdowns had a limited impact on behavior in these communities [61].

### Geographical Trends

In terms of regions, the West and South recorded the highest mortality rates. According to census reports, Southern states such as Virginia and Florida have median ages at or above 60 [62]. As previously established, older individuals are more predisposed to DM and its complications, which may help explain the elevated mortality in this region. Similarly, African Americans are more heavily concentrated in the Southern states [63], and we have shown that this population experiences higher mortality rates due to DM and pneumonia. The increased mortality rates observed in the West may be attributed to the rising populations of AI/AN individuals in states such as California, Alaska, and Arizona [64]. Given that AIs/ANs exhibited the highest mortality rates in our study, this demographic shift could be a contributing factor to the trend. However, literature on regional mortality trends due to DM and pneumonia remains limited, and further research is needed to better understand this variable.

### Mortality Stratified by Type of Diabetes Mellitus

The significant decline in AAMRs among patients with type 1 DM from 1999 (9.2) to 2015 (1.4) strongly suggests improved use of insulin pumps, continuous glucose monitors, mobile apps, and advanced insulin therapies, all of which have contributed to better glycemic control [65]. Moreover, improved influenza and pneumococcal vaccination coverage, along with early management of respiratory infections in younger populations with diabetes, has further contributed to reduced mortality over time [5]. However, the reversal of this trend after 2015, with AAMR peaking at 3.2 in 2021 before a slight decline in 2022, warrants attention. The rise in pneumonia-related mortality among patients with type 1 DM between 2015 and 2021 may be attributed to an increase in adult-onset type 1 DM, inadequate adult vaccination coverage, and poor glycemic control during transitional phases in adolescents and young adults. The COVID-19 pandemic further exacerbated these risks through immune dysregulation, altered angiotensin-converting enzyme 2 expression, and health care disruptions, which may have delayed appropriate management [66]. The decline observed after 2022 is likely attributable to the effectiveness of COVID-19 vaccines.

Contrastingly, in type 2 DM, AAMRs remained high but relatively stable from 1999 (18.8) to 2017 (19.4), suggesting a plateau in the effectiveness of interventions—a balance between improved care and the rising prevalence of diabetes. However, mortality increased significantly after 2017, reaching 62.2 by 2020. After 2017, the disproportionate impact of the COVID-19 pandemic—characterized by immune dysfunction, cytokine storms, hospital overload, and disruptions in diabetes care—combined with rising obesity, advanced age, and comorbidities to drive a dramatic increase in pneumonia-related deaths among patients with type 2 DM [67]. Polypharmacy, frailty, reduced physical activity, and mental health issues further compromised glycemic control. The subsequent decline after 2020 likely reflects the impact of targeted public health initiatives, improved treatment guidelines, the expansion of telemedicine, and prioritized COVID-19 vaccination [68].

### COVID-19 Pandemic–Driven Reversal of Mortality Gains

The pandemic reversed 2 decades of progress, erasing 17 years of declining mortality gains as overall rates rebounded to near-1999 levels by 2022. Adults aged 65 and older were most severely affected, with AAMRs rising sharply from 206.9 in 2017 to 371.3 in 2022, reversing prior improvements. Although men consistently had higher death rates, women experienced a steeper increase during the pandemic (APC 24.88 in males vs 27.60 in females). Rural communities—already at a disadvantage—experienced catastrophic spikes (APC 64.42 after 2018), while AI/AN populations faced the most severe inequities. The West and South bore the highest mortality burdens, likely due to their higher proportions of aging populations and AI/AN residents. Crucially, mortality related to type 2 diabetes and pneumonia—previously stable—surged during the pandemic, with AAMRs peaking at 62.2 in 2020. This spike reflects the lethal synergy between COVID-19 and metabolic dysfunction, exacerbated by disrupted care and widespread comorbidities.

### Future Interventions

A number of interventions can be implemented in the future to improve control and prevention. The first and foremost is greater vaccination coverage. Influenza vaccines, such as the 23-valent pneumococcal polysaccharide vaccine (PPV23) and the 13-valent pneumococcal conjugate vaccine (PCV13), have significantly improved the prognosis of patients with pneumonia with increased risk factors such as DM [69,70]. Second, controlling plasma glucose levels is essential for reducing the risk of pneumonia in patients with DM. Therefore, the next key intervention is improving glycemic levels and their control through the use of noninvasive glucose monitoring systems [71]. Telehealth opportunities and improving health care equity can help reduce rural-urban disparities in trends [72]. To enhance health literacy among the AI/AN population, the National Heart, Lung, and Blood Institute has developed the Honoring the Gift of Heart Health curriculum [73]. Health literacy plays an essential role in addressing medical mistrust within ethnic communities. The development of specific and targeted programs, such as the National Diabetes Education Program (to provide diabetes education for various audiences), the Chronic Kidney Disease Initiative, and the Diabetes Prevention Program (to improve lifestyle factors among patients with DM), has the potential to significantly reduce mortality trends across all age and racial groups.

### Limitations

There are several limitations to this study. First, reliance on death certificates and ICD codes may have resulted in both unintentional misreporting and underreporting of DM and



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pneumonia as causes of death. Cause-of-death reporting can be inconsistent; in particular, diabetes is frequently underreported on death certificates. A CDC analysis found that only 41% of decedents known to have diabetes had it recorded on their death certificate [74]. Therefore, the use of death certificates likely underestimates the true incidence of pneumonia-related deaths in individuals with diabetes and may bias results toward cases where physicians explicitly linked the 2 conditions. Furthermore, the potential impact of changes in coding practices (especially the shift in coding pneumonia vs COVID-19 in 2020 and beyond) cannot be ruled out. Second, variables such as vital signs, laboratory findings, and genetic data were not available, even though they are known to be important in understanding the extent of the disease. These omissions mean that potential confounders (eg, poverty, which correlates with both diabetes prevalence and pneumonia outcomes) could not be adjusted for, and causal inferences remain speculative. The study design is purely descriptive and therefore cannot determine why certain groups experience higher mortality—for instance, whether this is due to higher prevalence of diabetes, differences in health care, or other risk factors. Third, AAMRs reflect population-level burden but conflate DM prevalence with case-fatality risk. Future research would benefit from examining mortality rates specifically among individuals with diabetes, or determining the proportion of pneumonia deaths that occur in those with diabetes, to better assess the risk to patients with diabetes versus the broader population-level burden. Fourth, joinpoint analyses were conducted across multiple subgroups without formal correction for multiple comparisons. Although the major trend inflection observed around 2016 - 2018 was consistent across most subgroups, smaller or borderline changes in individual subgroups should be interpreted with caution. Identical settings were applied across subgroups, with weighted BIC selecting 2 joinpoints in each case to enable comparability; however, this uniform approach may underfit or overfit trends specific to individual subgroups. Formal sensitivity analyses to explore alternative parameter choices (eg, minimum observations between joinpoints, maximum number of joinpoints) were not conducted due to resource constraints; this may have affected the detection of shorter or additional trend segments. Residual diagnostics for the overall model indicated a Durbin-Watson statistic of 1.62, suggesting mild positive autocorrelation. While basic visual checks did not reveal extreme systematic departures, residual correlation cannot be entirely ruled out and represents a potential limitation. Fifth, data on the efficacy of interventions are limited, as information on the impact of medical therapies and treatments for DM and pneumonia is not available. Additionally, baseline characteristics such as atherosclerosis, atrial fibrillation, ischemic conditions, or other coexisting infections, which may significantly contribute to mortality in patients with DM or pneumonia, are also missing. Finally, datasets concerning socioeconomic factors and educational attainment are unavailable; these variables may influence access to care and health outcomes, further limiting the study's scope.

## Conclusion

Mortality trends among patients with DM and pneumonia varied across all demographic factors. Although an overall decline in mortality rates was observed across most groups, a significant increase occurred during the COVID-19 period. The highest mortality rates were reported among older individuals (65-86+ years), males, and NH AIs. Additionally, nonmetropolitan areas, especially in the West region, experienced the highest mortality. Therefore, glycemic control in all patients with DM is essential, whether through monitoring systems or preventive programs. There is a pressing need to allocate sufficient resources to underserved regions and overlooked populations to improve their mortality outcomes. Longitudinal surveillance and tailored interventions (eg, telehealth, mobile clinics) targeting high-risk populations are urgently needed to mitigate disparities.

## Data Availability

The raw data used to support the findings of this study are available for download from [17], and the processed data are available from [75]. This research did not receive any external funding.

## Authors' Contributions

Conceptualization: AD
Data curation: AZ, ASH, ARF
Formal analysis: AZ, ASH
Methodology: PS
Project administration: AD
Supervision: AD
Validation: RM, AD
Writing—original draft: AZ, ASH, ARF, MF, MAH, Abdullah, MS
Writing—review and editing: PS, RM, AD
All authors have read and agreed to the published version of the manuscript.

## Conflicts of Interest

None declared.

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## Abbreviations

**AAMR:** age-adjusted mortality rate
**AI:** American Indian
**AN:** Alaska Native
**APC:** annual percentage change
**BIC:** Bayesian information criterion
**CDC WONDER:** Centers for Disease Control and Prevention Wide-ranging Online Data for Epidemiologic Research
**CKD:** chronic kidney disease
**COPD:** chronic obstructive pulmonary disease
**CVD:** cardiovascular disease
**DM:** diabetes mellitus
**ICD-10:** International Statistical Classification of Diseases and Related Health Problems, 10th Revision
**NH:** non-Hispanic
**STROBE:** Strengthening the Reporting of Observational Studies in Epidemiology

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# Applications of AI in Predicting Drug Responses for Type 2 Diabetes

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## Abstract

Type 2 diabetes mellitus has seen a continuous rise in prevalence in recent years, and a similar trend has been observed in the increased availability of glucose-lowering drugs. There is a need to understand the variation in treatment response to these drugs to be able to predict people who will respond well or poorly to a drug. Electronic health records, clinical trials, and observational studies provide a huge amount of data to explore predictors of drug response. The use of artificial intelligence (AI), which includes machine learning and deep learning techniques, has the capacity to improve the prediction of treatment response in patients. AI can assist in the analysis of vast datasets to identify patterns and may provide valuable information on selecting an effective drug. Predicting an individual's response to a drug can aid in treatment selection, optimizing therapy, exploring new therapeutic options, and personalized medicine. This viewpoint highlights the growing evidence supporting the potential of AI-based methods to predict drug response with accuracy. Furthermore, the methods highlight a trend toward using ensemble methods as preferred models in drug response prediction studies.

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**KEYWORDS**

type 2 diabetes; artificial intelligence; machine learning; drug response; treatment response prediction; ML; AI; deep learning

## Introduction

Type 2 diabetes mellitus stands as one of the most common metabolic disorders, comprising 90% - 95% of all cases of diabetes and affecting millions of people worldwide. The condition arises from 2 main factors: malfunctions in insulin secretion by pancreatic β-cells and the resistance of insulin-sensitive tissues to insulin [1]. The aim of treatment for type 2 diabetes is to maintain good blood sugar (glucose) levels, which can reduce the risk of development of complications related to diabetes, such as retinopathy, nephropathy, neuropathy, and cardiovascular diseases. Initial therapies include lifestyle changes and certain medications such as metformin and sulfonylureas. The specific drug or combination of drugs used is based on individual needs and medical history. Treatment with certain drugs may be unsuccessful depending on the physiological and pathological characteristics of individuals.

There is considerable heterogeneity among people with type 2 diabetes and their response to different drugs. The use of ineffective drugs results in the deterioration of a patient's condition and raises health care expenses. Thus, there is a need to develop reliable drug response prediction methods to help identify the efficacy of potential treatments for an individual. The heterogeneity of disease and treatment response emphasizes the need for advanced analytical methods, such as artificial intelligence (AI), to understand complex patterns within data, identify patient subgroups with distinct characteristics and ultimately pave the way for personalized and precision medicine.

The main objective of this viewpoint is to review the literature exploring the use of AI-based techniques for predicting drug response in type 2 diabetes, as well as drawing upon other disease areas such as rheumatoid arthritis, multiple sclerosis, and cardiovascular diseases. For type 2 diabetes, AI methods can help gain insights into the determinants or predictors of drug response (age, sex, type of drug, dosage, duration, medical history, ethnicity, socioeconomics, blood biochemistry, and genetics) and identify characteristics that are responsible for poor drug response. The goal is to provide an extensive overview of the key findings, methodologies, algorithms, outcomes, and limitations identified in the reviewed studies. Through a critical evaluation, this review aims to assess the strengths and weaknesses of certain AI-based algorithms in predicting treatment response and to identify potential areas of future research.



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## Understanding the Role of AI

### AI in Drug Response Prediction

AI presents a compelling solution for drug response prediction due to several key factors. Traditional approaches to determining drug response often rely on limited datasets and simpler regression models, which may overlook the complex interplay of factors influencing treatment outcomes. Furthermore, these methods focus on a narrow set of variables, potentially missing crucial insights into individual patient characteristics and treatment responses. However, with the advancement of AI, particularly machine learning (ML) algorithms, there is an opportunity to leverage vast amounts of data, including electronic health records (EHRs), genomics data and real-world patient data [2]. AI enables a more comprehensive analysis, by considering multiple variables and confounders simultaneously [3]. By examining data holistically and identifying intricate patterns across diverse sources of information, AI has the potential to increase our understanding of drug response mechanisms.

### Leveraging a Diverse Data Source

There are a lot of data types available when considering drug response. AI can potentially use all of these to enable drug response prediction. The data that can be used by AI systems for observational studies includes laboratory findings, EHRs, claims and bills, genome sequencing data, clinical data, disease registries, patient-reported outcomes, data from wearable devices and sensors, pharmacogenomics data, demography data, hematology, etc [4,5]. Additionally, EHR data can itself provide detailed information about a patient's medical history, diagnoses, treatments, drug prescription records, dosage, clinical outcomes, etc. Furthermore, genetic data of patients, such as their genomic profiles can be helpful to understand individualized treatment responses. Pharmacogenomics studies can examine genetic variations and their influence on drug responses.

### AI Techniques and Their Applications

AI is a broad field comprising a wide range of technologies and techniques for building systems that can independently perform tasks associated with human intelligence. The applications of AI in health care have been used in patient data management, predictive medicine, clinical decision-making, diagnostics, and personalized medicine [6,7]. AI includes a range of methods, among which ML and deep learning (DL) stand out as 2 prominent subsets [8]. ML is involved in building systems that are capable of learning from data, identifying patterns, and making decisions. On the other hand, DL, is a special form of ML inspired by the structure and function of the brain, especially neural networks. These models learn from data autonomously and are adaptable to various features.

The most prominent methods for prediction modelling are ensemble-based methods, such as random forest (RF) and gradient boosting machines [9-11]. These methods combine the predictions of multiple models to produce a stronger overall prediction. They can reduce overfitting and increase robustness by using the diversity of the constituent models. This is achieved by training multiple base learners on different subsets of the data or with different algorithms and then combining their predictions [12].

### Explainable Artificial Intelligence

It is important to understand how AI functions to ensure trust and transparency. This is where explainable artificial intelligence (XAI) methods come into play [13-15]. In their review, Loh et al [13] discuss XAI and its practical applications. XAI methods have undergone significant advancements to enhance our trust in a model's predictions by providing insights into the reasoning behind them. Further, XAI proves to be a valuable tool alongside traditional statistical approaches when analyzing the connections between variables and outcomes. Some of the most popular XAI methods include local interpretable model-agnostic explanations, gradient-weighted class activation mapping, and Shapley additive explanations [16,17]. These methods are combined with ML models to make predictions. They showcase the importance of features independently of the model's structure, and the direction of influence from predictive variables.

### Advanced Modeling Techniques

Methods exploring interactions among input variables should also be considered in predictive modelling. These techniques capture complex relationships and nonlinear effects between predictors, improving model performance. Several methods can identify potential interactions, such as introducing polynomial features, adding interaction terms by multiplying variables, using tree-based algorithms, performing feature engineering, implementing neural networks to automatically learn complex interactions, and using domain knowledge. By accounting for these interactions, predictive models can become more accurate and informative, enabling better decision-making and personalized treatment strategies.

### Ensuring Transparency and Reproducibility

In drug response studies, mainly those leveraging AI techniques, adherence to transparent and standardized reporting guidelines is important. The Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis guidelines [18] ensures the robustness and reliability of predictive models. These guidelines provide a structured framework for model development, validation, and performance evaluation, thus enhancing transparency and reproducibility. Moreover, adherence to TRIPOD(Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis) guidelines enhances the clinical relevance of predictive models by promoting clarity and consistency in reporting key elements such as patient's characteristics, predictor variables, outcome measures, and model performance metrics.

### Model Selection and Performance Evaluation

Selecting the best AI model is a critical task. The ideal model is expected to be accurate and suitable for a specific task. Opting for a model with higher performance ensures reliable outcomes, improved predictions, and informed decision-making. Thus, performance comparison of different models is necessary to find the model with the highest accuracy and efficiency. The process involves evaluating the model's performance against each other using a set of metrices and techniques. Performance



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comparison can be done through various approaches, such as root-mean-square-error, accuracy, sensitivity, specificity, precision, area under the curve (AUC), mean absolute relative difference, receiver operating characteristic curve, mean squared error, etc [9,19]. These metrices offer insights into various aspects of model performance. In terms of AUC in drug response prediction, a higher AUC indicates better discriminative ability of the model, with values closer to 1 indicating stronger predictive performance. However, the interpretation of AUC should also consider factors such as the balance between specificity and sensitivity, as well as the clinical significance of false positives and false negatives [20].

Additionally, techniques such as cross-validation can be used to obtain robust performance comparison by assessing the model's generalization capabilities. This involves splitting the data into multiple folds and training or testing the models on subsets of data to perform a more comprehensive evaluation. It helps to reduce the chances of overfitting or underfitting by providing a more realistic estimate of the performance of any model. Methods for addressing generalizability in predictive modelling also include techniques such as bootstrapping and external validation. These methods ensure that the model's performance is not overly influenced by the specific characteristics of the training dataset and can be applied to new populations.

## Modeling Drug Response Using AI

To better understand the key aspects of drug response prediction methods using AI-based models, we examined the existing literature on the recent ML and DL-based models in specific disease domains. A comprehensive search was conducted in July 2023, across multiple academic databases, including PubMed, Scopus, and bioRxiv, using keywords related to drug treatment response, ML, and specific disease areas. The search strategy included keywords grouped into 2 sets: "AI-based keywords" and "drug response-based keywords." These keywords were selected based on a combination of domain knowledge, a review of existing literature, and consultation with subject matter experts. These 2 sets were combined using the Boolean operator "AND" to narrow down the search and identify relevant studies.

Keywords for AI were combined using the Boolean operator "OR" to capture a wide range of AI-related concepts: ("machine learning" OR "artificial intelligence" OR "deep learning" OR "prediction model" OR "statistical model" OR "neural network" OR "data science" OR "computational intelligence" OR "graph data" OR "machine intelligence" OR "convolutional network" OR "random forest" OR "reinforcement learning").

Keywords for drug response were similarly combined using the Boolean operators "OR" to encompass various related terms: ("treatment response" OR "drug response" OR "response prediction" OR "treatment prediction" OR "treatment outcome" OR "drug response prediction" OR "clinical outcome" OR "therapeutic outcome").

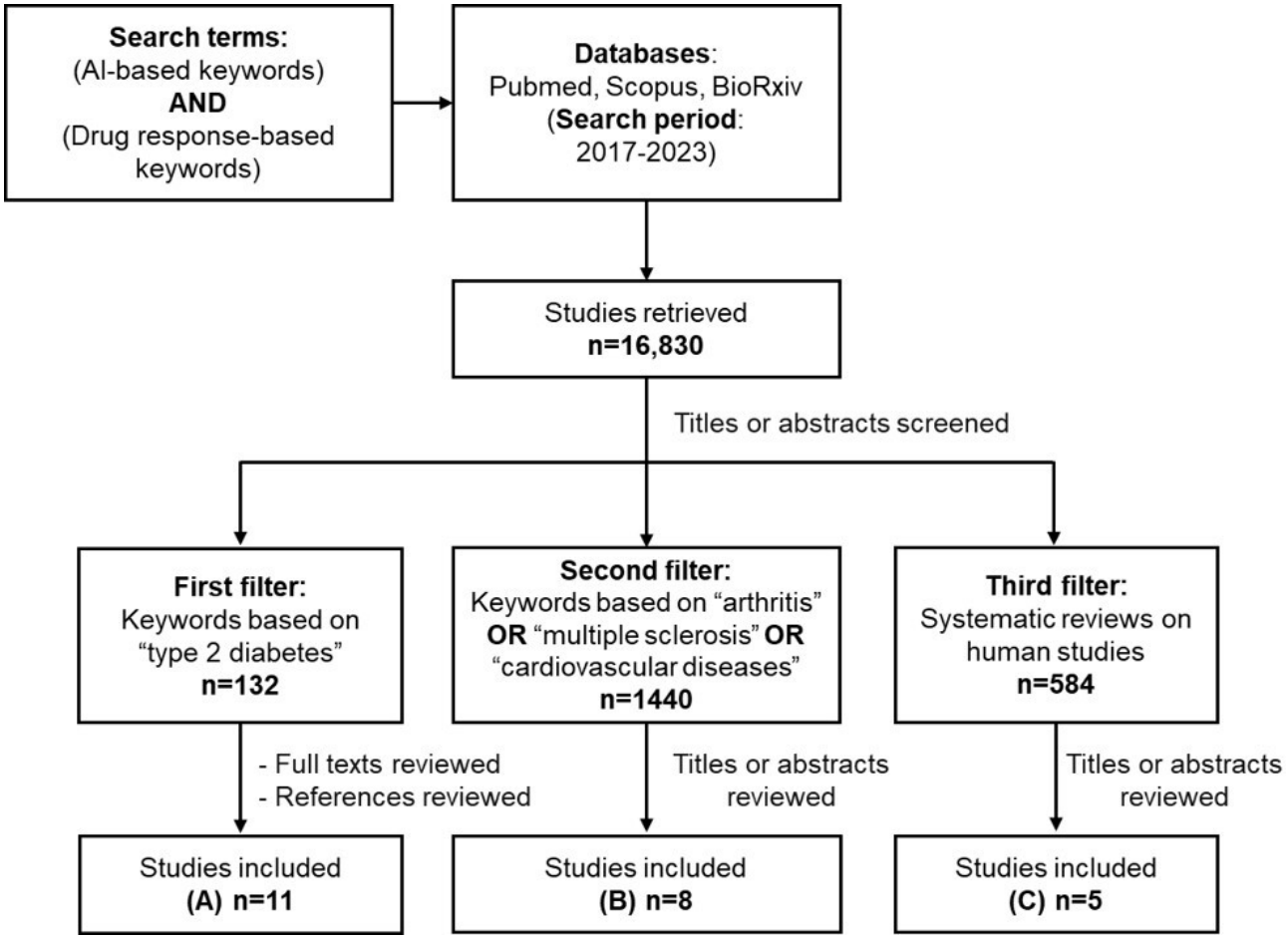
The studies were first filtered for "type 2 diabetes" and then for other disease areas such as arthritis, multiple sclerosis, and cardiovascular diseases (Figure 1A-C). These additional conditions were chosen because they are widely studied in relation to drug response and represent areas where AI methods have shown emerging applications. Additionally, we filtered for systematic reviews published on human studies to identify already published papers, as they provide a comprehensive summary of existing evidence.

The references of the retrieved studies were also reviewed to locate additional relevant papers. For this review, studies published between 2017 and 2023 were considered. We focused on papers that applied ML and DL algorithms specifically predicting treatment responses in clinical trials or observational studies.



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**Figure 1.** A flowchart representing this study's selection process. (A) references [21-31], (B) references [32-39], and (C) references [5-8,13].




## AI and Drug Response in Type 2 Diabetes

While much literature has been published on AI methods, their applications in life sciences are still comparatively limited. The field that has been most explored is oncology, where drug response prediction models are built using pharmacogenomic databases and cancer cell lines due to the impracticality and cost of clinical trials studies across diverse cancers [4,40,41]. Cardiometabolic diseases are a young upcoming field in the application of AI methodologies, likely due to limitations in data availability. The 11 studies identified in type 2 diabetes from the years 2017 to 2023 highlight the promise of data-driven insights in this field.

Most studies focus on predicting treatment responses to combinations of drugs, which aligns more closely with real-world scenarios where patients often receive multiple medications to treat the medical conditions. These studies use various criteria to make binary classification models. Some aim to predict whether a patient achieves a target $HbA_{1c}$ (glycated hemoglobin) goal, while others focus on predicting if the patient experiences a reduction in $HbA_{1c}$ by a certain number of units. Performance is evaluated using metrics such as AUC or accuracy, depending on the context. Additionally, we compare the quantity and nature of data used, as well as AI methods and outcomes.

In the field of drug response studies, traditional linear and logistic regression models have been staples for quite some time. For instance, Pantalone et al [21] developed a logistic regression model on 6973 patients to predict responders—patients who achieve an $HbA_{1c}$ goal of less than 8% when treated with a combination of multiple antidiabetic drugs (Table 1). Their binary classification model achieved an AUC of 0.648. In a separate observational study, Wang et al [22] used a logistic regression model alongside multiple ML models on 2787 patients' data to predict patients who achieve an $HbA_{1c}$ goal of less than 7% when treated with insulin. While the logistic regression model yielded an accuracy of 0.55, the RF reached an accuracy of 0.75, and both the back propagation artificial neural network and the support vector machine achieved an accuracy of 0.73. Notably, the support vector machine, RF, and back propagation artificial neural network models outperformed the logistic regression model in the accuracy metric. Both studies relied on traditional logistic regression models, which, as indicated by the results, demonstrated lower performance compared to ML methods [21,22]. These traditional models assume linear relationships between variables, which may not be well-suited for real-world data. As a result, they fail to capture the necessary associations for making accurate predictions.



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**Table .** Studies incorporating AI[a] to predict treatment response in type 2 diabetes using clinical trials or observational data.

| Reference | Study objective | Data type and number of patients (n) | Drug treatment (single or in combination) | AI methods | Prediction outcome | Performance |
|---|---|---|---|---|---|---|
| Tao et al [27] | Machine learning models to predict fasting blood glucose and $HbA_{1c}$[b] after 3 months of treatment | Retrospective study n=2169 | Metformin, sulfonylurea, thiazolidinediones, GLP-1[c], DPP-4[d], SGLT2[e], acarbose, meglitinide, insulin | Logistic regression, SGD[f], decision tree, Gaussian NB[g], QDA[h], Bernoulli NB, LDA[i], Multinomial NB, RF[j], Extra Tree, passive aggressive, AdaBoost, begging, GBM[k], XGBoost, ensemble learning | Reach $HbA_{1c}$ target below 7% | • AUC[l] (ensemble)>0.9 |
| Berchialla et al [24] | Machine learning models to predict treatment outcome | Clinical trials n=385 | Metformin, sulfonylurea, DPP-4 inhibitors | Ensemble algorithm (super learner: GBM, GLM[m], RF, MARS[n], SVM[o], CART[p], BART)[q] | Reduction in $HbA_{1c}$ of at least 0.5% | • AUC: 0.92 |
| Sun et al [28] | Effective treatment recommendations using reinforcement learning | Observational study n=189,520 | Metformin, sulfonylurea, thiazolidinediones, DPP-4, GLP-1, SGLT2, acarbose (AGI[r]), basal insulin, premixed insulin | Multivariate logistic regression, reinforcement learning | Odds of achieving target $HbA_{1c}$<7% among concordant compared to nonconcordant group | • Odds ratio: 1.73 (95% CI 1.69 to 1.76) |
| Pantalone et al [21] | Prediction model on probability of $HbA_{1c}$ goal attainment | Retrospective cohort study n=6973 | Metformin, sulfonylurea, thiazolidinediones, DPP-4, GLP-1, SGLT2, AGI, insulin | Logistic regression | Reach $HbA_{1c}$ target below 8% | • AUC: 0.648 (95% CI 0.633 to 0.663) |
| Wang et al [22] | Machine learning models for predicting $HbA_{1c}$ among patients treated with insulin | Observational study n=2787 | Insulin | Logistic Regression, RF, SVM, BP-ANN[s] | Reach $HbA_{1c}$ target below 7% | • AUC (LR[t]): 0.74<br>• AUC (RF): 0.75<br>• AUC (SVM): 0.72<br>• AUC (BP-ANN): 0.72 |
| Dennis [29] | Using individualized prediction models to optimize selection of treatment | Observational study n=8798 | Metformin, sulfonylurea, thiazolidinediones, DPP-4, GLP-1, SGLT2 | Individualized prediction models | 3-year change from baseline in $HbA_{1c}$ | • Reduction in $HbA_{1c}$ (mmol/mol):<br>• Concordant: −16.9 (95% CI −18.2 to −15.6) |
| Lopez et al [25] | Predicting the response to short-term intensive insulin therapy | Clinical trial n=24 | Insulin | RF | Percentage change in ISSI-2[u] | • AUC: 0.951 |
| Ngufor et al [30] | Mixed effect machine learning for predicting longitudinal change in $HbA_{1c}$ | Observational study n=27,005 | Metformin, sulfonylurea, thiazolidinediones, insulin, Meglitinide, AGI, GLP-1, DPP-4, amylinomimetics | Mixed effect Machine learning, RF, GBM, GLMs | Reach $HbA_{1c}$ target below 7% | • AUC: 0.7 - 0.8 |



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| Reference | Study objective | Data type and number of patients (n) | Drug treatment (single or in combination) | AI methods | Prediction outcome | Performance |
|---|---|---|---|---|---|---|
| Del Parigi et al [23] | Machine learning to identify predictors of drug response | Phase III clinical trial data<br>n=1363 | SGLT2, DPP-4 | RF, classification trees | Reach $HbA_{1c}$ target below 7% | • Prediction accuracy: 0.77 - 0.82 |
| Nagaraj et al [31] | Machine learning models to predict short and long-term $HbA_{1c}$ response | Observational study<br>n=1188 | Insulin | Generalized linear regression, SVM, RF | Reduction in $HbA_{1c}$≥5 mmol/mol or reach target $HbA_{1c}$ below ≤53 mmol/mol | • AUC (short term): 0.80 (95% CI 0.78 to 0.83)<br>• AUC (long term): 0.81 (95% CI 0.79 to 0.84) |
| Murphree et al [26] | Machine learning models to predict response after 1 year of metformin therapy | Health records<br>n=12,147 | Metformin | Stacked classifiers (ensemble): LR, RF, NN[v], k-NN[w], stochastic gradient boosting, SVM, CART, averaged neural network, FDA[x], GBM, PLS[y], SLDA[z] | Reach $HbA_{1c}$ target below 7% | • AUC: 0.58 - 0.75 |

[a]AI: artificial intelligence.
[b]$HbA_{1c}$: glycated hemoglobin.
[c]GLP-1: glucagon-like peptide 1.
[d]DPP-4: dipeptidyl peptidase 4.
[e]SGLT2: sodium-glucose cotransporter 2.
[f]SGD: stochastic gradient descent.
[g]NB: Naïve Bayes.
[h]QDA: quadratic discriminant analysis.
[i]LDA: linear discriminant analysis.
[j]RF: random forest.
[k]GBM: gradient boosted machine.
[l]AUC: area under the curve.
[m]GLM: generalized linear model.
[n]MARS: multivariate adaptive regression spline.
[o]SVM: support vector machine.
[p]CART: classification and regression tree.
[q]BART: Bayesian additive regression tree.
[r]AGI: alpha-glucosidase inhibitor.
[s]BP-ANN: back propagation artificial neural network.
[t]LR: linear regression.
[u]ISSI-2: insulin secretion-sensitivity index-2.
[v]NN: neural network.
[w]k-NN: k-nearest neighbor.
[x]FDA: flexible discriminant analysis.
[y]PLS: partial least square.
[z]SLDA: sparse linear discriminant analysis.

Some of these studies use clinical trial data, which is more organized, and cleaner compared to observational data for building ML models. Del Parigi et al [23] used a clinical trial data of 1363 patients and applied 2 ML algorithms, namely RF and classification trees, to find predictors of glycemic control in patients treated with a combination of sodium-glucose cotransporter 2 and dipeptidyl peptidase 4 inhibitors, both as dual-therapy and mono-therapy. The prediction accuracy of their models ranged from 0.77 to 0.82, with fasting plasma glucose and $HbA_{1c}$ emerging as the most influential predictors of achieving glycemic control.



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Berchialla et al [24] used a clinical trial data of 385 patients and used a weighted combination of 7 algorithms (Table 1) using an ensemble approach known as the super learner to predict responders, specifically patients who achieve a reduction in $HbA_{1c}$ of at least 0.5% when treated with conventional drugs and dipeptidyl peptidase 4 inhibitors. Their ensemble model yielded an AUC of 0.92. In a different study, Lopez et al [25] used clinical trial data from 24 patients to develop an RF model for predicting the response to short-term intensive insulin therapy. Their binary classification model yielded an accuracy of 0.91 and an AUC of 0.951. These 2 analyses yield very high AUC values, which raise some concerns. Their sample sizes are very small, presenting a high risk of overfitting. Models trained on such limited data may not generalize well to broader populations. Additionally, with a small sample size, there is a higher risk of selection bias, where the characteristics of the patients could be very similar and may not represent larger populations. This can skew the results and lead to an overestimation of model performance.

We found that most studies that used ML approaches used ensemble-based methods to build predictive models [22-27,30]. Ensemble-based techniques, such as gradient boosting machines, RFs, and stacking, have become popular due to their high performance and capability to work with complex datasets. For instance, Murphree et al [26] established an ensemble-based ML model using 20 base models (Table 1) to predict glycemic response after 1 year of metformin therapy. Their models achieved AUC values ranging from 0.58 to 0.75 with baseline $HbA_{1c}$, metformin dosage, and diabetic complications being the strongest predictors. In a different study, Tao et al [27], also developed ensemble-based ML models to predict patients who achieve an $HbA_{1c}$ goal of less than 7% after 3 months of treatment with multiple antidiabetic drugs. They compared the performance of 16 different ML models (Table 1), where AUC values of the top 5 models were all greater than 0.9. Overall, these ensemble-based methods have the capability to combine multiple weak learners and generate a more accurate and robust final model, that can reduce bias and overfitting, resulting in better predictions [42,43]. Additionally, these methods have become more accessible with the development of user-friendly libraries and packages, which helps researchers use them effectively.

All these ML models identified the significant features associated with drug response. The most crucial indicators of drug response included the patient's baseline $HbA_{1c}$, fasting blood glucose, BMI, medication compliance, dietary habits, age, race, family history, diabetes duration, blood pressure, and dosage and usage of specific antidiabetic drugs [21-31]. These variables are derived from a combination of clinical trials and health records.

These studies provide a basis for understanding observational data, clinical data, interpreting drug responses, using statistical and ML algorithms, and suggesting tools and packages for data analysis. In most of the studies, a general trend of using ensemble-based models is observed, but it is essential to consider other DL-based modelling techniques for more complex datasets or when dealing with nonlinear relationships between variables. These advanced AI methods can offer the potential to find predictive factors that can help identify patients who can benefit most from a given treatment.

## AI and Drug Response in Other Disease Areas

Exploring disease areas other than diabetes that have used ML models for predicting drug responses can offer a broader perspective and valuable insights. By studying how AI models are applied in other disease contexts, we can adapt and refine these methods for type 2 diabetes. Further, learning additional techniques for data processing, feature engineering, and cross-validation can enhance the reliability of AI-driven drug response models. We identified numerous examples in the literature of the application of ML and DL methodologies in various disease domains [5,32-39], including rheumatoid arthritis, multiple sclerosis, cardiovascular disorders, and neurological conditions (Table 2).



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**Table .** Studies incorporating AI[a] to predict treatment response using clinical trials or observational data in nondiabetes conditions.

| Reference | Study objective | Disease state | Data type and number of patients (N) | AI methods | Performance |
|---|---|---|---|---|---|
| Zhao et al [36] | Machine learning and statistical analysis to predict drug treatment outcome | Pediatric epilepsy | Retrospective study n=103 | Multilayer perceptron, logistic regression, Naïve Bayes, SVM[b], RF[c], decision tree | • AUC:[d] 0.812 |
| Duong et al [37] | Using machine learning to find clinical predictors of drug response | Rheumatoid arthritis | Clinical trial data n=775 | LASSO[e] regression, RF | • AUC (LASSO): 0.74 - 0.84<br>• AUC (RF): 0.62 - 0.73 |
| Myasoedova et al [38] | Using machine learning for individualized prediction of drug response | Rheumatoid arthritis | Observational study n=643 | RF | • AUC: 0.84 |
| Falet et al [35] | Using deep learning to estimate individual treatment effect on disability progression | Multiple sclerosis | Clinical trial data n=3830 | Multilayer perceptron | • HR:[f] 0.743 |
| Koo et al [32] | To develop machine learning models for predicting remission in patients treated with biologics. | Rheumatoid arthritis | Observational study n=1204 | LASSO and ridge regression, SVM, RF, XGBoost, SHAP[g] | • Accuracy: 52.8% - 72.9%<br>• AUC: 0.511 - 0.694 |
| Liang et al [39] | Machine learning to predict response after cardiac resynchronization therapy | Cardiovascular disease | Retrospective study n=752 | LR[h], SVM, RF, LASSO, ridge, NN[i], EN[j], k-NN[k], XGBoost | • AUC>0.77 |
| Norgeot et al [34] | Using longitudinal deep learning model to predict controlled or uncontrolled state with clinical disease activity index | Rheumatoid arthritis | Electronic health records n=820 | Longitudinal deep learning | • AUC (UH[l] cohort): 0.86 - 0.96<br>• AUC (SNH[m] cohort: 0.65 - 0.83) |
| Guan et al [33] | Using AI to predict the responses to TNF[n] inhibitors in patients using clinical and genetic markers | Rheumatoid arthritis | Observational study n=2572 | Gaussian process regression model | • AUC: 0.66<br>• Correlation coefficient: 0.405 |

[a]AI: artificial intelligence.
[b]SVM: support vector machine.
[c]RF: random forest.
[d]AUC: area under the curve.
[e]LASSO: least absolute shrinkage and selection operator.
[f]HR: hazard ratio.
[g]SHAP: Shapley additive explanation.
[h]LR: linear regression.
[i]NN: neural network.
[j]EN: elastic net.
[k]k-NN: k-nearest neighbor.
[l]UH: university hospital.
[m]SNH: safety-net hospital.
[n]TNF: tumor necrosis factor.

In the case of rheumatoid arthritis, Koo et al [32] developed multiple ML models (Table 2) for prediction of remission in patients who are treated with biologic disease-modifying antirheumatic drugs. They used Shapley additive explanation values for explaining the predictions and ranking of important features. The AUC for these models ranged from 0.511 to 0.694. Guan et al [33] developed a Gaussian process regression model for the prediction of responses in terms of changes in Disease



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Activity Score-28 to tumor necrosis factor inhibitors. They used clinical and genetics data, and their model yielded an AUC of 0.66. In another study, Norgeot et al [34] developed a longitudinal DL model with clinical disease activity index to predict controlled (low activity or remission) or uncontrolled state (moderate or high activity). The AUC ranged from 0.86 to 0.96 in 1 cohort and from 0.65 to 0.83 in another cohort.

For predicting treatment response to anti-CD20 monoclonal antibodies in multiple sclerosis, Falet et al [35] used a DL-based method called multilayer perceptron (MLP). Their model yielded hazard ratio of 0.743. Similarly, Zhao et al [36] used multiple ML models (Table 2) and MLP in case of pediatric epilepsy to predict the drug treatment outcomes of antiseizure medications. Their top performing MLP model achieved an AUC of 0.812. The MLP is based on a neural network architecture with the ability to approximate any mathematical function, handle nonlinear relationships and work with diverse datasets. MLPs can compute outputs based on input data through a process called feed propagation. MLPs use an optimization algorithm called backpropagation to adjust the weights and minimize the prediction error. The flexibility of MLPs contribute to their role in various classification and regression tasks [44,45].

## Challenges and Limitations

### Data Quality and Accessibility

Using AI for predicting treatment response from observational studies comes with several challenges and limitations that must be carefully considered. First, obtaining high-quality and diverse patient data, including longitudinal and genetic data, can be challenging. Obtaining individual-level patient data linked to health outcomes can be restricted in several geographic regions, and not adequately linked. Real-world data often presents a high burden of curation and contains gaps, such as mixed-up units or incorrect health care recordings which diminish the data quality. Moreover, there are very few data sources that offer harmonized data across different medical systems, further complicating analysis, and interpretation.

### Data Biases and Missingness

Limited or biased data may prevent the AI model's ability to make precise predictions across various patient populations. Biases in the data could arise from various sources, such as demographic biases (eg, underrepresentation of certain age groups or ethnicities), clinical biases (eg, overrepresentation of patients with certain medical conditions or treatments), or geographic biases (eg, data collected predominantly from specific regions or health care settings). Furthermore, data limitations could arise from insufficient sample sizes, imbalanced class distributions, missing or incomplete data points, etc. These limitations can impact a model's ability to perform better.

It is also possible that some of the important predictive factors are not measured and therefore not included in most of the analyses. For instance, when predicting disease progression or treatment response, factors such as patient's socioeconomic status, medication history, adherence to treatment regimens, genetic variations, or lifestyle behaviors (eg, diet or exercise) could be critical for accurate predictions. However, if these factors are not routinely collected or integrated into the analysis, the model's predictive performance may be compromised.

### Data Security and Privacy

It is important to address concerns related to data security and privacy when handling patient data. Health care organizations must safeguard sensitive patient information from unauthorized access or misuse to ensure patient confidentiality. Additionally, there are ethical considerations in AI pertaining to how AI systems are developed, deployed, and used in health care. AI models should not discriminate against certain demographic groups or perpetuate existing biases in health care delivery.

### Model Interpretability, Validation, and Clinical Integration

Furthermore, ensuring the interpretability and explainability of AI models is crucial, as clinicians and researchers require insight into the factors influencing predictions for improved understanding and translation, to see increased adoption. Thorough validation and testing of the model's performance on an independent patient set is essential to ensure the clinical utility. Moreover, the integration of AI models into existing clinical workflows requires clinical collaborations. Addressing these challenges requires a collective action from stakeholders across the health care ecosystem, including researchers, policy makers, health care providers, and technology developers. By acknowledging and overcoming these challenges, AI can be a valuable tool in predicting treatment responses.

## Conclusion

This viewpoint highlights the potential of AI in predicting treatment response in people with type 2 diabetes as well as other diseases. From this literature survey, we discovered that methods such as Gaussian process regression and DL techniques such as the MLP that have been used successfully in other disease areas have not been extensively investigated for predicting drug responses in type 2 diabetes. Yet, they show significant potential for developing prediction models due to several factors. Gaussian process regression offers the advantage of providing probabilistic predictions, which can capture uncertainty in the data. On the other hand, DL techniques such as the MLP has capabilities to learn complex patterns and representations from large-scale datasets, which is useful in capturing heterogeneous drug response.

After reviewing the literature, it becomes evident that integrating diverse data sources, using feature selection algorithms, implementing effective model optimization strategies, and validation through external validation have collectively resulted in the development of robust predictive models. Moving forward, it is essential to continue exploring the innovative approaches to overcome limitations, such as the interpretability, the curse of dimensionality [46], and low-quality data.

Our viewpoint sheds light on the limitations of traditional statistical models in handling high-dimensional data effectively. To overcome these constraints, advanced ML methods should be considered, such as ensemble methods and DL, which



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demonstrate high performance in handling complex datasets. However, while these models excel in predictive accuracy, their opaque nature presents challenges in understanding the contributions of individual features to predictions. This underscores the importance of exploring methods to enhance the transparency and interpretability of models by including XAI techniques.

In summary, the literature reviewed demonstrates the successful use of AI methods for predicting drug responses in type 2 diabetes, while also identifying key clinical predictors of drug response. These models lay the foundation for the development of treatment recommendation systems, offering the potential for enhanced diabetes management, and ultimately leading to improved patient care.

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## Authors' Contributions

EP contributed to conceptualization and supervision. SG collected the existing studies and wrote the original draft. SG, EP, RK, and RG contributed to the reviewing and editing.

## Conflicts of Interest

None declared.

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## Abbreviations

**AI:** artificial intelligence
**AUC:** area under the curve
**DL:** deep learning
**EHR:** electronic health record
**$HbA_{1c}$:** glycated hemoglobin
**ML:** machine learning
**MLP:** multilayer perceptron
**RF:** random forest
**XAI:** explainable artificial intelligence


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# Digital Decision Support for Perioperative Care of Patients With Type 2 Diabetes: A Call to Action

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## Abstract

Type 2 diabetes mellitus affects over 500 million people globally, with 10% - 20% requiring surgery. Patients with diabetes are at increased risk for perioperative complications, including prolonged hospital stays and higher mortality, primarily due to perioperative hyperglycemia. Managing blood glucose during the perioperative period is challenging, and conventional monitoring is often inadequate to detect rapid fluctuations. Clinical decision support systems (CDSS) are emerging tools to improve perioperative diabetes management by providing real-time glucose data and medication recommendations. This viewpoint examines the role of CDSS in perioperative diabetes care, highlighting their benefits and limitations. CDSS can help manage blood glucose more effectively, preventing both hyperglycemia and hypoglycemia. However, technical and integration challenges, along with clinician acceptance, remain significant barriers.

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**KEYWORDS**

perioperative diabetes; artificial intelligence; clinical decision support systems

## Impact of Type 2 Diabetes Mellitus in the Perioperative Period

Type 2 diabetes mellitus affects over 500 million individuals globally with 10% - 20% of these patients requiring surgery during hospitalization [1,2]. Throughout the whole perioperative period, patients with diabetes need more stringent blood glucose management, thorough complication evaluation, and multidisciplinary collaboration to mitigate mortality risk and enhance recovery, because diabetes is associated with an increased frequency of surgical interventions and prolonged hospital stays, with perioperative death rates 50% greater than those in the population without diabetes [3]. The contributing factors for these negative outcomes are multiple, but the main reason is perioperative hyperglycemia [4]. It can result in severe metabolic and organ dysfunction, exacerbate organ damage, trigger various disorders, increase infection risk, and even lead to postoperative death [5]. Although optimal glycemic control significantly improves postoperative outcomes in patients with diabetes, particularly in mitigating the risk of infection [6], there have long been obstacles regarding achieving the ideal method for managing blood glucose levels.

## Limitations of Current Perioperative Blood Glucose Management

Currently, perioperative blood glucose management is primarily categorized into three phases: preoperative assessment, intraoperative care and monitoring, and postoperative medication and diet [7]. Regular blood glucose monitoring during surgery is essential for effective perioperative control, often necessitating checks every 2 hours [8]. Nonetheless, stress responses, medication interventions, and several other circumstances can cause significant short-term elevations and rapid fluctuations in blood glucose levels [9]. Conventional measurement intervals are inadequate for detecting fast fluctuations in blood glucose



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levels and the cumulative impact of risk variables, thereby overlooking critical intervention chances. The American Diabetes Association's Standard states that perioperative patients require more frequent blood glucose monitoring, particularly when insulin therapy is administered [10]. A 2-hour measurement interval may be insufficient for real-time control; thus, more frequent or continuous monitoring during surgery is recommended. In addition, blood glucose variability exposes patients to dual risks of hyperglycemia and hypoglycemia. Throughout this period, the Centre for Perioperative Care recommendations advise maintaining blood glucose levels between 6 and 12 mmol/L [1], contingent upon the administration of insulin and glucose, while either stringent or lenient blood glucose management may easily disrupt this "equilibrium." Consequently, tools are required for real-time glucose data monitoring and individualized medication distribution [11].

## Potential of Clinical Decision Support Systems in Perioperative Blood Glucose Management

### Clinical Decision Support Systems

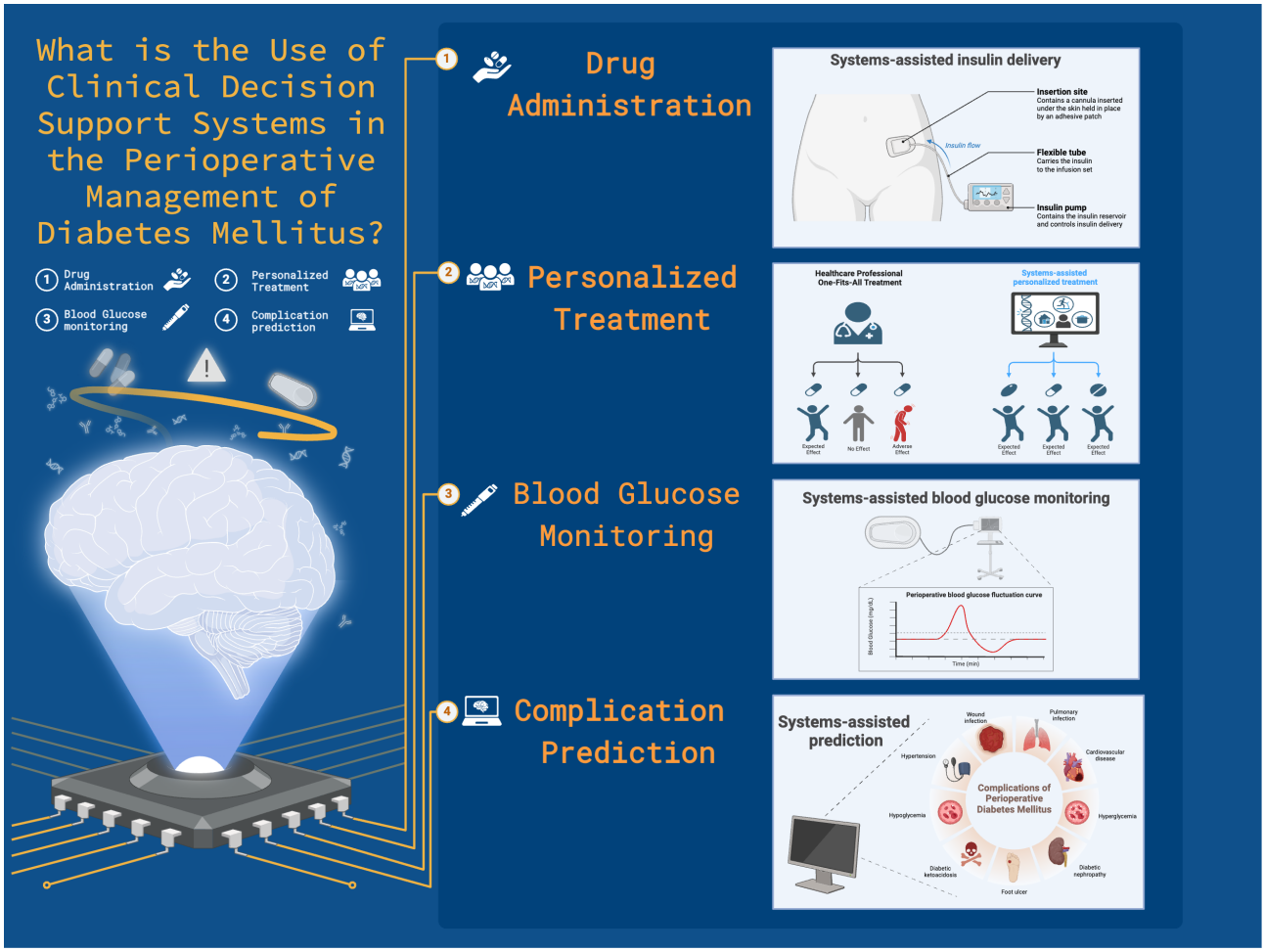
Clinical decision support systems (CDSS) have gained significant traction due to the widespread adoption of electronic medical records and electronic health records in the past decades. These computerized systems may provide clinicians with a wide range of support, from basic pop-up warnings for medication errors to sophisticated tools that offer evidence-based recommendations for certain clinical situations (Figure 1) [12-14]. During the perioperative period, surgeons and anesthesiologists must consider multifaceted care, including blood glucose management, which requires experience and integrity in practice. The complexity of these tasks can be challenging for junior physicians and may create a gap between real-world clinical effectiveness and the efficacy observed in clinical trials. However, the advent of CDSS has introduced novel technical advancements to conventional perioperative management techniques.

A systematic review by Cai and colleagues summarizes trials and observational studies about the effectiveness of the CDSS in real-world settings [15]. As the American Association of Clinical Endocrinology stated in their 2023 Type 2 Diabetes Management Algorithm [16], personalized care is emphasized through evidence-based tools such as continuous glucose monitoring and automated insulin dosing systems. These technologies facilitated the ongoing surveillance of glucose levels and the secure delivery of insulin during surgical procedures. Furthermore, they have the potential to mitigate the likelihood of perioperative complications by assuring adherence to optimal glucose management guidelines [17]. Considering the aforementioned qualities, in contrast to conventional perioperative blood glucose control techniques, CDSS can address the challenge of detecting fast changes inherent in typical 2-hour monitoring intervals and provide real-time data to seize the critical intervention opportunities. Simultaneously, CDSS may precisely modify insulin dose according to real-time blood glucose data and specific patient situations, mitigating the twin hazards of hyperglycemia and hypoglycemia, thereby facilitating more effective and safer blood glucose regulation.



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**Figure 1.** Application of clinical decision support systems in the perioperative care and management of diabetes mellitus.




### Personalized Drug Delivery

Glucommander (Glytec) has set an example as an electronic glycemic management system since 1984 using a computer-based algorithm to guide the administration of intravenous insulin [18]. Glucommander (Glytec) formulates insulin dosage recommendations by analyzing patient-specific blood glucose patterns after health care professionals choose either a personalized dosage or a weight-based multiplier as the first dosing approach for the first 24 hours [19]. Until now, after undergoing integration and evaluation at multiple medical centers, Glucommander (Glytec) has demonstrated its effectiveness in enhancing outcomes for surgical patients with both type 1 and type 2 diabetes. Specifically, it has reduced the occurrence of hyperglycemia and hypoglycemia, treated diabetes ketoacidosis, and increased adherence to the guidelines for achieving individualized treatment [20-22].

### Intraoperative Blood Glucose Level Monitoring

Similarly, there are CDSS that continuously monitor changes in perioperative blood glucose levels by providing in-room pop-up prompts. In a systematic review [15], one of the included studies [23] designed and evaluated a new CDSS using Epic's best practice advisory (BPA) framework. This tool is designed to remind anesthesia providers to measure blood glucose levels at specified intervals for patients at risk of abnormal perioperative blood glucose levels. The research results found that the implementation of the BPA CDSS significantly improved intraoperative blood glucose monitoring and management in the postanesthesia care unit (PACU). The PACU hyperglycemia rate decreased from no CDSS to the BPA CDSS (10.4% to 7.2%, *P*=.031).

## *Dispersion and Untimely Integration of Data Affects the Functionality of CDSS*

### Barriers Hindering the Effectiveness of CDSS

Notably, several barriers currently hinder the effectiveness of CDSS, highlighting the call for action. For patients with type 2 diabetes during the perioperative period, multimodal data are necessary for the development and maintenance of an effective CDSS, such as blood glucose monitoring data, drug information, surgical types, comorbidity, and more. However, such data are often scattered across various systems and require manual input. The integration of a substantial volume of data from many systems and the necessity for real-time updates in CDSS impose significant requirements on technical and system compatibility attributes. Moreover, blood glucose levels change continuously throughout the whole perioperative period caused by surgery, stress, or fasting. Without timely integration, decisions may be delayed or based on outdated information, thereby adversely impacting patient outcomes. Insufficient integration between electronic health records and CDSS might compromise the real-time prediction and accuracy of critical data [24].



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### Alarm Fatigue and Clinician Skepticism

CDSS-based decisions combine data, algorithms, clinicians' expertise, and clinical judgment. An estimated 95% of CDSS alerts were declined by clinicians [25]. The sheer volume of redundant messages exacerbates the burden in the practice. Some clinicians may develop "alarm fatigue" and become desensitized to all warnings, including those that are clinically valuable. Nonetheless, placing excessive reliance on CDSS recommendations is not always appropriate. Despite the exceptional accuracy of the generated data, CDSS are fundamentally an opaque system with an internal operational mechanism that is hard to interpret [26]. If professionals simply press the button of CDSS without comprehending the underlying principles, such decisions will be very dangerous. Assuming that patients with diabetes mellitus experience hypoglycemia and hyperglycemia crises, professionals should not only be proficient in how to obtain emergency care advice through CDSS, but also implement appropriate care measures based on their own experience and understanding of patient data. Therefore, what stands out the most is striking a balance between CDSS and clinicians, or in other words, algorithms and clinical experience of diabetes management.

### Balancing Cost-Effectiveness

The development and maintenance of CDSS require acknowledging the need for robust data sources, advanced informatics systems, technical support, and personnel training. Building CDSS from the ground up to meet criteria can incur substantial costs, ranging from hundreds of thousands to millions of dollars. Custom-developed systems also require ongoing maintenance and upgrades. Maintenance expense usually varies from 10% to 20% of the original development expenditure. The annual cost of maintaining CDSS for diabetes management is approximately US $9500 for one small-sized institute, US $20,600 for medium-sized, and US $76,000 for large-sized ones [27]. For medical institutions with limited resources, managers need to weigh whether the potential improvements in patient outcomes or compliance with perioperative medical personnel guidelines are worth the high cost [28]. After rigorous evaluation, the effectiveness of some CDSS has been found to be disappointing. Jeffery and colleagues [29] systematically reviewed 15 randomized trials that assessed the effectiveness of CDSS in diabetes mellitus management compared with a non-CDSS control group (usual care, seminars, educational material, and glucose monitoring systems), but found no significant outcome that CDSS could reduce hospitalizations and improve quality of life. Meanwhile, the study found that in the third month, the pooled estimate of the change in glycated hemoglobin ($HbA_{1c}$) was 5 mmol/mol (95% CI –9 to 1; ie, –0.5%, 95% CI –1.0 to 0.1), but it is only a clinically significant threshold and this result is not significant. Blindly using CDSS may result in getting half the results with double the effort.

### Future Direction

The number of CDSS specifically designed for diabetes management remains limited. The majority of CDSS development is directed towards traditional perioperative patients, emphasizing factors such as surgical type, patient age, and vital signs; however, limited attention is given to comorbidities, such as diabetes, in patients undergoing surgery. A prospective study in 29 countries across Europe identified diabetes mellitus as the fourth most common long-term condition (15.4%). Meanwhile, diabetes mellitus also accounts for a large share of patients with multimorbidity, with 19.4% of patients having two long-term health conditions and 43.8% having more than three long-term health conditions [30]. The coexistence of multiple diseases substantially elevates the mortality rate of patients undergoing surgery, sometimes doubling it. Poorly controlled chronic diseases, such as those with high American Society of Anesthesiologists scores, and compromised functional status (eg, frailty) further heighten these risks. If the database used for developing CDSS does not cover specific patients (such as those with complex comorbidities), this deficiency may lead to the system ignoring the risk factors of specific patients and providing treatment recommendations with biased risks.

The disparity in diabetes care throughout the world is becoming worse. The treatment rate of diabetes has remained low and relatively unchanged for many low-income and middle-income nations during the last several decades. More than 90% of people with diabetes in some nations did not get treatment between 1990 and 2022 [31]. Limited by the ratio of doctors-to-patients and infrastructure, diabetes may impose a heavier burden on these low-resource clinical environments, which may require the introduction of CDSS. However, its effectiveness in the low-resource environment remains to be explored [32]. In the presently advanced CDSS applications, the initial datasets used for development mostly originate from populations in developed countries, and their efficacy is often poor when applied to other locations or populations. A skin cancer diagnostic algorithm developed using data from White patients may have reduced efficacy for those with darker skin tones [33]. Prior to implementing these systems, it is essential to analyze data bias to avert unjust decision-making and mitigate health disparities among ethnic minorities or resource-limited regions. Furthermore, the deployment of CDSS necessitates the integration of information systems and financial investment, taking into account the restricted accessibility and technical capacities in resource-constrained regions. This has prompted demands for international collaboration, including the implementation of remote medical platforms or the direct supply of digital medical assistance [34].

In light of the issues faced by present CDSS implementations, the following recommendations are anticipated to be implemented (Table 1). Initially, at the source, deep learning techniques may be used to extract unstructured data from multimodal text and combine it into a unified system for analysis after standardization [35]. This metric enhances both the frequency of CDSS use and its real-time performance [36]. A potential innovation is the digital twin, a mathematical model of a system created from all accessible data. This technique may generate a virtual personal twin of a perioperative patient, capture the patient's perioperative trajectory without affecting their physiological condition, and be used for complication prevention and rehabilitation treatment [37]. Secondly, given that clinical physicians' adoption of CDSS and alarm fatigue may arise from their skepticism towards the system and their



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proficiency in computer abilities, it is essential to investigate their requirements and formulate targeted training programs during the design phase of CDSS [36]. The alarm system may be enhanced by applying human factors engineering principles, hence minimizing false alarms and overlooked alerts [38]. Lastly, a systematic, step-by-step strategy is essential. It is advisable to do feasibility studies and pilot studies prior to real-world implementation, not only to identify software and hardware difficulties during the deployment phase but also to assess the long-term cost-effectiveness across various health care settings [39].

**Table .** Functions of clinical decision support systems (CDSS), limitations, and evidence-based solutions.

| Functions of CDSS | Limitation of CDSS | Solutions to break limitations | Explanation of solutions |
|---|---|---|---|
| **Personalized Drug Delivery**<br>Based on real-time blood glucose data and the patient's specific condition to calculate and recommend the appropriate insulin dosage. | **Data Integration Defects**<br>The data required for CDSS are usually scattered across various systems and require manual input, which affect the real-time performance of analysis. | Integrate the required data for analysis into the same system adopting new technologies. | Deep learning techniques can extract and analyze relevant unstructured information from clinical records, including single concept extraction, temporal event extraction, relation extraction, and abbreviation expansion [35]. |
| **Blood Glucose Monitoring**<br>Real-time monitor changes in perioperative blood glucose levels by providing in-room pop-up prompts. | **Alarm Fatigue**<br>Too many unnecessary alerts or suggestions lead to providers losing trust or being insensitive to CDSS. | Applying human factors engineering principles to design the alarm systems. | A system designed based on human factors principles may alleviate alarm fatigue, with specific strategies including reducing errors related to availability, delivering clinical data nearer to the decision point, and presenting alert text in a tabular style [38]. |
| **Blood Glucose Management**<br>Adherence to clinical guidelines to perform clinical procedures. | **Clinician Skepticism**<br>Clinicians have a resistant or opposing attitude towards the opinions or suggestions given by CDSS. | Consider the needs of clinicians and develop specific training plans. | Clinicians should be involved in the design and development of CDSS in the early stages, and receive hands-on training and education before implementation. Clinicians' negative attitudes and resistance towards CDSS can be alleviated during this process [36]. |
| **Complication Prediction**<br>Utilizing patient perioperative information to predict the incidence of adverse events (such as hyperglycemia, hypoglycemia, etc) | **Cost Challenges**<br>The development and maintenance of CDSS may consume capital or human resources and cannot guarantee long-term cost-effectiveness. | Do feasibility studies and pilot studies prior to real-world implementation.<br>Long term follow-up to collect cost-effectiveness data. | Feasibility studies and pilot studies can help determine whether CDSS can transfer its good performance from the development phase to real-world settings, ensuring its correct and safe use in health care practice [39].<br>In addition to collecting cost data, long-term indicators such as patient prognosis or quality-adjusted life years should also be collected to determine whether the implementation of CDSS is a good return on investment for both hospitals and patients [28]. |

## Conclusion

In summary, CDSS are revolutionizing the paradigm of perioperative diabetes mellitus care and management in the real world, shifting from conventional strategies to data-driven real-time monitoring and individualized treatment. Given the high volume of surgeries for patients with diabetes and the elevated incidence of postoperative complications, these systems are promising in many ways: integrating patients' blood glucose monitoring data and providing real-time blood glucose fluctuation warnings, offering personalized medication recommendations to prevent drug interactions or improper dosage adjustments, and assisting health care providers in predicting the surgical risk based on the patient's historical data ($HbA_{1c}$, preoperative blood glucose control, complications, and other factors). However, several barriers currently hinder the effectiveness of CDSS, though the original intention of these intelligent health intervention measures is to address the existing difficulties in the management and care of perioperative patients with diabetes mellitus. Thus, future research on CDSS must prioritize model optimization, particularly enhancing performance for patients with intricate comorbidities, especially diabetes, and develop techniques to bolster physicians' confidence and acceptance. Several randomized controlled trials and cost-benefit analyses with extended follow-up durations across various countries to validate the system's efficacy, universality, and practicality, and a pilot study are recommended before implementation. This will ultimately ensure that the



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system can cover high-risk factors and provide evidence-based treatment recommendations, reducing the worldwide diabetes care disparity and advancing health equality.

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## Authors' Contributions

JC wrote the first draft of this manuscript. All authors (JC, PL, WL, XH, SL, and TZ) developed the viewpoint design, carefully reviewed the manuscript, and edited the whole manuscript.

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## Conflicts of Interest

The Co-Editor in Chief of *JMIR Diabetes*, SL, is a co-author on this paper.

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## Abbreviations

**BPA:** best practice advisory
**CDSS:** clinical decision support systems
**$HbA_{1c}$:** glycated hemoglobin
**PACU:** postanesthesia care unit

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# Revolutionizing Hypoglycemia Management in Long-Term Care: Lessons Learned From a Pilot Quality Improvement Initiative Using Continuous Glucose Monitoring

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## Abstract

Despite efforts to raise glycemic targets and reduce modifiable risk factors, hypoglycemia continues to impact a large number of long-term care (LTC) residents living with diabetes mellitus and remains one of the leading causes of hospitalization in this cohort. Effective, sustainable practice strategies to monitor and maintain glycemic control in LTC are lacking. We describe the stepwise approach used by 2 LTC homes that switched from traditional fingerstick testing to a continuous glucose monitoring (CGM) system as part of a quality improvement initiative to reduce nursing workload and address hypoglycemia. This was an exploratory pilot project. A working group was established at each of the 2 participating LTC homes, including representatives from management and direct care staff. Kickoff meetings were held with key direct care staff to discuss the limitations of current monitoring practices and potential solutions. The following interventions were agreed upon and implemented by the working groups: (1) the initiation of structured glucose monitoring for residents using CGM (FreeStyle Libre 2), requiring scanning of sensors 4 times per day; (2) provision of staff education and training on CGM by a diabetes expert; and (3) scheduling of interdisciplinary rounds as needed to optimize diabetes management. System changes were gradually introduced in a stepwise manner over a 3-month period (intervention phase), during which the LTC homes progressed from traditional fingerstick testing to point-of-care sensor readings and then to full use of the CGM software platform. Hypoglycemia was defined as a glucose reading of ≤4 mmol/L. Glucose readings were collected from 38 residents living with diabetes mellitus and receiving insulin in the 6 months before the start of the intervention phase (baseline evaluation) and in the 6 months after the end of the intervention phase (post-launch evaluation). All hypoglycemic readings detected by a sensor at a point-of-care test were validated using a fingerstick test. Nursing workload associated with glucose testing was assessed in an anonymous survey of nursing staff at baseline and after the launch. The approach resulted in a 40% reduction in nursing time required to complete a glucose reading (from 5.1 min per test at baseline to 3.1 min per test at the post-launch evaluation). The frequency of glucose monitoring increased from a total of 19,438 glucose readings in the baseline evaluation to 35,971 point-of-care sensor scans in the post-launch evaluation. The number of detected hypoglycemic events increased 12-fold, from 88 in the baseline evaluation to 1049 in the post-launch evaluation. Hypoglycemic events continue to impact a large number of LTC residents living with diabetes mellitus. CGM can improve the detection of hypoglycemic events while decreasing nursing workload. A gradual transition to CGM can help overcome underlying barriers and concerns and ensure a sustainable approach.

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**KEYWORDS**

hypoglycemia; diabetes; long-term care; continuous glucose monitoring; detection; nursing

## Introduction

### Impact of Hypoglycemic Events in Long-Term Care

Hypoglycemia affects a large number of long-term care (LTC) residents living with diabetes mellitus [1] and is recognized as one of several leading causes of potentially avoidable hospitalizations in this cohort [2]. Based on an analysis of US hospital data, hypoglycemia is diagnosed in roughly 6% (6609/106,602) of hospital admissions among LTC residents living with diabetes [3]. Results of another US-based study suggest that, on average, 1 in 4 LTC residents living with type 2 diabetes mellitus experience severe hypoglycemia (<3 mmol/L) each year [4]. Severe hypoglycemia has been shown to be approximately 2-fold more prevalent in LTC residents with dementia than in those without dementia [5]. Other



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independent risk factors for hypoglycemia include increasing age, frailty, and reduced renal function [6,7]. Modifiable risk factors include erratic meal consumption and the administration of sulfonylureas and/or insulin [8]. As awareness of the considerable impact of hypoglycemia on resident health increases, current practice guidelines for older adults with diabetes mellitus have revised glycemic targets, including raising glycated hemoglobin ($HbA_{1c}$) levels, to help prevent hypoglycemic events [6,9].

## Barriers to Preventing Hypoglycemic Events in LTC

Despite the revised glycemic targets, there remains continued reluctance among prescribers to de-intensify hypoglycemic regimens [10]. Recent studies have found that up to 40% of residents met the criteria for "overtreatment" or "potential overtreatment" with the continued use of potentially hypoglycemia-inducing drugs such as insulin or a sulfonylurea [11-13]. Following an emergency department visit or hospitalization for hypoglycemia, fewer than half of all patients had documented reductions in sulfonylurea or insulin use [14]. Reluctance to de-intensify may be due, in part, to a fear of jeopardizing diabetes control and forfeiting health benefits associated with the current medication regimen [15]. It may also reflect a need for better guidance on how to deprescribe hypoglycemic regimens [16]. Limitations inherent to current glycemic monitoring practices in the LTC setting may also contribute to hesitation among prescribers in changing treatment regimens. At present, fingerstick blood glucose testing is the preferred approach for glycemic monitoring with continuous glucose monitoring (CGM) still viewed as an emerging technology in LTC. While efforts in LTC have focused on moderating glycemic control and setting more appropriate $HbA_{1c}$ targets, a rigorous and non-invasive approach for detecting and preventing hypoglycemia events is still lacking.

## Structured Blood Glucose Monitoring and the Prevention of Hypoglycemia

Structured blood glucose monitoring, which is characterized by a set schedule of actionable blood glucose measurements taken at specific times to guide individualized care, has been shown to improve glycemic control compared with unstructured testing [17]. Traditionally, structured blood glucose monitoring has involved either taking 5 - 7 measurements daily over 1 - 3 days or through "staggered" testing across a week. The current clinical practice guidelines of Diabetes Canada recommend the use of structured glucose monitoring, including the gathering of a 7-point blood glucose profile every 1 - 3 months until glycemic targets are achieved. The guidelines also recommend more frequent glucose testing (4 times per day and/or overnight) when $HbA_{1c}$ is not at target or there are episodes of hypoglycemia [18]. Unfortunately, time constraints, staffing shortages, resident discomfort, and resistance to multiple daily fingersticks are significant barriers to this intensive monitoring approach in LTC [17]. Dehydration and poor circulation, both of which are common among elderly people, may also affect the accuracy of fingerstick test results [19,20].

## Incorporating CGM Into Hypoglycemia Prevention Strategies

There is growing evidence demonstrating that CGM can serve as an effective alternative to structured blood glucose monitoring and help to reduce hypoglycemic events and glycemic variability [21,22]. CGM has the potential to provide a more comprehensive view of hypoglycemic events than fingerstick testing [23] while reducing nursing workload and improving resident quality of life. In fact, current guidelines now recommend CGM when possible as a way to reduce $HbA_{1c}$ levels and the duration of hypoglycemia [18].

Despite these potential benefits, the adoption of this new technology in the LTC setting has been slow, with blood glucose monitoring remaining the standard approach. Concerns regarding accuracy and reliability are often cited as the primary reasons for not using the technology. These concerns may stem from outdated manufacturer warnings associated with early versions of CGM technology, which indicated that readings might be inaccurate for a few hours after a new sensor is applied due to "sensor calibration." There is sometimes apprehension related to the clinical importance of "lag time," the time required for glucose to diffuse across blood vessel walls into the interstitial space. Lastly, attempts to compare the performance of different glucose monitoring systems using the mean absolute relative difference (MARD) have also contributed to misgivings regarding the technology. Additional barriers in the LTC setting include the practical considerations related to accessing test results using the CGM software platform, developing fluency with CGM metrics (eg, time in range and trend arrows), and communicating results to those unfamiliar with the system. While successful incorporation of CGM into daily monitoring strategies can effectively reduce hypoglycemia as well as assist in the detection of hypoglycemic events [24], overcoming these practice barriers requires a comprehensive, stepwise implementation strategy to ensure staff are adequately trained and comfortable with the system.

## Implementation of a Hypoglycemia Prevention Strategy Using CGM in LTC Practice

Quality improvement initiatives focusing on implementing CGM in LTC can serve as useful guides for overcoming practical challenges related to everyday practice [25,26]. In October 2021, a pilot quality improvement initiative was launched at 2 LTC facilities in northern Ontario. The pilot initiative focused on a new diabetes practice model in LTC using CGM to reduce nursing workload and address hypoglycemic events. While the use of CGM successfully reduced nursing time, it also led to a 12-fold increase in the detection of hypoglycemic events, highlighting the extent of previously unrecognized episodes. This enhanced detection provided critical visibility into the problem and represented an essential first step toward driving meaningful reductions. Despite the pilot project not yet having led to reductions in the frequency of hypoglycemic events over a predetermined 6-month time period, it produced a suitable framework for overcoming major barriers to detecting hypoglycemia in LTC. The intent of this study is to describe the stepwise approach used by the LTC homes that participated in this quality improvement initiative.



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Learnings from this project may help other LTC homes transition smoothly and safely to a new diabetes management practice model for detecting hypoglycemic events while improving resident health and safety as well as reducing nursing workload.

## Step-Wise Approach to CGM Implementation

### Planning

Prior to commencement, the project received approval from the LTC homes' internal research ethics board. The ARECCI Ethics Guideline Tool was used to confirm that the initiative qualified as a quality improvement project. As such, resident-level data collected during the initiative were accessed only by individuals within the circle of care. Home-level findings were de-identified and shared only in aggregate with the broader team, and only to the extent necessary to support quality improvement efforts. No additional compensation was provided to residents or staff as part of this project.

### Baseline Evaluation

In order to adhere to formal quality improvement methodology, a working group was established at each facility. The working group included representatives from both management and direct care staff who had an interest in mitigating the risk of hypoglycemic events. A baseline assessment of current diabetes management practices and the incidence of hypoglycemic events were shared with the working group. At program launch, both LTC homes were performing glucose monitoring using registered staff in accordance with each resident's individualized care plan. This was being done predominantly through fingerstick testing. Although CGM had already been partially introduced at one of the two facilities at the time of program start-up, the CGM software was not being used and all clinical decisions were based on the point-of-care scanning of glucose readings. These were being transcribed to the electronic health record in the same way as fingerstick test results.

All residents with diabetes on insulin were considered eligible for inclusion in this study (based on Ontario requirements for coverage). At baseline, a cohort of 38 residents living with diabetes mellitus and receiving insulin were initially examined from the participating LTC homes. This represented 31% (38/121) of residents living with diabetes mellitus and 28% (38/429) of the total resident population across both facilities. A preliminary analysis included a review of 19,438 glucose readings recorded over the previous 6 months.

Nursing workload associated with fingerstick testing was assessed using the aggregate findings of the self-reported estimates of time taken to complete glucose monitoring (including the time taken to access the resident's record, approach the resident, perform the scan, and record the data) in an anonymous paper-based survey of nursing staff, completed during mandatory staff meetings.

Clinical outcome measures were selected from a variety of available surrogate markers of health (eg, glucose readings and the presence of risk factors) and critical health events (hypoglycemia, falls, and hospitalizations) with consideration given to both relevance and sustainability. Hypoglycemic events, defined as glucose readings ≤4 mmol/L, were chosen as the most straightforward outcome measure for this pilot project.

### Implementation of the CGM System

Kickoff meetings with key direct care staff were held both to discuss limitations associated with current monitoring practices and to empower staff with some potential solutions. Issues raised at the kickoff meetings are summarized in Table 1.

**Table .** Problems with the current approach to glucose monitoring as discussed at the kickoff meetings along with proposed solutions.

| Problem | Key concerns | Proposed solutions |
|---|---|---|
| Majority of point-of-care glucose test readings are not incorporated into clinical decision making | • Large number of glucose readings are collected and entered into the electronic health record but not used<br>• Chronological list of glucose readings does not facilitate trend analysis<br>• Current timing of point-of-care testing does not provide a complete 24-h glycemic profile<br>• Hypoglycemia prevention is left in order to deal with more urgent health matters; also, difficulty in detecting trends with linear reporting of values | • Introduction of the CGM[a] software to provide a comprehensive glycemic profile<br>• Implementation of 4 daily scans of the sensor in order to capture a complete 24-h view of glycemic control<br>• Scheduling of diabetes medication review |
| Continued uncertainty as to whether sensor readings are reliable and accurate and when to double-check readings using a fingerstick blood glucose test | • Unclear if newly applied sensors are reliable. Historically, staff were instructed to perform fingerstick testing for 48 h following the initial application of a FreeStyle Libre sensor<br>• Unclear when sensor readings should be validated using fingerstick testing | • Discontinuation of LTC[b] home policy requiring 48-h fingerstick monitoring following the initial application of a new sensor (with sensor scanning now possible 1 h after application)<br>• Verification using fingerstick testing only for unexpected readings and hypoglycemic events |

[a]CGM: continuous glucose monitoring.

[b]LTC: long-term care.

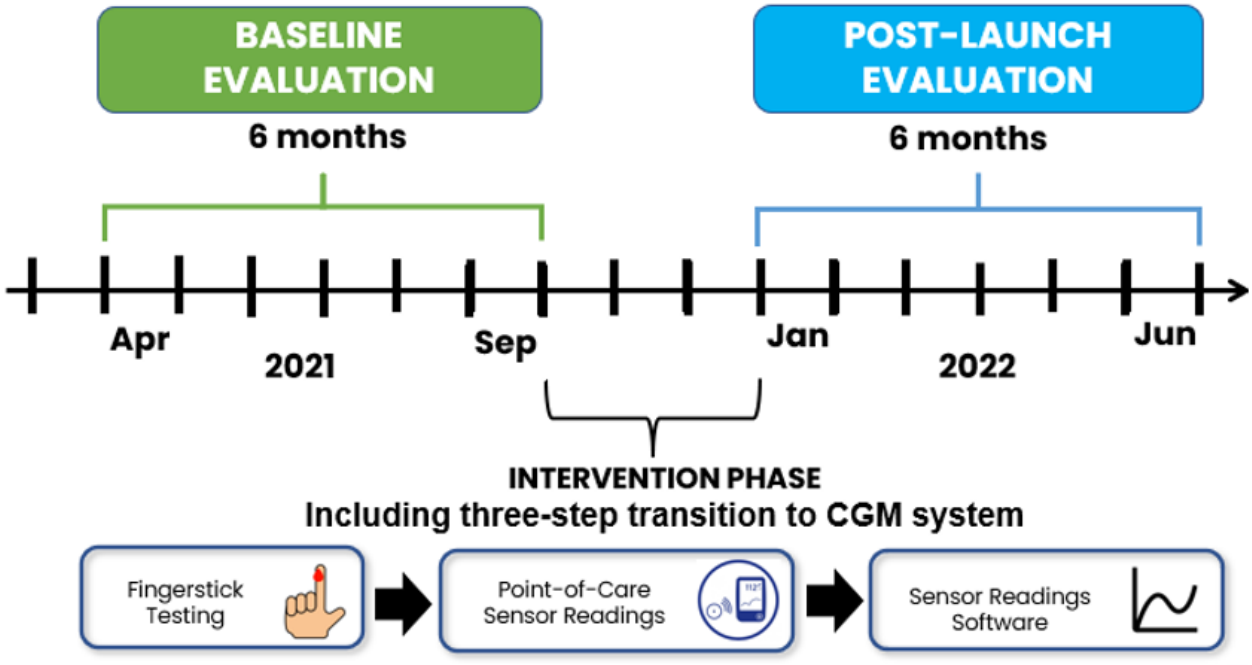


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Proposed solutions vetted at the kickoff meetings were then carried forward for implementation by the working groups. Key interventions that were agreed upon included: (1) the initiation of structured glucose monitoring for residents using CGM, requiring scanning of sensors 4 times per day to ensure a complete 24-hour glycemic profile; (2) the provision of staff education and training, by a diabetes expert, on CGM and use of the LibreView platform (Abbott Diabetes Care) for making clinical recommendations; and (3) the scheduling of interdisciplinary rounds as needed to optimize diabetes management, involving nursing staff, the clinical consultant pharmacist, and the dietician.

Over a 3-month period, system changes were gradually introduced following a stepwise approach to allow each facility to transition to CGM monitoring while addressing perceived risk associated with adoption of the new practice model. LTC homes progressed from traditional fingerstick testing to point-of-care sensor readings (where the reader was used simply to check readings at a point in time) and then to the full use of the software platform (Figure 1). All hypoglycemic readings detected by a sensor at a point-of-care test were validated using a fingerstick test.

**Figure 1.** Project timeline including baseline evaluation, intervention phase, and post-launch evaluation. CGM: continuous glucose monitoring.




## CGM Technology Used

The CGM sensor used was FreeStyle Libre 2 (Abbott Diabetes Care), with scans conducted using the FreeStyle Libre reader. One reader per resident was needed for scanning the sensors, which was carried out 4 times per day. Readers were then connected to a computer to upload data to the LibreView platform.

## Post-Launch Evaluation

### *Overview*

Following implementation of the agreed changes, a 6-month evaluation was conducted to determine the sustained impact of the intervention. During this time, 35,971 glucose readings were gathered to evaluate changes in glucose management. Nursing staff were surveyed again to measure changes in nursing workload.

### *Nursing Workload*

Nursing workload reduced from a mean (SD) of 5.1 (1.4) minutes per test to 3.1 (1.7) minutes per test, resulting in a 40% reduction in nursing time for an equivalent number of tests. This was estimated from survey results completed by over 60% of nursing staff.

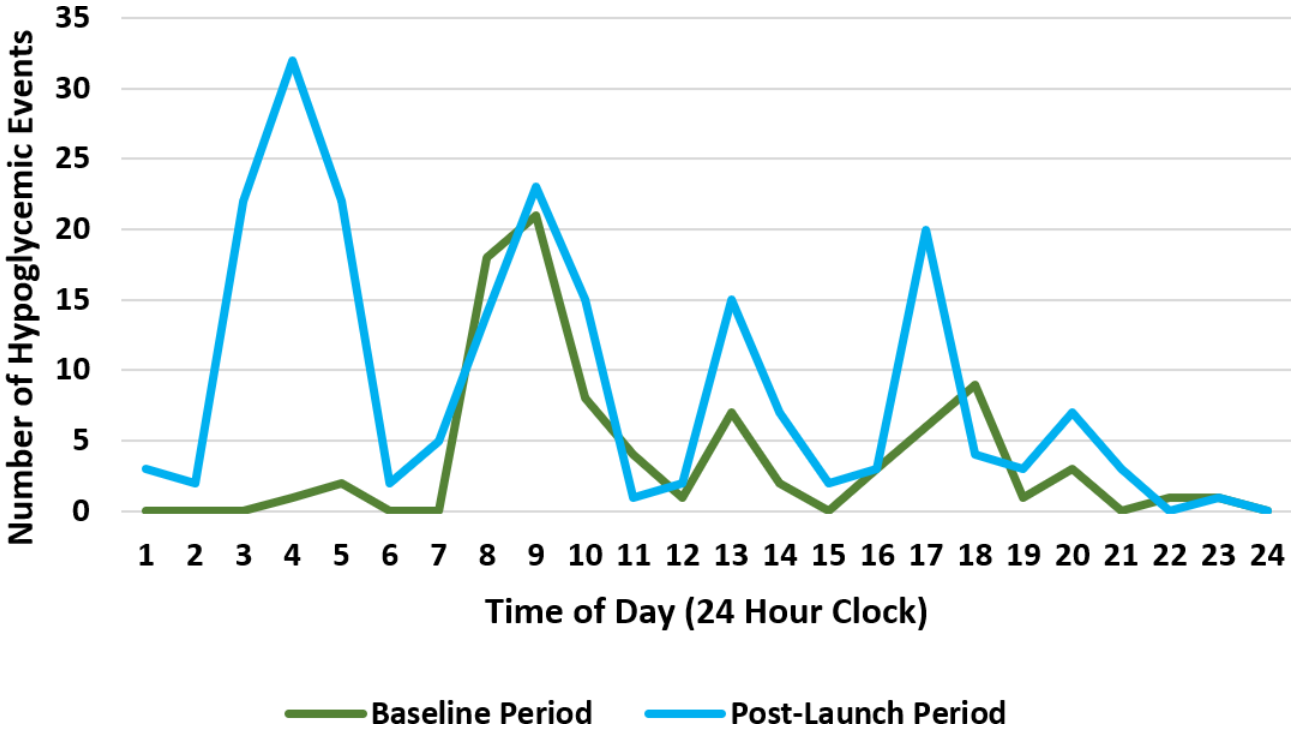
### *Hypoglycemic Events*

Based on the aggregate findings from the 2 participating LTC homes, point-of-care scans increased from 19,438 glucose readings in the 6-month baseline evaluation period to 35,971 glucose readings in the 6-month post-launch evaluation period, showing an increased frequency of monitoring. The number of hypoglycemic events detected (defined as glucose readings ≤4 mmol/L) increased from 88 (baseline) to 208 (post-launch evaluation) using CGM as a point-of-care test (Figure 2).



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**Figure 2.** Hypoglycemic events detected at baseline versus post-launch evaluation by the time of day.




Repeat testing using a fingerstick device was performed for all observed hypoglycemic events, representing 0.6% (208/35,971) of all post-launch readings. The analysis of glucose data using the LibreView glucose monitoring software identified 1049 hypoglycemic events during the same post-launch period, representing a 12-fold increase in the number of detected events compared with the baseline period (Table 2).

**Table .** Number of hypoglycemic events detected at baseline versus the post-launch evaluation according to the screening method used.

| Assessment period and screening method used | Number of hypoglycemic events |
|---|---|
| Baseline | |
| Blood Glucose Testing | 88 |
| Post-launch period | |
| Sensor reading only | 208 |
| Sensor reading software (Libreview) | 1049 |

## Discussion

### Lessons Learned

This quality improvement initiative has shown that CGM can be successfully adopted in an LTC setting, reducing the amount of nursing time required per test. Importantly, there is an expected positive effect on residents' quality of life by using sensor scans to reduce invasive fingerstick testing by over 99%.

### Importance of Previously Undetected Hypoglycemia

By capturing a 24-hour glycemic profile, this quality improvement monitoring strategy uncovered approximately 800 hypoglycemic events that would not have been detected using point-of-care scanning. These previously undetected hypoglycemic events occurred predominantly in the early morning hours when conventional blood glucose testing is difficult to perform with sleeping residents. Although these hypoglycemic events did not require rescue measures, the inherent risk associated with recurrent asymptomatic hypoglycemia is incontrovertible. The findings of this quality improvement initiative are in keeping with current research completed in older adults showing that at least 46% of hypoglycemic events happen overnight [23,27]. Using CGM software to understand the onset and duration of these hypoglycemic events can inform efforts to both reduce glycemic variability and increase time in range [9,21,22]. Clinical research has shown that raising $HbA_{1c}$ targets in older patients, although recommended, does not obviate the risk of hypoglycemic events [22,28]. While $HbA_{1c}$ continues to serve as a gold standard for assessing glycemic control, it does not confirm glycemic variability or the frequency of hypoglycemic events [29]. The time in range and time below range calculated by the CGM software can better measure the risk of hypoglycemic events [1,30].

### Impact on Nursing Workload and Resident Quality of Life

By saving 2 minutes per test with an average of 1030 tests per resident per year (the testing frequency in the 6-month baseline evaluation period), approximately 34 hours of nursing time



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could be saved per resident per year. At US $38.43 per hour, this would result in potential annual savings of nursing costs of over US $1306.45 per resident per year. While this is a simplified estimate that does not represent a formal health economic analysis or account for variability in wages, indirect costs, or other system-level considerations, time savings shown through this project nevertheless support the growing evidence that CGM can reduce costs associated with diabetes management outside of the hospital [31]. At the time of this initiative, it was necessary to tether the CGM reader device to a computer to upload data. More recently, the ability to use mobile device apps to scan CGM sensors and automatically upload data may mean that greater time savings can be achieved.

In LTC, full provincial coverage is available in Ontario for CGM readers and sensors for residents using insulin, as well as blood glucose test strips and readers. However, lancing devices and related supplies remain an ongoing cost incurred by LTC homes. While CGM is comparable in cost to intensive blood glucose monitoring, four or more blood glucose checks daily over an extended period is often impractical in LTC, so average traditional monitoring costs tend to be lower in practice. This initiative showed that there is a clear need for greater vigilance around glycemic variability, and demonstrated how CGM can make intensive glucose monitoring feasible. During the study period, CGM use allowed a larger number of point-of-care glucose tests to be conducted in a given amount of nursing time compared with fingerstick testing. Further use of the data uploaded to LibreView may allow intensive glucose monitoring to take place alongside reductions in nursing workload. The number of hypoglycemic events detected during this project highlights that, even when CGM technology is not available, periodic intensive glucose monitoring using fingerstick testing should be considered.

### Concerns About the Use of CGM Technology for Residents Living With Cognitive Impairment

For residents living with cognitive impairment, reducing fingerstick tests would be beneficial, as they may cause distress and reduce well-being among people who do not understand the purpose of the tests [32]. However, one concern expressed in advance of this project was that residents living with cognitive impairment might remove the sensors if they did not understand their purpose. Although this was not measured as an outcome of this pilot study, staff did not report sensor removal to be a major issue, and any problems of this sort that made glucose checking more time consuming would have been captured within the staff survey.

### Overcoming Concerns Regarding Accuracy and Reliability of CGM Readings

While CGM has the potential to reduce hypoglycemia and improve time in range, user acceptance remains a critical component for translating clinical findings into meaningful changes in therapy [33]. Numerous studies have attempted to validate CGM systems by comparing sensor readings to concurrent capillary blood draws [34,35]. These comparisons typically report analytical performance in terms of a MARD using these paired measures. The average discrepancy observed between glucose readings performed by a device under review and capillary glucose measures as the gold standard offers an intuitive method to compare the performance of different glucose monitoring systems. The top seven highest-performing fingerstick glucometers have MARDs between 5.6% and 8.2% versus reference measurements, compared with 9.2% for FreeStyle Libre 2 and 12.8% for another CGM system [36-38]. It is important not to overemphasize differences in MARD but consider whether the differences are clinically significant. In the case of a device with a MARD of 12% being compared with a device with a MARD of 6%, for a capillary blood glucose reading of 4 mmol/L, the first device would on average generate a reading between 3.5 mmol/L and 4.5 mmol/L, while the second device would on average generate a reading between 3.8 mmol/L and 4.2 mmol/L. It is unlikely that the wider range of values of the former device would alter how this clinical situation is handled, particularly if coupled with a trend arrow. Error grids such as the consensus error grid are another way to infer the clinical relevance of these ranges [39]. A study of a CGM system with a MARD of 12.8% showed that 98.7% of values fell within the preferred Zones A and B [38]. In the context of managing medication regimens in LTC, this would suggest that CGM is sufficiently accurate. Regardless, our project demonstrated that ongoing concerns regarding meter accuracy can be effectively addressed using a fingerstick confirmation in cases where there is a low glucose reading or a suspected hypoglycemic event. This requires a fingerstick test in fewer than 1% of sensor readings. Rather than relying on a single system or value, combining both CGM and fingerstick monitoring allowed for a more complete and clinically useful picture of glucose control. This integrated approach supported more confident decision-making, particularly when interpreting outlier readings or managing suspected hypoglycemia.

The trend arrow provided by the CGM reader was new to many staff, who were accustomed to the point-in-time results obtained from fingerstick testing. Because part of the concern around CGM accuracy was based on the delay between readings taken from blood and those from interstitial fluid (for the most recent generation of CGM sensors, the mean lag in readings is 1.8 min vs venous blood glucose [40]), the trend arrow was found to be helpful. However, as noted above, the electronic health record system used did not include information on whether trend arrows were used to guide decisions.

### Future Directions

This pilot project has shown that transitioning to CGM use in LTC is possible and can substantially reduce the nursing time needed for glucose monitoring. By the end of the study period, the 2 participating LTC facilities had switched to using CGM for point-of-care scans, with some use of glucose trend arrows (although this could not be measured directly), and were beginning to make use of the LibreView platform. As CGM enables more frequent and sensitive glucose monitoring, there is a potential risk of overtreatment. Careful interpretation of CGM data within the context of each resident's clinical situation will be essential to avoid unnecessary interventions. At this stage, CGM was still largely being used as a direct replacement for fingerstick testing (ie, as a method of checking residents' glucose levels before administering insulin). Future research will investigate how the detailed data captured by the CGM



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system can translate into better diabetes management, including potentially medication changes and, where appropriate, deprescribing, in the LTC setting. Furthermore, the study did not formally capture data on sensor wear time, dislodgements, or skin reactions, factors that are particularly relevant to evaluating feasibility in cognitively impaired residents. Collecting such data in future studies could strengthen the assessment of real-world usability and clinical integration.

## Conclusions

The introduction of more intensive monitoring using CGM in LTC can significantly improve the detection of hypoglycemic events while reducing nursing workload. Future studies are needed to quantify the impact on health outcomes including quality of life measures. Opportunities to further reduce nursing workload and improve care may exist through further advances in the use of CGM technology and potential coverage for residents on non-insulin treatment regimens.

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### Authors' Contributions

All authors participated in the design and execution of the quality improvement initiative and critically reviewed the results. The manuscript was drafted by DOD and critically reviewed by SB, SD, LQ, and BY. All authors approved the submitted version.

### Conflicts of Interest

SD has ongoing consulting work with Abbott Canada as an educator/trainer to support the use of FreeStyle Libre in long-term care homes. She is paid for consulting hours involved to deliver education directly from Abbott. The remaining authors declare no conflicts of interest.

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## Abbreviations

**CGM:** continuous glucose monitoring
**$HbA_{1c}$:** glycated hemoglobin
**LTC:** long-term care
**MARD:** mean absolute relative difference

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Viewpoint

# Enhancing Health Equity and Patient Engagement in Diabetes Care: Technology-Aided Continuous Glucose Monitoring Pilot Implementation Project

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This is a corrected version. See correction statement: https://diabetes.jmir.org/2025/1/e72689

## Abstract

Federally Qualified Health Centers (FQHCs) provide service to medically underserved areas and communities, providing care to over 32 million patients annually. The burden of diabetes is increasing, but often, the vulnerable communities served by FQHCs lag in the management of the disease due to limited resources and related social determinants of health. With the increasing adoption of technologies in health care delivery, digital tools for continuous glucose monitoring (CGM) are being used to improve disease management and increase patient engagement. In this viewpoint, we share insights on the implementation of a CGM program at an FQHC, the Community-University Health Care Center (CUHCC) in Minneapolis, Minnesota. Our intent is to improve diabetes management through better monitoring of glucose and to ensure that the CGM program enables our organization's overarching digital strategy. Given the resource limitations of our population, we provided Libre Pro devices to uninsured patients through grants to improve health care equity. We used an interdisciplinary approach involving pharmacists, nurses, and clinicians and used hemoglobin A1c (HbA1c) levels as a measure of diabetes management. We assessed the CGM program and noted key aspects to guide future implementation and scalability. We recruited 148 participants with a mean age of 54 years; 39.8% (59/148) self-identified their race as non-White, 9.5% (14/148) self-identified their ethnicity as Hispanic or Latino, and one-third (53/148, 35.8%) were uninsured. Participants had diverse language preferences, with Spanish (54/148, 36.5%), English (52/148, 35.1%), Somali (21/148, 14.2%), and other languages (21/148, 14.2%). Their clinical characteristics included an average BMI of 29.91 kg/m2 and a mean baseline HbA1c level of 9.73%. Results indicate that the CGM program reduced HbA1c levels significantly from baseline to first follow-up (P<.001) and second follow-up (P<.001), but no significant difference between the first and second follow-up (P=.94). We share key lessons learned on cultural and language barriers, the digital divide, technical issues, and interoperability needs. These key lessons are generalizable for improving implementation at FQHCs and refining digital strategies for future scalability.

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**KEYWORDS**

consumer health informatics; patient engagement; diabetes mellitus; DM; glucose monitoring; continuous glucose monitoring; CGM; health equity; health information technology; patient centered care; diabetes; pharmacists; clinicians; nurses; device; patient monitoring; technology-aided; health informatics

# Introduction

## Growing Burden of Diabetes

Diabetes mellitus is a chronic metabolic, autoimmune, and genetic disease involving elevated levels of blood glucose [1,2]. It poses a significant public health challenge globally as the estimated prevalence of diabetes among people aged 20-70 years was 10.5% in 2021, or approximately 536 million people. It is expected to rise to 12.2% (783.2 million people) by 2045. The burden of diabetes is rising among vulnerable populations too, because they frequently face obstacles to effective diabetes management [3,4]. According to the Health Center Program Uniform Data System by Health Resource and Service Administration (HRSA), the percentage of patients with diabetes has been increasing in the last 5 years [5].

## Digital Technology for Diabetes Management, Patient Engagement, and Health Equity

Current health care processes are increasingly utilizing digital technology to provide innovative solutions for patient care and management [6]. One example is remote patient monitoring (RPM) technologies, such as continuous glucose monitoring (CGM) devices, which are becoming an important tool used in diabetes management [7-9]. The CGM devices provide continuous monitoring of blood glucose levels, thereby offering an all-encompassing picture of glucose fluctuations throughout the day and night [8,10]. In contrast to conventional glucose monitoring methods, which require intermittent finger stick tests, CGM devices use sensors positioned under the skin to measure sugar levels continuously [11-13]. This real-time data help patients and clinicians to make decisions about identifying appropriate drugs for intervention and adjusting drug therapy. The patient can also make changes in lifestyle or dietary choices based on monitoring information. These interventions by clinician and patient can lead to better diabetes management [14-16].

Evidence suggests that an underserved population could benefit from digital technologies like CGM. However, many obstacles still exist in providing service to these communities [17,18]. From the health care provider's perspective, these challenges include a lack of infrastructure, insufficient staffing, lack of electronic data exchange, and limited patient engagement capacity [19,20]. From a patient's perspective, inadequate broadband access, language barriers, and lack of digital literacy are some important barriers to accessing digital health [20-22]. The limited literature on RPM and telehealth outcomes among racial minority populations and vulnerable groups indicates that health care disparities still exist and stresses the need for targeted efforts to overcome these barriers [8,23].

## Prior Research

Evidence has emerged that shows that the use of RPM in health care settings helps reduce hemoglobin $A_{1c}$ ($HbA_{1c}$) levels in patients with type 2 diabetes [24-26]. In addition, research also suggests that CGM devices show higher acceptance by patients, help in lowering $HbA_{1c}$ levels, and reduce incidences of hypoglycemic events [27]. A pilot study provided evidence for the feasibility of using CGM devices such as Libre Pro in medically vulnerable and underserved populations at a Federally Qualified Health Center (FQHC). It also showed that this digital technology can be used in resource-constraint organizations like primary care health centers [28]. However, the prescription of CGM devices is low in Black and Hispanic populations in comparison to their White counterparts. At the same time, the rate of diabetes is higher in the Black and Hispanic populations [29-31].

## Population Served and Services at the Community-University Health Care Center

Our health care clinic, the Community-University Health Care Center (CUHCC) was founded in 1966 by 2 University of Minnesota pediatricians and is the first and longest-running Community Health Center in Minnesota [32]. It is an FQHC providing comprehensive primary care services to the medically underserved area/population and is funded by the HRSA [33,34]. The CUHCC, being an FQHC, provides services to everyone regardless of their ability to pay and offers sliding scale fees. This makes sure that care is available to all patients regardless of their insurance status, which plays a role in reducing health care inequities [34,35]. The CUHCC provides medical, dental, mental health, and social services to about 10,000 patients a year across 49,000 visits annually. It operates with approximately 170 full-time equivalent (FTE) staff members, have an operating budget of US $26 million, and supports over 170 learners annually [36]. The CUHCC serves a diverse and underserved population, with 91% of patients having a known income level at or below 200% of the federal poverty guidelines in 2021. Of the patient population, 29% identify as Hispanic and 37% as BIPOC (Black, Indigenous, and People of Color). In 2022, close to half (48%) of the CUHCC's patients preferred a language other than English for their care. A majority of CUHCC patients are covered by Medicaid/Children's Health Insurance Program (57%) or uninsured (25%), reinforcing its role as a critical health care safety net for vulnerable populations. The burden of diabetes in our population is higher than the national statistics, per HRSA data [5,37].

## Project Objective

Recognizing these gaps, we implemented a CGM program at our site, the CUHCC. Our objective is to share insights on the implementation and outcome of the CGM program for diabetes management among the CUHCC's patient population and to enumerate lessons learned for an overarching digital strategy for our organization.



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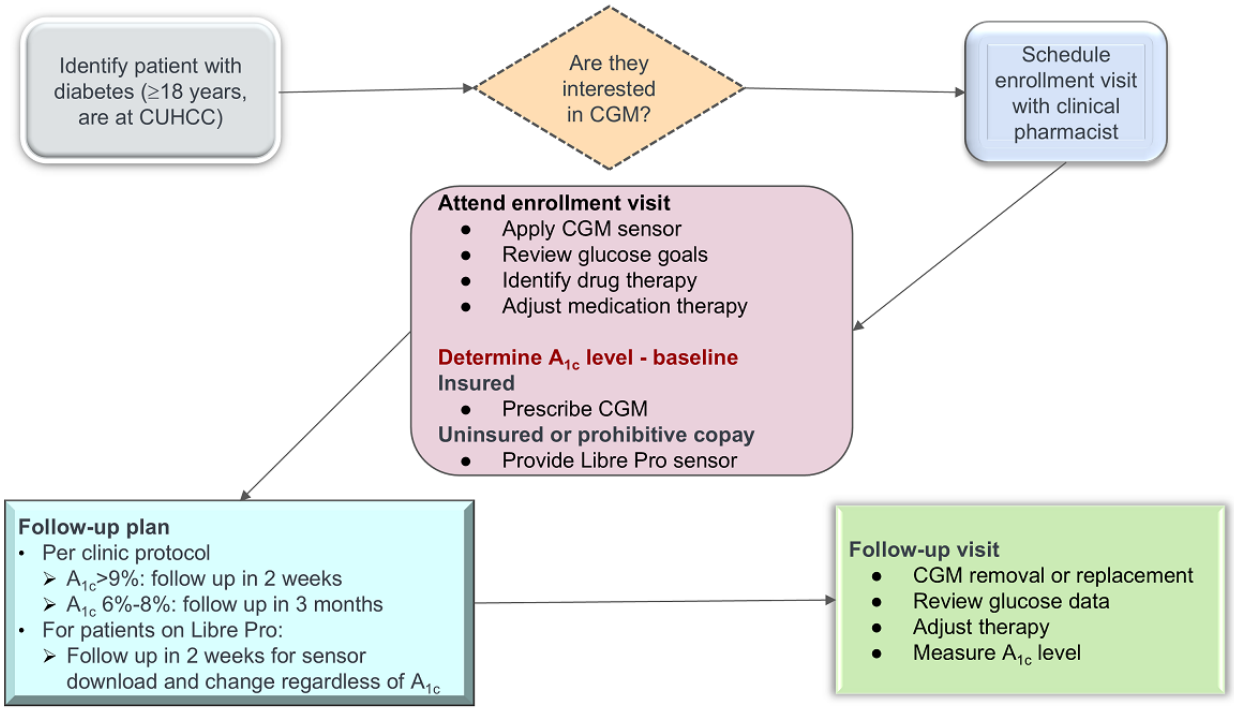
## Methods

### Study Eligibility Criteria and Approach

Patients were eligible for the CGM program if they had established care at the CUHCC, were aged 18 years or older, and had been diagnosed with diabetes. Clinicians and nurse practitioners introduced the option of CGM to eligible patients during routine visits. Patients who agreed to participate in the program were scheduled for enrollment visits with clinical pharmacists.

Our pilot implementation study of CGM was led by a pharmacist team, which consisted of 1.2 FTE clinical pharmacists and 2 FTE pharmacy residents. This interdisciplinary approach with recruitments by clinicians and nurses and follow-up by pharmacy team was chosen based on the evidence that collaborative health care teams are effective in integrating digital health in primary care settings [38,39]. The detailed schema of our approach is depicted in Figure 1.

**Figure 1.** Process for CGM implementation. CGM: continuous glucose monitoring; CUHCC: Community-University Health Care Center.




### CGM Program Protocol and Analysis

The CGM program followed a structured protocol (refer to Figure 1). During enrollment and subsequent visits, pharmacists were responsible for the application and removal of CGM sensors. They also provided patient education and instructions on how to use CGM devices. There was no real-time monitoring of CGM data given the technological barriers, but in follow-up visits, pharmacists downloaded and reviewed the glucose data and adjusted patients' medications. Follow-up visits were scheduled according to the patient's $HbA_{1c}$ levels. For patients with $HbA_{1c}$ levels greater than 9%, follow-up visits were recommended every 2 weeks. In contrast, patients with $HbA_{1c}$ levels between 6% and 8% (relatively stable glucose control) were scheduled for follow-up every 3 months. For patients receiving Libre Pro sensors from the clinic, follow-up is required every 2 weeks for sensor download and replacement. The program ensured CGM device accessibility to all eligible patients. For insured patients, a CGM device was prescribed and dispensed through their pharmacy. The CUHCC used Libre Pro CGM sensors donated by the funder to patients who were uninsured or those with unaffordable copays. We defined the outcome measure of interest as the change in levels of $HbA_{1c}$ over time. Baseline $HbA_{1c}$ level is defined as the result closest in time prior to CGM enrollment. Follow-up $HbA_{1c}$ level is defined as the first and second results (about 3 months after the baseline $HbA_{1c}$ level and 6 months after the baseline $HbA_{1c}$ level, respectively) after CGM enrollment.

To assess the effectiveness of the CGM program, a repeated measure ANOVA with Greenhouse-Geisser correction and post hoc pairwise comparisons with Bonferroni correction was performed. These tests are used to determine if there is a statistically significant difference in mean $HbA_{1c}$ level between 3 points: baseline, first follow-up, and second follow-up.

### Lessons Learned

We enumerated the key takeaways from this project with a team-based approach involving key stakeholders in the program including the lead pharmacist and the data analyst. The chief executive officer and the chief innovation & strategy officer, both of whom are advocates for digital technology to address health equity, were an integral part of this collaborative effort.

### Ethical Considerations

This study was a quality improvement project at the CUHCC and did not require institutional review board determination.



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Participation was voluntary, and patients verbally consented to participate in the CGM program. Program details were shared with participants including data protection, sharing of data from devices, use of individual data for diabetes management, and deidentified data for secondary purposes. One patient opted out of data sharing and their data were removed from this program evaluation. There was no monetary compensation for participation in this project. Patients who were not able to afford the CGM sensor were provided with Libre Pro CGM sensors, which were donated to the CUHCC by Abbott.

## Results

### Demographics and Clinical Characteristics

There were 149 patients who were enrolled in the CGM program at the CUHCC from January 20, 2022, to September 27, 2023. One patient opted out of sharing their medical records and was excluded from the analysis. As shown in Table 1, the patient cohort had a mean age of 54 years, ranging from 19 to 86 years, and consisted of 54.7% (n=81) female participants. The cohort was racially diverse, with one-third (50/148, 33.8%) being Black and African American, 4.1% (6/148) being American Indian or Alaska Native, and 2% (3/148) being Asian. There were 18 (12.2%) patients whose race was unknown, and the rest identified as White (71/148, 48%). In terms of ethnicity, 9.5% (n=14) of the patients identified as Hispanic or Latinx, and ethnicity was not documented for 29.7% (n=44) of patients. Table 1 also shows that the group had a diversity of language preferences, with one-third speaking Spanish (54/148, 36.5%), followed by English (52/148, 35.1%), Somali (21/148, 14.2%), and other languages (21/148, 14.2%). In terms of insurance, approximately one-third (53/148, 35.8%) were uninsured, and the rest (95/148, 64.2%) were insured. The average BMI of the participants was 29.91 (SD 7.66) $kg/m^2$, with a range from 18.27 to 56.64 $kg/m^2$. The baseline $HbA_{1c}$ levels average 9.73% (SD 2.24), with a range from 5% to 14%. Of the 148 patients in the sample, 65 (43.9%) received Libre Pro CGM sensors, which were provided by the CUHCC.

**Table 1.** Sociodemographic and clinical characteristics of participants (n=148).

| Variable | Values, n (%) |
|---|---|
| **Age group (years)** | |
| 18-40 | 22 (14.9) |
| 41-63 | 91 (61.5) |
| 64-86 | 35 (23.6) |
| **Sex** | |
| Female | 81 (54.7) |
| Male | 67 (45.3) |
| **Race** | |
| White | 71 (48.0) |
| Black or African American | 50 (33.8) |
| American Indian or Alaska Native | 6 (4.1) |
| Asian | 3 (2.0) |
| Unknown | 18 (12.2) |
| **Ethnicity** | |
| Hispanic or Latino | 14 (9.5) |
| Non-Hispanic or Latino | 90 (60.8) |
| Unknown | 44 (29.7) |
| **Preferred language** | |
| Spanish | 54 (36.5) |
| English | 52 (35.1) |
| Somali | 21 (14.2) |
| Other[a] | 21 (14.2) |
| **Insurance status** | |
| Insured | 95 (64.2) |
| Uninsured | 53 (35.8) |

[a]Other languages were Central Khmer, Hmong, Korean, Oromo, sign language, and Vietnamese.



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### $HbA_{1c}$ Level Outcome

A repeated-measure ANOVA with Greenhouse-Geisser correction was used, as the same metric ($HbA_{1c}$) was measured in participants over time, which enabled the ability to attribute differences related to treatments. This test showed that the difference between the mean $HbA_{1c}$ levels among the 3 points (baseline, first follow-up, and second follow-up) was statistically significant ($F_{1.153,113.38}$=38.29; $P$<.001). As presented in Table 2, post hoc pairwise comparisons with Bonferroni correction indicated a statistically significant reduction in $HbA_{1c}$ levels from baseline to the first follow-up ($P$<.001) and from baseline to second follow-up ($P$<.001), but no significant difference between the first and second follow-up ($P$=.94).

**Table 2.** Comparison of follow-up hemoglobin $A_{1c}$ ($HbA_{1c}$) measurements.

| Time period | $HbA_{1c}$ measurements | | | |
|---|---|---|---|---|
| | Mean difference in $HbA_{1c}$ level (%) | SE | 95% CI | *P* value |
| Baseline to first follow-up | –1.66 | 0.22 | 2.20 to –1.13 | <.001 |
| Baseline to second follow-up | –1.68 | 0.26 | –2.32 to –1.03 | <.001 |
| Between first and second follow-up | –0.01 | 0.156 | –0.39 to 0.37 | .94 |

### Lessons Learned

During the implementation of the CGM program, several key lessons were learned that had implications for the future scalability and sustainability of the program, along with laying the groundwork for an overarching digital strategy for the organization (presented in Table 3).



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**Table 3.** Lessons learned from technology-aided patient engagement.

| Topic | Lessons learned | Program implications |
|---|---|---|
| **Patient perspectives** | | |
| Cultural and language barriers | Diverse patient population requires tailored communication strategies | Enhance staff training in cultural competence and develop multilingual resources |
| Patient education | Importance of comprehensive education on CGM[a] benefits and use | Develop comprehensive patient education materials in multiple languages and provide ongoing support |
| Financial barriers | Half of patients (44%) required financial assistance for CGM devices, and this needs to be addressed to promote health equity | Secure funding or subsidies to ensure equitable access |
| Follow-up adherence | Effective follow-up based on $HbA_{1c}$[b] levels requires active communication | Implement robust patient follow-up systems and reminders |
| Social drivers of health | Numerous socioeconomic and contextual factors influence health | Develop RPM[c] in context of SDoH[d] for sustainability |
| **Organizational perspectives** | | |
| Health equity | Technology offers various tools to improve access but needs to focus on digital equity | Ensure that technology implementations have health equity at the forefront |
| Digital divide | Some subsets of the population do not have access to technology or the ability to use it | Need for digital navigators for assistance |
| Interdisciplinary collaboration | Pharmacist-led approach proved valuable for diabetes management | Foster interdisciplinary teamwork in program design and implementation |
| Patient motivation | Maintaining patient motivation over time was challenging | Use motivational strategies and digital tools to keep patients engaged |
| Staff time and effort to set up programs | Recognizing that technology implementations do require time and effort to set up | Gain efficiencies quickly to demonstrate ROI[e] for these programs |
| **Technical perspectives** | | |
| Technical barriers | Some patients had difficulties using digital health tools | Provide more extensive technology training support |
| Need for interoperability | Data need to flow seamlessly across devices and settings | Address data entry burden for staff by device data integration |
| Workflow integration | Integration of CGM data requires adjusting clinic workflows and appointment structures | Design workflows that include specific times for CGM review during patient visits |
| Utility of PROM[f] data | CGM data need to be integrated into clinical decision-making | Explore solutions and national standards to integrate CGM data in EHRs[g], along with visuals/trends for providers |
| Digital strategy | CGM/RPM enables technology-aided patient engagement | Include these tools as part of an overall digital strategy for the organization |

[a]CGM: continuous glucose monitoring.

[b]$HbA_{1c}$: hemoglobin $A_{1c}$.

[c]RPM: remote patient monitoring.

[d]SDoH: social drivers of health.

[e]ROI: return on investment.

[f]PROM: patient-reported outcome measure.

[g]EHR: electronic health record.

# Discussion

## Findings and Implications

Our pilot project was able to successfully recruit 148 participants for the CGM program, along with an enumeration of lessons learned. The reduction of $HbA_{1c}$ levels from baseline to follow-up periods demonstrates the potential and possibility of CGM devices in glycemic control. This suggests that CGM is an effective tool for the management of diabetes, even in resource-constrained environments serving diverse patient populations. Along with statistical significance, these results are clinically significant as achieving this reduction in $HbA_{1c}$ level has the immense benefits of reducing complications from diabetes. Our program evaluation also identified several lessons that include education, financial barriers, follow-up adherence, cultural and language barriers, and context around social drivers of health from a patient's perspective. In terms of organization,



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the insights for future implementation are health equity, digital divide, staff time and efforts, and patient motivation.

From the technical side, the barriers include the need for interoperability, workflow integration, and the utility of patient-reported outcome measure data. The result of the CGM program at an FQHC builds on recent literature on RPM and CGM in diabetes. For example, a Digital Health Pilot program for diabetes was implemented at a rural FQHC, which led to improvement in $HbA_{1c}$ levels in the participants [31]. Another pilot study demonstrates a reduction of $HbA_{1c}$ levels and a decrease in hypoglycemic episodes after the implementation of CGM program at an FQHC [33]. These findings have implications for future scalability, sustainability of CGM programs, overall RPM programs, and overarching digital strategy for an organization.

### Strengths and Limitations

An important strength of our pilot project is its focus on a diverse and medically underserved population. This is valuable because there is a scarcity of research focused on these communities. The use of an interdisciplinary approach led by pharmacists, clinicians, nurse practitioners, and nutritionists/dieticians is consistent with the growing evidence of the impact of using collaborative models for disease management. Additionally, our program used broad eligibility criteria, ensuring inclusivity and making certain that patients who meet basic requirements get access to the program.

There are several limitations that need to be addressed. First, the program was implemented at a single site and with a limited number of participants. This may limit the generalizability of the findings to other settings, such as rural FQHCs or other private clinics. Second, this pilot project did not include control groups, which may limit our ability to attribute the changes in $HbA_{1c}$ levels solely to CGM intervention.

### Future Directions

This CGM pilot implementation resulted in an improvement in $HbA_{1c}$ levels in patients with diabetes at an urban FQHC serving a diverse, medically underserved patient population. Our program has expanded to include nurses to make it scalable. Given these positive findings, we are exploring options for the continuation of this program, including ongoing collaboration with Abbott for the CGM sensors and pursuing additional sources for support. Additionally, we are planning a qualitative study with interviews to elicit further details about what worked and what is needed to sustain and scale this program. We advocate for additional studies to be conducted in other FQHCs to determine if this can be replicated and if there are site-specific factors that influence implementation and outcomes. Future research needs to evaluate patient and clinician satisfaction with CGM and other related RPM tools.

### Conclusions

Our pilot experience at the CUHCC indicates that the implementation of digital technologies like the CGM program is feasible and effective in the management of diabetes in a diverse and medically underserved population. The future success of our CGM program will depend on addressing the lessons learned and developing an overarching digital strategy for our organization to promote health equity.

## Acknowledgments

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## Data Availability

The datasets generated and analyzed for this study are not publicly available as the data used are protected with individual identifiers and collected as part of the care delivery process.

## Authors' Contributions

The conceptualization of this pilot project was done by the site leadership (RD and EWM). The project was implemented by KNT and her team, and data extraction and analysis were completed by AT. MT and SR supported the drafting of the manuscript and its revisions. All authors read and approved the final version.

## Conflicts of Interest

None declared.

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## Abbreviations

**BIPOC:** Black, Indigenous, and People of Color
**CGM:** continuous glucose monitoring
**CUHCC:** Community-University Health Care Center
**FQHC:** Federally Qualified Health Center
**FTE:** full-time equivalent
**HbA1c:** hemoglobin A1c
**HRSA:** Health Resource and Service Administration
**RPM:** remote patient monitoring



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# Evaluating Digital Health Solutions in Diabetes and the Role of Patient-Reported Outcomes: Targeted Literature Review

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## Abstract

**Background:** Digital health solutions (DHS) are technologies with the potential to improve patient outcomes as well as change the way care is delivered. The value of DHS for people with diabetes is not well understood, nor is it clear how to quantify this value.

**Objective:** We aimed to summarize current literature on the use of patient-reported outcome measures (PROMs) in diabetes as well as in selected guidelines for Health Technology Assessment (HTA) of DHS to highlight gaps, needs, and opportunities for the use of PROMs to evaluate DHS.

**Methods:** We searched PubMed and ClinicalTrials.gov to establish which PROMs were most used in diabetes clinical trials and research between 1995 and May 2024. HTA guidelines on DHS evaluation from France, Germany, and the United Kingdom were also assessed to identify PROMs for DHS evaluation in general.

**Results:** A total of 46 diabetes-specific PROMs and 16 nondiabetes-specific PROMs were identified. The most used diabetes-specific PROMs were (1) Diabetes Distress Scale, (2) Problem Areas in Diabetes, (3) Diabetes Empowerment Scale, (4) Diabetes Quality of Life, and (5) Diabetes Treatment Satisfaction Questionnaire. The most used nondiabetes-specific PROMs were Beck Depression Inventory, Sickness Impact Profile, EuroQol 5-Dimension, and Short Form 36-Item Health Survey. In HTA guidelines, the most prominent domain was health-related quality of life, for whose assessment there are well-established measures (Short Form 36-Item Health Survey and EuroQol 5-Dimension).

**Conclusions:** Of the many PROMs used in diabetes care, few are currently used to evaluate DHS, and certain domains of value in diabetes are not mentioned in HTA guidelines. A common, comprehensive DHS-specific HTA framework could facilitate and accelerate the evaluation of DHS.

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**KEYWORDS**

diabetes; patient-reported outcome; digital health solutions; people with diabetes; digital health; diabetic; diabetes mellitus; type 2 diabetes; type 1 diabetes; patient care; diabetic patients; health technology assessment; health technology; clinical trials; evaluation; treatment; health-related; diabetes care

## Introduction

Despite innovative technologies and major advances in drug discovery, treatment goals in diabetes have not been fully met [1] and access for populations at risk is still lacking [2]. More holistic and integrated treatment modalities are needed to improve treatment goals and access to care for people with diabetes worldwide [3]. Digital Health Solutions (DHS) may offer a viable way to tackle these challenges. The potential of DHS for improving health and well-being is becoming increasingly evident [4], and health authorities have begun to acknowledge the benefits of these solutions for patients and health care systems [5-8].

The concept of digital health has been defined by the US Food and Drug Administration (FDA) as the use of technologies for health care and related purposes [9]. “Technologies” encompass mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine, while “health care purposes” include preventing and treating disease, improving diagnosis, and enhancing health care delivery. The UK National Institute of Health and Care Excellence (NICE) characterizes digital health as technological solutions that



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improve (1) the efficiency of health systems, (2) understanding and communication about health, or (3) health interventions [5]. Digital health interventions provide health care stakeholders with a means to address unresolved health system challenges, according to the World Health Organization (WHO) [10].

Traditionally, outcomes of health interventions have been measured using "narrow" clinical, biological, and metabolic endpoints. However, the WHO's definition of health is broad: "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [11]. By improving outcomes related to patients and health care systems, DHS may benefit patient's health and well-being beyond clinically measurable values [4,9]. Assessing these patient-reported perceived elements, for example, empowerment, self-efficacy or health literacy, is central to holistically understanding the effects of health interventions and capturing the full range of benefits from DHS [12].

Compared with existing interventions, DHS could provide near-constant monitoring and feedback, helping patients to better understand their disease and supporting them in making health care decisions [10]. At a system level, DHS could automatically collect, manage, and store health data. By providing this information to health care professionals, the quality of care could improve, and encounters could become more effective. There is an emerging need to provide validated tools that reliably assess these parameters of health and health care benefits. Patient-reported outcome measures (PROMs) are expected to play a key role in understanding patients' perspectives of the mentioned outcomes to fully understand the range of benefits from DHS.

PROMs are instruments to capture the impact of treatment on relevant patient perspectives and health-related outcomes usually outside the scope of clinical or biological endpoints. Examples include standardized, validated questionnaires on health status, perceived level of impairment, empowerment, or health-related quality of life PROMs used in health technology assessment (HTA) [6,7], which is defined by the WHO as "the systematic evaluation of properties, effects, and impacts of health-care technology" [13]. In this research, we will focus on the potential value of PROMs for assessing DHS for people with diabetes.

The objectives of this research are to (1) review current literature on the use of PROMs in diabetes and in selected HTA guidelines for DHS (2) and describe the challenges, needs, and opportunities for the use of PROMs to evaluate DHS.

## Methods

### Use of PROMs in Diabetes: Literature and HTA Guidelines Review

We conducted a literature review to identify the PROMs used in diabetes. In addition, 3 databases were scanned—ProQolid, ClinicalTrials.gov, and PubMed—as these are the main sources where research on PROMs is being published. ProQolid was used to identify diabetes- and nondiabetes-specific PROMs. Findings were complemented by data from literature reviews of PROs used in prominent diabetes outcome consortiums, such as the International Consortium for Health Outcomes Measurement. Furthermore, PubMed and ClinicalTrials.gov were searched to establish which PROMs were most used in diabetes clinical trials and research between 1995 and May 2024 to identify the use of these PROMs for evaluating DHS (Multimedia Appendices 1 and 2).

In PubMed, the PROs name and "diabetes" were used to search for relevant results and in ClinicalTrials.gov the PROs name and "type 1 diabetes" and "type 2 diabetes" were used. Then, to determine associations with DHS, PROs name and "diabetes" were used in conjunction with "mobile application," "telemedicine," "telehealth," "health digital solutions," and "e-health" in PubMed. Not all articles mentioning DHS were selected; 2 data scientists independently read all abstracts to identify the peer-reviewed publications where PROs were used in relation to DHS. Therefore, in the final list of selected publications, a DHS was used, as well as a PRO in relation to this DHS.

PROM type (diabetes-specific or nondiabetes-specific [generic]), domain and objective, and occurrences in literature were collected for each PROM. The number of items, format, and administration time were collected for disease-specific PROMs, and copyright and language versions were collected for generic PROMs. Any mentions of PROMs used in reimbursement studies were noted. The PROMs most used in diabetes were analyzed, by determining which PROMs appeared in all 3 PubMed and ClinicalTrials.gov searches and were mentioned in HTA guidelines, as described next.

Alongside this, we retrieved and assessed guidelines about DHS evaluation from health authorities in France (HAS), Germany (BfArM), and the UK (NICE) [5-8]. These countries were chosen because of recent initiatives by their HTA authorities offering guidance on DHS assessment (Textbox 1).



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**Textbox 1.** French, German, and UK health technology assessment guidelines for evaluating digital health solutions.

Health authority Country (Year) and Guidelines

**Haute Autorité de Santé France [7] (2019)**

- Assessment of medical devices: Assessment principles established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to determine the reimbursement eligibility of medical devices for individual use

**Haute Autorité de Santé France [8] (2019)**

- 2019 Prospective Analysis Report - Digital technology: what (R)evolution? [in French]

**German Federal Institute for Drugs and Medical Devices (BfArM) Germany [6] (2020)**

- The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V - A Guide for Manufacturers, Service Providers and Users (version 1.0)

**National Institute of Health and Care Excellence UK [5] (2019)**

- Evidence standards framework for digital health technologies

## Results

Overall, 62 PROMs were identified from the literature review: 46 diabetes-specific PROMs and 16 nondiabetes-specific PROMs (Multimedia Appendix 3). The diabetes-specific PROMs most used in diabetes clinical trials and research are shown in Table 1.



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**Table .** Most used diabetes-specific patient-reported outcome measures.

| PROM[a] | Domain or objective | Items | Format | Admin time (min) | Occurrences | | | | | Mentions HTA[c] guidelines or DHS[d] reimbursement |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | ClinicalTrials.gov[b] | | | PubMed | | |
| | | | | | Diabetes, n | T1D[e], n | T2D[f], n | PROMs and diabetes[b], n | PROMs and diabetes for digital solutions[g], n | |
| Summary of Diabetes Self-Care Activities (SDSCA) [14] | Diabetes self-management | 11 | Self-report questionnaire with scores | <10 | 159 | 9 | 105 | 306 | N/A9 | N/A |
| Diabetes Distress Scale (DDS) [15] | Psychosocial distress | 17 | 6-point Likert Scale | 10 | 243 | 105 | 124 | 277 | 10 | N/A |
| Areas in Diabetes (PAID) scale [16] | Emotional functioning | 1, 5, 20 | Questions with values from 0 (“no problem”) to 4 (“serious problem”) | NA | 255 | 112 | — | 400 | 10 | United Kingdom |
| Diabetes Empowerment Scale (DES) & DES-sf [17] | Diabetes-related psychosocial self-efficacy | 8, 28 | Response categories ranging from “strongly disagree” to “strongly agree” | NA | 92 | 21 | 47 | 99 | 9 | N/A |
| Diabetes Quality of Life (DQOL) [18] | Relative burden of an intensive diabetes treatment regimen | 46 | 5-point Likert scale in 3 main domains: “satisfaction”, “impact”, and “worry” | NA | 92 | 52 | 39 | 274 | 3 | • French[i] |
| Diabetes Treatment Satisfaction Questionnaire (DTSQ) [14] | Satisfaction with diabetes treatment regimens and changes in satisfaction with treatment | 8 | 7-point scale ranging from 0 to 6. The questionnaire assesses treatment satisfaction and burden from hyper- and hypoglycemia | — | 219 | 135 | 83 | 110 | 8 | • French[i] |

[a]PROM: patient-reported outcome measurement.

[b]The keywords used were: “full name of PROM” AND diabetes; “full name of PROM” AND type 1 diabetes; “full name PROM” AND type 2 diabetes.



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[c]HTA: health technology assessment.

[d]DHS: digital health solution.

[e]T1D: type 1 diabetes.

[f]T2D: type 2 diabetes.

[g]The keywords used were: “full name of PROM” AND diabetes AND (“mobile application” OR telemedecine OR telehealth OR “health digital solutions” OR “e-health”).

[h]not available.

[i]Haute Autorité de Santé. Assessment of medical devices: assessment principles established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to determine the reimbursement eligibility of medical devices for individual use (La Plaine Saint-Denis, France; 2019).

These PROMs cover a wide range of outcomes, including diabetes self-management (SDSCA [15]), psychosocial distress (DDS [16]) and diabetes distress (PAID [17]), diabetes-related psychosocial self-efficacy (DES [18]), relative burden of an intensive diabetes treatment regimen (DQOL [19]), and satisfaction with diabetes treatment (DTSQ [14]). Furthermore, 3 PROMs were mentioned in HTA guidelines: PAID [17] in UK guidelines [5], and DQOL [19] and DTSQ [14] in French guidelines [7].

Table 2 shows the most prominent nondiabetes-specific PROMs used in diabetes clinical trials and research. The domains covered by these PROMs include severity of depression (BDI [20]), patient dysfunction assessed through everyday behavior (SIP [21]), health outcome from interventions on a common scale (EQ-5D [22]), and generic health concepts (SF-36 [23]). Two PROMs were mentioned in 3 HTA guidelines: EQ-5D [22] in French guidelines [7,8], and SF-36 [23] in French and German guidelines [6,7].



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**Table .** Most used nondiabetes–specific patient-reported outcomes measures.

| PROM[a] | Domain or objective | Copyright | Language | Occurrences | | | | | Mentions |
|---|---|---|---|---|---|---|---|---|---|
| | | | | ClinicalTrials.gov[b] | | | PubMed | | |
| | | | | Diabetes | T1D[c] | T2D[d] | PROMs and diabetes[b] | PROMs and diabetes for digital solutions[e] | HTA[f] guidelines or DHS[g] reimbursement |
| Beck Depression Inventory (BDI) [20] | Severity of depression in adults and adolescents | Aaron T. Beck | English +73 others | 82 | 13 | 37 | 581 | 3 | —[h]N/A |
| Sickness Impact Profile (SIP) [21] | Patient dysfunction measured via everyday behavior, generally related to disease | Johns Hopkins University, 1977 | English | 2 | 1 | 1 | 397 | 2 | —N/A |
| EQ-5D [22] | Health outcome from interventions on a common scale, for evaluation, allocation, and monitoring | EuroQoL Group | English +181 others | 312 | 47 | 157 | 895 | 8 | • French[i]<br>• United States[j] (specific example, FDA) |
| Short Form (SF-36) [23] | Generic health concepts relevant across age, disease, and treatment groups | Medical Outcomes Trust (MOT), Dr J. Ware | English +160 others | 392 | 39 | 195 | 1387 | 10 | • French<br>• German[k] (specific example)<br>• United States (specific example, FDA) |

[a]PROM: patient-reported outcome measure.

[b]The keywords used were: “full name of PROM” AND diabetes; “full name of PROM” AND type 1 diabetes; “full name PROM” AND type 2 diabetes.

[c]T1D: type 1 diabetes.

[d]T2D: type 2 diabetes.

[e]The keywords used were: “full name of PROM” AND diabetes AND (“mobile application” OR telemedecine OR telehealth OR “health digital solutions” OR “e-health”)

[f]HTA: health technology assessment

[g]DHS: digital health service.

[h]Not available.

[i]Haute Autorité de Santé. Assessment of medical devices: assessment principles established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to determine the reimbursement eligibility of medical devices for individual use (La Plaine Saint-Denis, France; 2019).

[j]Food & Drug Administration Center for Devices and Radiological Health. Value and Use of Patient-Reported Outcomes (PROs) in Assessing Effects of Medical Devices - CDRH Strategic Priorities 2016-2017. (Silver Spring, MD; 2017).

[k]Federal Institute for Drugs and Medical Devices (BfArM). The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V - A Guide for Manufacturers, Service Providers and Users (version 1.0) (Bonn, Germany; 2020).

The review of the 3 HTA guidelines identified 12 recommended patient outcomes and 5 outcome categories (Table 3). The most prominent domain, Quality of Life, was recommended by the 3 HTA guidelines and there were well-established nondiabetes-specific PROMs for its assessment, for example, SF-36 and EQ-5D [22,23]. EQ-5D is directly linked to reimbursement processes in many countries and is used to derive quality-adjusted life year. The next most prominent domain was



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acceptability, from the DHS outcome category. Acceptability was highly relevant in both French and UK HTA guidelines [5,7]. Two diabetes-specific PROMs were mentioned in French HTA guidelines: DTSQ [14] for the assessment of acceptability, and DQOL [19] for quality of life (QOL) assessment.



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**Table .** Domains identified in French, UK, and German health technology assessment guidelines for evaluating digital health solutions. +: outcome mentioned; ++: special attention paid to this outcome; +++: outcome of great importance (patient-reported outcomes measures in guideline linked to outcome, if mentioned).

| Outcome category | France (HAS[a]) Assessment of medical devices: assessment principles established by the CNEDiMTS[d] [7] | United Kingdom (NICE[b]) Evidence standards framework for digital health technologies[e] [5] | Germany (BfArM)[c] The Fast-Track process for digital health applications (DiGA)[f,g] [6] |
|---|---|---|---|
| Acceptability | | | |
| DHS[h] | ++ (DTSQ[i] [14]) | ++[j] | |
| User satisfaction[k] | | | |
| DHS | | +[l] | + |
| Engagement | | | |
| DHS | | +[l] | |
| Patient empowerment[k] | | | |
| Patient sovereignty | | ++[l] | |
| Health literacy | | | |
| Patient sovereignty | | | + (HLS-EU-Q[m] [24]) |
| Quality of life[k] | | | |
| [n]QoL/disease management | +++ (EQ-5D [22], SF-36 [23], DQOL[o] [19]) | +++[l] | +++ (SF-36[p] [23]) |
| Symptom severity | | | |
| QoL/disease management | | +[l] | +++ (NRS[q] [25], SCL-90[r] [GSI[s], PSDI[t], PST][u] [26]) |
| Autonomy | | | |
| QoL/disease management | + | +[l] | + |
| Coping with illness-related difficulties | | | |
| QoL/disease management | | | + |
| Reduction of therapy-related effort and strain (for patients or relatives) | | | |
| QoL/disease management | + | | + |
| Adherence | | | |
| Adherence | | | ++ (MAQ[v] [27], Morisky Score [28]) |
| Enhanced safety | | | |
| Safety | | | + |

[a]HAS: Haute Autorité de Santé.

[b]NICE: National Institute for Health and Care Excellence.

[c]BfArM: [German] Federal Institute for Drugs and Medical Devices.

[d]CNEDiMTS: [French] Medical Device and Health Technology Evaluation Committee.

[e]DHT: digital health technology.

[f]All PROMs mentioned were given in specific examples.

[g]DiGA: digital health application.

[h]DHS: digital health solution.

[i]DTSQ: Diabetes Treatment Satisfaction Questionnaire.

[j]Applies to DHTs in tiers 1, 2, 3a and 3b.

[k]Domain covered satisfactorily by existing diabetes-specific PROMs.



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[l]Applies to DHTs in tiers 3a (disease prevention and management) and 3b (treatment, diagnostic, active monitoring, and calculation tools with measurable user benefits) only.

[m]HLS-EU-Q: European Health Literacy Survey Questionnaire.

[n]QoL: quality of life.

[o]DQOL: Diabetes Quality of Life [instrument].

[p]SF-36: Short Form (36) Health Survey.

[q]NRS: Numerating Rating Scale.

[r]SCL-90: Symptom Checklist 90.

[s]GSI: Global Severity Index.

[t]PSDI: Positive Symptom Distress Index.

[u]PST: Positive Symptom Total.

[v]MAQ: Medication Adherence Questionnaire.

# Discussion

## Principal Findings

In this targeted literature review, we identified 46 diabetes-specific and 16 nondiabetes-specific PROMs that were most used in diabetes clinical trials and research between 1995 and May 2024. In addition, this review shows that HTA guidelines on DHS evaluation from France, Germany, and the United Kingdom primarily reflect well-established PROMs for health-related quality of life.

## Challenges in Using PROMs for the Evaluation of DHS

Our review highlights that major HTA bodies acknowledge the importance and emerging needs of accepting PROMs as valuable outcomes to evaluate digital health interventions. However, by comparing the patient outcomes recommended in these guidelines to the number of prominent PROMs listed in the literature, there is still a lot of room for increasing the adoption and recommendation of PROMs by HTA bodies. Overall, in the literature as well as in the guidelines we identified a gap for PROMs that are relevant in evaluating DHS, such as disease knowledge (eg, carb counting in diabetes), eHealth literacy, digital burden (eg, data overload, fear of digital surveillance, and adverse effects associated with using digital technology), sexual life, family life, or well-being at work.

PROMs that were developed decades ago, as many of the PROMs we found in the literature, are likely to require updating before they can be used to assess the value of DHS. This is because they were developed to capture the impact of other types of interventions, and they may not be relevant for DHS and how these might affect patients' overall well-being. In addition, more research needs to be done into associations between the domains measured by the PROMs and other outcomes, for example, clinical and economic outcomes that are important in a reimbursement process.

Although we see PROMs being used more frequently in modern diabetes interventions [29], their use is currently neither widespread nor consistent. One of the reasons that few DHS-specific PROMs have been used until now is the relative "youth" of digital health. The term "digital health" was coined in 2000 [30], and the WHO published a guide to harmonize the use of digital health terminology as recently as 2018. By contrast, diabetes-specific PROMs first appeared in the late 1980 s—Self-Efficacy for Diabetes (SED-D) [31] and the Hypoglycemic Fear Survey (HFS) [32] appeared in 1987—while generic, nondiabetes-specific PROMs used in diabetes first appeared even longer ago in the 1960 s, for example, the Beck Depression Inventory (BDI) [20] in 1961 and the Affect Balance Scale (ABS) [33] in 1969. The difference in PROMs and development lifecycles of digital products means that DHS may require existing PROMs to be adapted to a digital environment [34] or for new, bespoke PROMs to be created to adequately characterize the value and impact of DHS on patients' health perceptions, QOL, and general well-being [35]. Either way, the lack of PROMs related to specific attributes of DHS needs to be addressed.

Specific, validated PROMs related to diabetes DHS have already been developed [36,37]. For new PROMs, patient communities emphasize the importance of assessing outcomes such as numeracy or health literacy, coping with diabetes, knowledge in diabetes management, evaluating problems with DHS (eg data overload), and evaluation of trust in health care providers.

The HTA bodies of France, Germany, and the UK generally agree that PROMs are valuable for the evaluation of DHS, but the scope of current HTA guidelines is limited to specific types of DHS, eg, medical devices or digital health applications. For these HTA bodies, there is broad consensus about the importance of assessing DHS based on functional, technical, and organizational characteristics, such as data security, practicality, quality, interoperability, and safety. Moreover, not only the investigated HTA bodies and countries focus on reimbursing and evaluating DHS, but most developed countries are working on frameworks and policies to provide faster access to DHS for patients and people with diabetes [38]. Obtaining a consensus on the best way to use PROMs to evaluate DHS is a necessary next step.

In France, although different types of DHS have been approved for reimbursement (mobile apps, telemonitoring systems, etc), the principles of evaluation published by the French health authority are specific to medical devices [7]. Deliberation about future frameworks for digital health interventions (including medical devices with artificial intelligence) is currently ongoing at the request of the French government and pharmaceutical companies. In the guideline specific to medical devices, PROs are highly recommended for supporting claims for reimbursement. Specific PROs are listed to demonstrate the impact on QOL [7].



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In 2019, Germany adopted the Digital Health care Act (DVG), to promote the use of telehealth, mobile apps, and other digital solutions, as well as the use of health data for research purposes. The DVG entitles all individuals covered by statutory health insurance to reimbursement for certain digital health applications. The manufacturer must provide evidence of the positive effect of the digital application on care. In the Fast Track process guideline [6], which details how mobile app manufacturers can apply for reimbursement, the BfArM defines a full set of requirements for DiGAV (digital health applications), such as the types of study expected, and provides examples of PROs that would be suitable for the evaluation of certain endpoints. However, the scope of the DVG is limited to lower-risk medical devices, and many potentially valuable digital health applications are therefore not covered by the provisions of the DVG.

Early in 2019, NICE published the Evidence Standards Framework for Digital Health Technologies [5]. It is not suitable for all digital solutions, as it excludes mobile applications directly downloaded on app stores by users and solutions incorporating artificial intelligence using adaptive algorithms. In this guideline, digital solutions are classified in 4 categories or tiers: the higher the category, the more important the request for evidence is. Endpoints may vary depending on the category. Using PROs is highly recommended.

### Needs and Opportunities of Using Patient-Reported Outcome Measures for the Evaluation of DHS

A major need in diabetes care is to improve behavior change techniques. Existing evidence shows that behavioral change can improve disease trajectories and reduce the risk of severe complications [39]. PROMs are at the core of understanding patient-relevant endpoints and how these relate to behavioral change as well as helping us understand where the unmet needs for people with diabetes are. By systematically assessing these outcome domains, therapy and behavioral decisions can be personalized for people with diabetes and therefore maximize the benefit of diabetes treatment. DHS may be a key catalyst for improving adherence to behavior change techniques and treatment overall [40]. By comprehensively understanding the effects of digital health interventions on both metabolic and patient-reported outcomes, people with diabetes may feel better informed about and included in treatment decisions, which has been shown to positively affect adherence and long-term outcomes [41].

As technologies quickly develop and become more available, it is vital to identify the unmet needs, through PROs, to properly assess the value of these solutions. As touched upon before, personalization of treatment plays a major role in increasing quality-of-care standards. The identification of unmet needs in outcome domains such as patient empowerment, QOL or health literacy should be a major deciding factor when tailoring treatment to people with diabetes. Much research is still needed in this area to provide evidence for unmet needs and PROMs tailored for DHS.

### The Need for a Holistic Treatment Approach

A holistic approach to improving health in diabetes looks beyond the attainment of established clinical endpoints and aims at including patient relevant dimensions. For example, improving metabolic control by reducing HbA1c can enhance QOL in diabetes, but it is not the only way of doing so. Decreased physical functioning and well-being of people with diabetes leads to a diminished QOL, but people with diabetes can actively improve QOL themselves through empowerment and self-efficacy [42,43]. Empowerment is the process by which patients gain the information and confidence to make independent, educated decisions about their diabetes using solid reasoning skills. Empowerment helps patients feel involved in treatment decisions and supports the ideal doctor-patient relationship, as defined in this quote, “The doctor is there to give the patient all the information the patient needs in order that the patient can make a decision, and the doctor should then implement the decision once the patient has made it” [44]. Self-efficacy is a measure of patients’ ability to manage their own diet, exercise, and medical treatment with assurance. DHS offer people with diabetes a way to increase empowerment and self-efficacy and thus both QOL and clinical outcomes. The number of DHS available to people with diabetes is increasing [45,46], which bodes well for patient-driven approaches to improving QOL and clinical outcomes in diabetes.

### Harmonizing the Evaluation of DHS

A common, comprehensive HTA framework to guide the use of PROMs in the context of DHS would help harmonize the evaluation of DHS. This, in turn, would facilitate and expedite the path of DHS to market and ultimately enhance the quality of support and education for people with diabetes. At present, HTA guidelines differ in terms of scope, types of DHS evaluated, and the role PROMs play in DHS reimbursement and evaluation [5-7]. These differences make the evaluation of DHS more complex and slower than it needs to be. Difficulties with evaluation may partly explain why DHS are struggling to be accepted by health systems despite promising results, and the harmonization of outcome measures may be one critical stepping-stone to simplify and accelerate the evaluation of DHS [47].

### Limitations of the Targeted Literature Review

While interpreting the results of this targeted literature review, the following limitations need to be considered. First, it is difficult to describe DHS as one category as they vary substantially in terms of disease area, treatment regimen, type, and their regulatory risk classification. Second, as this review reflects on the two databases PubMed and Clinical Trial.gov trials that are listed in other databases may not be captured. Third, the patients’ perspective is missing in this research although it is a key topic around the use of PROMs for evaluating DHS. Finally, our assessment focused only on HTA-driven European countries.

### The Impact and Challenges of PRO Data Collection

A crucial prerequisite for the use of PROMs is the cooperation of patients in data collection. Patients may not be willing to share this data, for example for data privacy reasons or because



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the respective PROMs are too tedious to fill in. For example, Skovlund et al [48] described that patients ask for shorter questionnaires with dichotomous items instead of Likert-scale response formats to minimize complexity, to lower the cognitive burden, and to reduce the risk of questionnaire fatigue. Moreover, it is important that patients' data is collected accurately and the entry of wrong data is avoided. Therefore, the items' wording and terminology needs to be clear to prevent misleading or misinterpretation [48]. Ultimately, the data collection method can also influence the use and the validity of PROMs as there might be a difference between data collected by digital tools (eg smartphone apps and SMS text messaging) used by the patients on their own versus paper-based questionnaires filled in at the doctor's office.

## Conclusions

Many PROMs are used in diabetes care, although few currently exist with the aim to evaluate DHS. Certain domains of value to people with diabetes have few or no PROMs to evaluate them at present. Generally, key HTA bodies are acknowledging the value of PROMs, but there is a need to harmonize the outcomes and evaluation processes for DHS between countries. In diabetes, PROMs can help provide a more holistic assessment of patient health beyond the control of clinical and metabolic outcomes. Therefore, the value of DHS may be best captured through PROMs, which will increase our understanding of the full range of benefits from these interventions.

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## Authors' Contributions

PC and MG contributed to conceptualization, funding acquisition, methodology, project administration, supervision and writing. PV and OW assisted with methodology, investigation, project administration, and writing.

## Conflicts of Interest

MJ has received fees for advisory/speaking services and research grant form Abbott, Air Liquide Santé International, Amgen, Astrazeneca, Bayer, BMS, Boehringer-Ingelheim, Dexcom, Glooko, Lifescan, Lilly, Medtronic, MSD, Nestle HomeCare, NovoNordisk, Orkyn', Roche Diabetes, Sanofi, Vitalaire, and Voluntis. NO has received research funding from Dexcom, Roche Diabetes and Medtronic Diabetes and has participated in advisory boards for Dexcom, Roche Diabetes and Medtronic Diabetes. SG at Imperial College London receives research funding from Roche and Prova Health receives consulting payments from Roche. PV and OW are or were full-time employees for Else Care (Carenity) who received funding from Roche Diabetes Care to conduct the literature review. PC works for Roche Diabetes Care.

Multimedia Appendix 1
List of all assessed PROMs.
[PDF File, 454 KB - diabetes_v10i1e52909_app1.pdf ]

Multimedia Appendix 2
Search strategy per database.
[DOCX File, 16 KB - diabetes_v10i1e52909_app2.docx ]

Multimedia Appendix 3
PROMs, assessed HTA guidelines and expert opinions.
[PDF File, 99 KB - diabetes_v10i1e52909_app3.pdf ]

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## Abbreviations

**ABS:** Affect Balance Scale
**BDI:** Beck Depression Inventory
**CNEDiMTS:** Medical Device and Health Technology Evaluation Committee



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**DHA:** Digital Health care Act
**DHS:** digital health solutions
**FAD:** Food and Drug Administration
**HFS:** Hypoglycemic Fear Survey
**HTA:** health technology assessment
**MOT:** Medical Outcomes Trust
**NICE:** National Institute of Health and Care Excellence
**PROM:** patient-reported outcomes measure
**QOL:** quality of life
**SED-D:** Self-Efficacy for Diabetes
**SIP:** Sickness impact profile
**WHO:** World Health Organization

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# Early Detection of Elevated Ketone Bodies in Type 1 Diabetes Using Insulin and Glucose Dynamics Across Age Groups: Model Development Study

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## Abstract

**Background:** Diabetic ketoacidosis represents a significant and potentially life-threatening complication of diabetes, predominantly observed in individuals with type 1 diabetes (T1D). Studies have documented suboptimal adherence to diabetes management among children and adolescents, as evidenced by deficient ketone monitoring practices.

**Objective:** The aim of the study was to explore the potential for prediction of elevated ketone bodies from continuous glucose monitoring (CGM) and insulin data in pediatric and adult patients with T1D using a closed-loop system.

**Methods:** Participants used the Dexcom G6 CGM system and the iLet Bionic Pancreas system for insulin administration for up to 13 weeks. We used supervised binary classification machine learning, incorporating feature engineering to identify elevated ketone bodies (>0.6 mmol/L). Features were derived from CGM, insulin delivery data, and self-monitoring of blood glucose to develop an extreme gradient boosting-based prediction model. A total of 259 participants aged 6-79 years with over 49,000 days of full-time monitoring were included in the study.

**Results:** Among the participants, 1768 ketone samples were eligible for modeling, including 383 event samples with elevated ketone bodies (≥0.6 mmol/L). Insulin, self-monitoring of blood glucose, and current glucose measurements provided discriminative information on elevated ketone bodies (receiver operating characteristic area under the curve [ROC-AUC] 0.64 - 0.69). The CGM-derived features exhibited stronger discrimination (ROC-AUC 0.75 - 0.76). Integration of all feature types resulted in an ROC-AUC estimate of 0.82 (SD 0.01) and a precision recall-AUC of 0.53 (SD 0.03).

**Conclusions:** CGM and insulin data present a valuable avenue for early prediction of patients at risk of elevated ketone bodies. Furthermore, our findings indicate the potential application of such predictive models in both pediatric and adult populations with T1D.

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**KEYWORDS**

type 1 diabetes; machine learning; diabetic ketoacidosis; ketone level; diabetic complication; prediction model

## Introduction

Diabetic ketoacidosis (DKA) represents a significant and potentially life-threatening complication of diabetes, predominantly observed in individuals with type 1 diabetes (T1D), although occurrences in those with type 2 diabetes are not uncommon [1,2]. DKA arises from an inadequate supply of insulin, leading to dysregulation of blood glucose levels. Consequently, the body resorts to metabolizing fat for energy, resulting in the accumulation of ketone bodies in the bloodstream alongside elevated blood sugar levels. This metabolic disturbance manifests in symptoms such as nausea, vomiting, abdominal pain, confusion, excessive thirst, and frequent urination [1]. If left untreated, DKA can progress to coma and, in severe cases to mortality, necessitating immediate medical intervention comprising insulin administration and fluid replacement to restore normal blood glucose and ketone levels [3] .

Children and adolescents are particularly susceptible to DKA due to their ongoing growth and development, which introduce complexities in diabetes management [4]. Factors such as missed insulin doses, illness, or infection can rapidly precipitate DKA in this demographic.

Studies have documented suboptimal adherence to diabetes management among children and adolescents, as evidenced by deficient ketone monitoring practices [5-7] . For instance, a recent study involving 2995 participants revealed that a significant proportion lacked ketone testing supplies at home, with a considerable proportion reporting infrequent ketone checks, particularly in instances of elevated glucose levels [7].



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Closed-loop systems offer a promising approach to addressing the challenges of diabetes management in both pediatric and adult populations [8,9]. Leveraging CGM technology provides real-time feedback on blood glucose levels, facilitating automated adjustments to insulin delivery via an insulin pump. By delivering precise insulin doses tailored to individual glucose fluctuations, closed-loop systems can reduce the risks of both hypoglycemia and hyperglycemia, thereby diminishing the likelihood of DKA development. However, this technology does not eliminate the risk of DKA [10-12].

A recent study by Cichosz and Bender [13] demonstrated the potential of CGM data in predicting elevated ketone levels among adults with T1D. However, such investigations remain scarce in pediatric populations and have not incorporated insulin data. Consequently, this study aims to explore the predictive potential of CGM and insulin data for elevated ketone bodies in pediatric and adult patients with T1D using a closed-loop system.

## Methods

### Data Sources

To ascertain whether patterns derived from CGM and insulin usage could serve as predictive indicators for elevated ketone bodies—a potential risk factor for DKA in individuals with diabetes—data sourced from the intervention arm of The Insulin-Only Bionic Pancreas Pivotal Trial (NCT04200313) [14] were analyzed. This trial constituted a multicenter randomized controlled study comparing an at-home closed-loop system with the prevailing standard of care.

The participant cohort encompassed individuals diagnosed with T1D aged 6 to 79 years. Participants used the Dexcom G6 CGM system in conjunction with the iLet Bionic Pancreas system for insulin administration for up to 13 weeks. Additionally, participants were equipped with a blood ketone meter and test strips and were provided instructions to measure ketone levels if glucose readings surpassed 300 mg/dL. The intervention group comprised 219 patients with T1D, exhibiting a mean glycated hemoglobin of 7.9 (SD 1.2%); 63 mmol/mol with a mean age of 28 (SD 19) years, and a female representation of 49% (n=107) within the cohort.

For this analysis, inclusion criteria required the presence of ketone measurements along with corresponding CGM and insulin data within a 12-hour timeframe preceding the ketone measurements. CGM data periods had to demonstrate a wear time of ≥50% to be considered for inclusion. Given the sampling rate of the CGM system of 12 readings per hour, inclusion mandated a minimum of 72 glucose samples within the 12-hour observation window.

This study adheres to the recommended guidelines delineated in the “Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis” (TRIPOD).

### Model Target

In this study, we used a supervised binary classification machine learning methodology to discern elevated ketone bodies. It is well established that ketone levels below 0.6 mmol/L fall within the reference range, whereas levels at or above 0.6 mmol/L pose a significantly augmented risk of DKA [15]. Therefore, we defined the binary classification task as the identification of elevated ketone bodies (≥0.6 mmol/L) versus nonelevated ketone bodies (<0.6 mmol/L) during episodes of elevated glucose readings.

### Feature Engineering

Feature engineering is a process within machine learning wherein new features are generated from raw data through a series of transformations, aggregations, or extractions of information from existing variables. The primary objective is to enhance the performance of machine learning algorithms by constructing new features that more accurately capture the underlying relationships in the data, thereby augmenting prediction accuracy and model effectiveness [16]. To identify the most relevant predictors of elevated ketone levels in patients with diabetes, we explored a broad range of potential features over the preceding 12-hour period. This included absolute values, summations, and dynamic patterns to capture temporal variations. Given the limited literature on the most effective individual features or their optimal combinations for detecting ketone elevation, our approach aimed to systematically identify the best subset of predictors.

A total of 26 features were extracted from CGM, insulin data, and glucose meter readings within a 6- and 12-hour window preceding the ketone samples, as depicted in Figure 1. Table 1 enumerates the features extracted from each data source. These features encompassed mathematical transformations of the signals to characterize their dynamics, range of variation, cumulative effects, distribution, and extreme values. The methodology adopted was data-driven and exploratory, devoid of prior assumptions regarding which features of the signal that would yield optimal discriminative information when combined. The dynamics of glucose levels are intricately shaped by diurnal patterns, influenced by factors such as dietary intake, basal and bolus insulin administration, endocrine activity, and behavioral habits including physical exertion and sleep.



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**Figure 1.** Overview of the data pipeline for predicting ketone levels using machine learning. Data from multiple sources, including the iLet closed-loop system, continuous glucose monitor (CGM), glucometer, and ketone meter, are collected and processed. A window of CGM, insulin, and self-monitored blood glucose (SMBG) data is extracted for feature engineering. Various feature subsets, such as the hour of day, SMBG, insulin, and CGM trends over different timeframes, are used as input to train a model. Stratified cross-validation ensures balanced class distribution, and model performance is evaluated using receiver operating characteristic (ROC) and precision-recall (PR) curves.

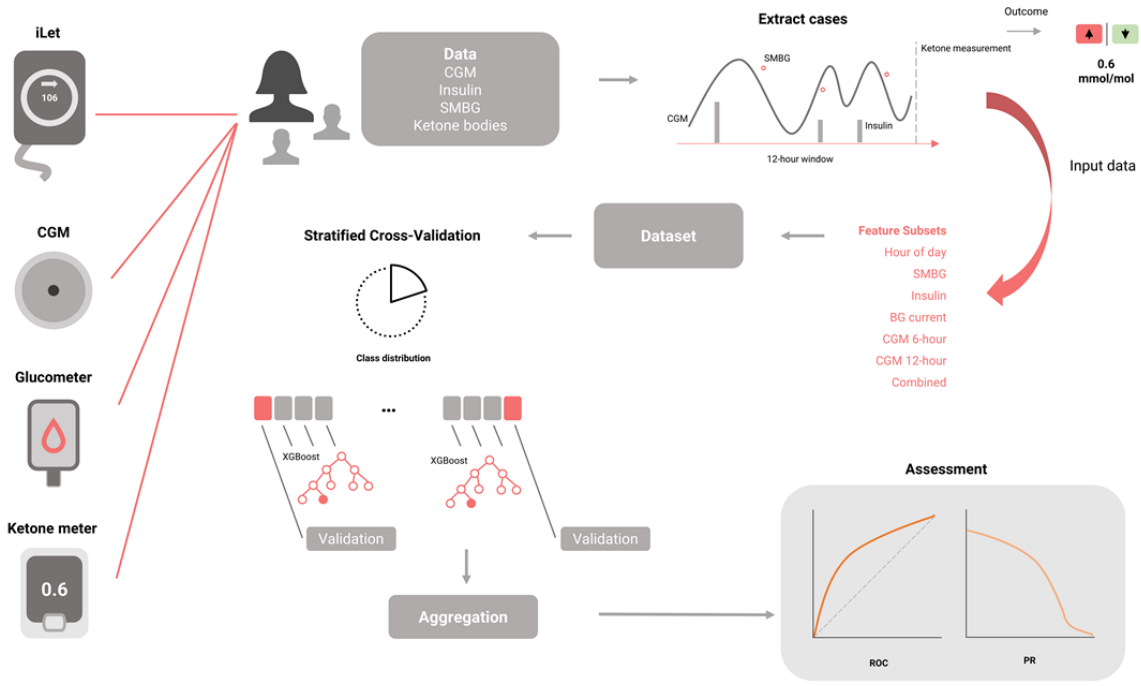



**Table .** Extracted features for CGM[a], insulin, and BGM[b] data. Features marked with "√" indicate inclusion for the respective data type and time division.

| Feature | CGM (6h) | CGM (12h) | Insulin basal (6 - 12h)[c] | Insulin bolus (6 - 12h)[c] | Insulin meal (6 - 12h)[c] | BGM (12h) |
|---|---|---|---|---|---|---|
| Latest | √ | √ | | | | |
| Maximum | √ | √ | | | | √ |
| Minimum | √ | √ | | | | √ |
| Sum | | | √ | √ | √ | |
| Mean | √ | √ | | | | |
| Standard deviation | √ | √ | | | | |
| Time spent when blood glucose levels >300 mg/dL | √ | √ | | | | |
| Decreases ratio | √ | √ | | | | |
| Mean decrease | √ | √ | | | | |
| Hour of the day | √ | | | | | |

[a]CGM: continuous glucose monitoring.

[b]BGM: blood glucose monitoring.

[c] Insulin features are extracted from both a 0 - 6 hour and a 6 - 12 hour window.

While many features entailed straightforward mathematical derivatives such as summations, standard deviations, and the proportion of time spent above 300 mg/dL blood glucose levels, we additionally incorporated a metric assessing the rate of glucose decline relative to preceding measurements to capture finer-scale dynamics within the glucose signal. The formulation for this calculation is delineated below:

$$cgm=[x1,x2,x3...xn]$$

$$Decreasesn=\sum i=1n-1\{1ifi+1-xi<00otherwise$$

$$Decreaseratio=decreasesn/cgm/$$

## Model Development

For model development, we used a supervised binary classification approach using an extreme gradient boosting



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(XGBoost) classifier to predict elevated levels of ketone bodies. XGBoost is a renowned machine learning algorithm known for its ability to handle intricate datasets by amalgamating weak prediction models (decision trees) into a robust ensemble [17]. It excels in capturing nonlinear relationships, managing missing or imbalanced data, and mitigating overfitting, thereby typically yielding high predictive performance. This efficacy has been demonstrated in clinical prediction models across a spectrum of medical domains [18-21].

The model was trained using features from each data type individually and in combination, aiming to ascertain their predictive capacity for the target variable. We used 5-fold stratified cross-validation to ensure an unbiased estimation of the model's performance and hyperparameter estimation, with stratification ensuring uniform proportions of events across folds [22]. The following parameters were optimized using a grid search strategy: learning rate (0.01, 0.1, 0.3), number of estimators (50, 100, 150), max depth (2, 4, 8), minimum child weight (1, 3, 5), subsample (0.6, 0.8, 1.0), and $\gamma$ (0, 1, 5).

All analyses were conducted using MATLAB (version R2021b; MathWorks) and Python (version 3; Python Software Foundation), leveraging the Scikit-learn package (version 0.23.2) for machine learning utilities, the SHapley Additive exPlanations (SHAP) package (version 0.43.0) for interpretability assessment, and the XGBoost package (version 1.7.5) for implementing the classifier.

### Model Assessment and Interpretability

The discriminative performance of the model was assessed using the computation of the area under the receiver operating characteristic curve (ROC-AUC) and the area under the precision-recall curve (PR-AUC) [23]. The uncertainty of estimates was calculated as the SD across folds. To enhance model interpretability, SHAP average values across folds were leveraged for explanatory purposes. These values offer insights into the contribution of individual features towards model predictions, thereby enhancing the interpretability and transparency of the modeling process [24]. .

### Sensitivity Analysis

In a sensitivity analysis, we restricted the subgroup to patients aged <18 years. The objective of this analysis was to assess the model's performance in pediatric and adolescent patients, as these groups have a higher risk of developing DKA [25]. The objective was to test whether any substantial difference was observed in ROC-AUC performance in patients under 18 years.

### Ethical Considerations

This study is a reanalysis of existing and anonymized data from the Insulin Only Bionic Pancreas Pivotal Trial [14]. According to Danish law (Komitéloven, kap. 4, § 14, stk. 3) on the ethical review of health science research projects and health data science research projects, this study did not require approval from an institutional or licensing committee.

The original Insulin Only Bionic Pancreas Pivotal Trial protocol and informed consent forms were approved by institutional review boards. Written informed consent was obtained from each participant prior to enrollment. An independent data and safety monitoring board provided trial oversight reviewing unmasked safety data during the conduct of the study.

We confirm that all methods were carried out in accordance with relevant guidelines and regulations. The data was accessed and analyzed in an anonymized form.

## Results

### Participant Characteristics

In total, 259 patients (n=93 for patients aged <18 years) were included in the analysis. Another 181 patients did not have qualified ketone measurements with a CGM window (n=71) or were part of the control group, which did not use a connected insulin pump (n=110). Among the included patients, 1768 ketone samples were eligible for modeling, including 383 event samples with ketone levels ≥0.6 mmol/L. Overall, the patients had over 14,300,000 CGM measurements, corresponding to over 49,000 days of full-time monitoring.

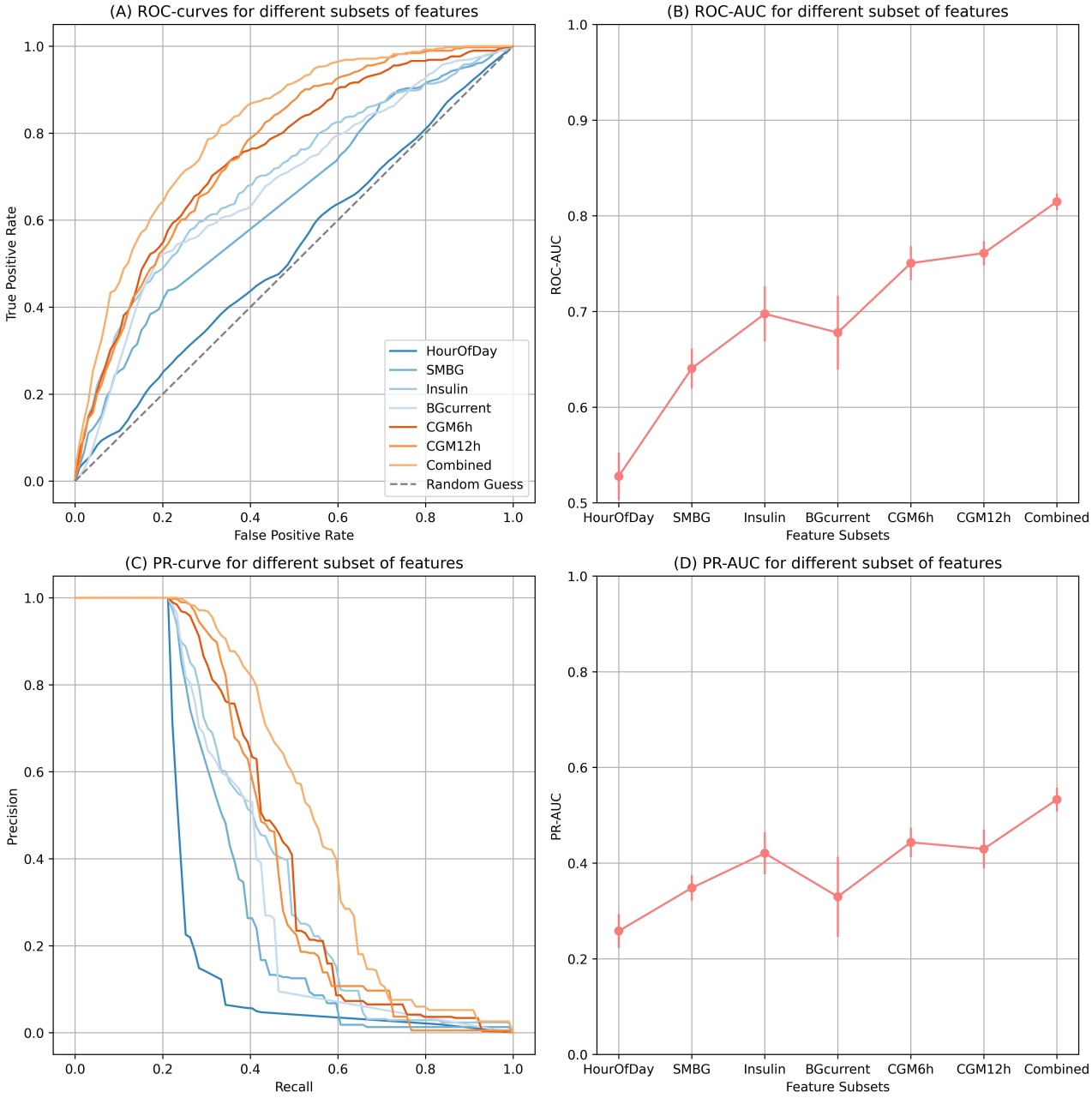
### Model Performance

The ROC-AUC, PR-AUC, and individual curves are presented in Figure 2. The plots illustrate the performance of adding individual datatypes and a combined estimate. Insulin, self-monitoring of blood glucose (SMBG), and current glucose measurements, all provided discriminative information on elevated ketone bodies (ROC-AUC 0.64 - 0.69). The features derived from the CGM window demonstrated greater discrimination (ROC-AUC 0.75 - 0.76). Notably, extending the CGM window from6 hours to 12 hours only added minimal discriminative power, as measured by ROC-AUC. Combining all feature types yielded an ROC-AUC estimate of 0.82 (SD 0.01) and a PR-AUC of 0.53 (SD 0.03). In the sensitivity analysis including only pediatric patients (age <18 years), the ROC-AUC estimate was 0.80 (SD 0.01). The final selected hyperparameters were a learning rate of 0.2, 100 estimators, a maximum depth of 8, a minimum child weight of 1, a subsample ratio of 1.0, and a $\gamma$ value of 1.



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**Figure 2.** For endpoint 1, (A) ROC-curves for different subsets of features, (B) ROC-AUC for different subset of features , (C) PR-curve for different subset of features, (D) PR-AUC for different subset of features. AUC: area under the curve; BG: blood glucose; CGM: continuous glucose monitoring; PR: precision recall; ROC: receiver operating characteristics; SMBG: self-monitoring of blood glucose.



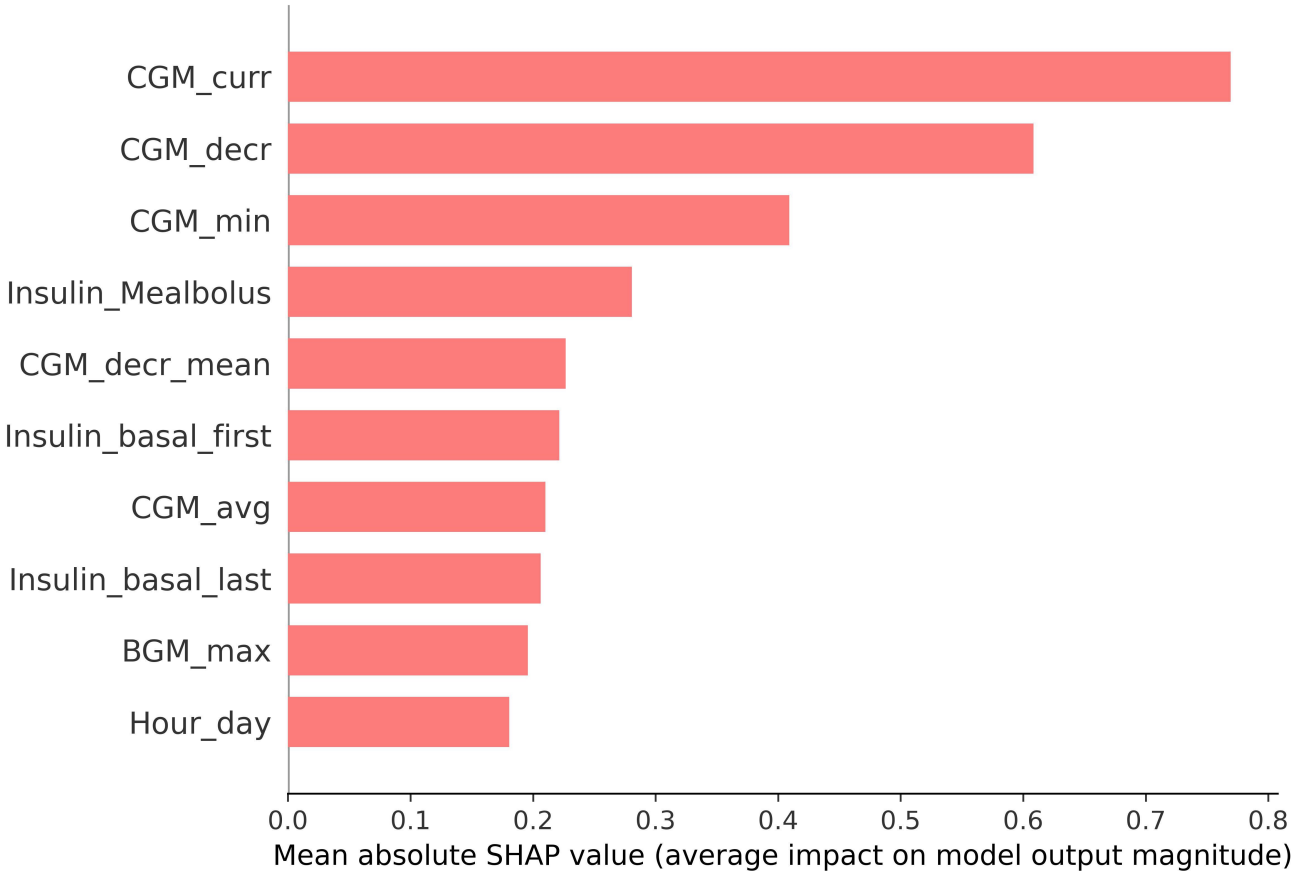

## Interpretability

Feature importance analysis including the combined features showed that data from both CGM and insulin deliveries adds significant information to the models' predictive capabilities. The mean SHAP values for the 10 highest-ranking features are presented in Figure 3. Furthermore, a SHAP Beeswarm plot is provided in Multimedia Appendix 1. As expected, the current CGM value had the highest contribution, followed by the ratio of decrease in the CGM window. Further, insulin-related features such as meal bolus and basal insulin deliveries had significant impacts.



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**Figure 3.** SHAP bar plot illustrating the 10 features with most important features in the model's prediction. BGM: blood glucose measurement; CGM: continuous glucose monitoring; Avg: average; Min: minimum; Decr: decrease; Max: maximum.



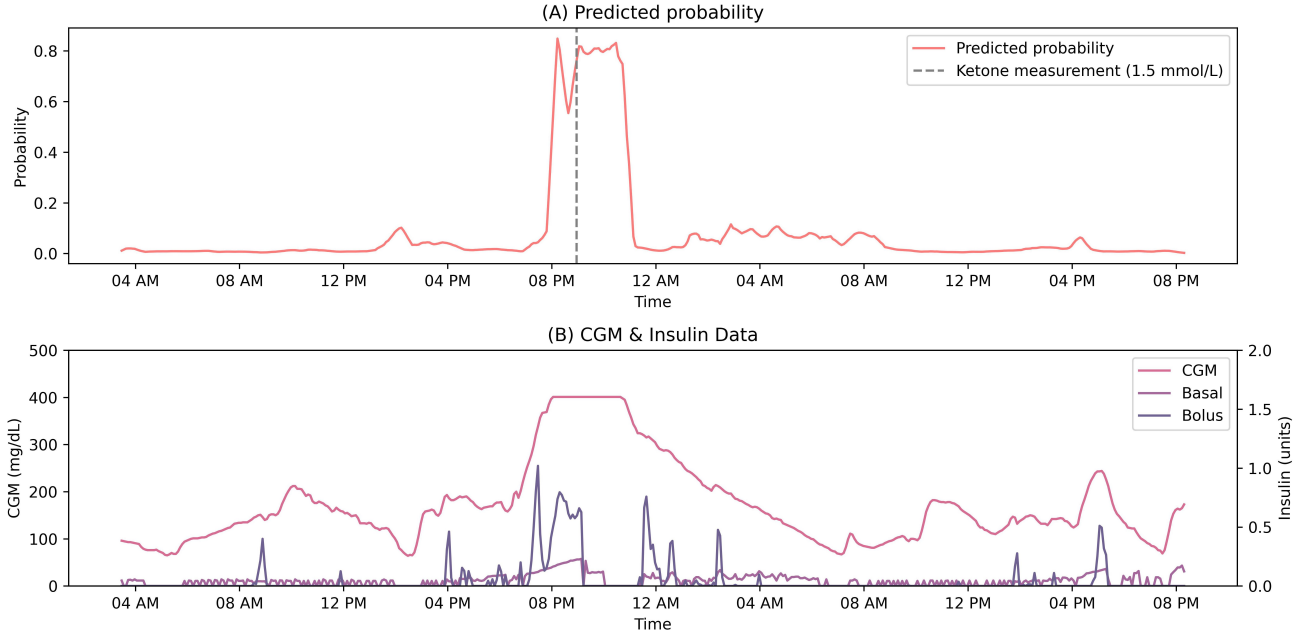

## Patient Example

An illustrative depiction of the predicted probability, representing the model output for elevated ketone bodies, is presented alongside CGM data and insulin delivery records for a specific patient in Figure 4. Notably, the probability of a heightened risk of elevated ketone bodies increases around 8 PM, coinciding with a ketone meter measurement confirming elevated ketones at 9 PM. This example underscores the potential utility of a predictive model, such as the one proposed in our study, for identifying impending instances of elevated ketone levels based on continuous monitoring of patients' data. Such a model holds promise for alerting patients to take timely action, thereby mitigating the progression of adverse developments associated with diabetic ketoacidosis.



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**Figure 4.** Patient example: (A) Predicted probability for elevated ketone bodies over two days of monitoring; (B) The corresponding CGM and insulin inputs to the model. CGM: continuous glucose monitoring.




## Discussion

### Principal Findings

The objective of this investigation was to formulate and assess various data sources, including CGM, insulin, and SMBG, as potential inputs for a prediction model designed to provide timely alerts regarding the risk of developing DKA through elevated ketone body levels. The findings underscore the potential utility of patterns derived from CGM data obtained from individuals with T1D in identifying and signaling patients at risk of elevated ketone levels. It is imperative to note that elevated ketone levels serve as a precursor to DKA, a critical and potentially life-threatening complication of diabetes.

We previously showed that CGM data could be used for prediction of elevated ketone bodies in an adult population with T1D [13]. The present findings validate this observation and expand on the initial findings by examining the added predictive value of insulin and SMBG data. Furthermore, this study strongly indicates that this approach is applicable to both pediatric and adult individuals. To our knowledge, this study, along with our previously published study, is the first to explore the potential of predicting elevated ketone bodies using a combination of CGM and insulin data. However, numerous studies have reported the usage of CGM for prediction of other complications related to diabetes and diabetes treatment, such as hypoglycemia, gastroparesis, and future glucose levels [26-31].

The clinical implications of implementing a system based on the proposed model in our study are vividly illustrated through the patient's continuous data depicted in Figure 4. The predicted risk or probability of elevated ketone bodies offers patients a more nuanced and informative warning compared to solely relying on glucose levels. This enhanced information could prompt early intervention to prevent further progression to DKA. Potential actions triggered by these alerts may include promptly checking ketone bodies using a ketone meter, verifying the functionality of the infusion set to ensure proper insulin delivery, and corroborating CGM measurements with SMBG readings. By facilitating proactive measures, such a system has the potential to significantly mitigate the risk of adverse outcomes associated with DKA.

### Limitations

Despite the robust design of our study, which encompassed a substantial dataset and measures to estimate generalizability, several limitations warrant acknowledgment. First, while our analysis involved a sample size of 259 individuals with numerous measurements of ketone bodies (n=1768), the number of outcome events (elevated ketone levels ≥0.6 mmol/L) remained relatively small (n=383). This limited number of outcome events is reflected in the SD of the estimate observed in the ROC-AUC. Consequently, the reliability of our model's performance on new data remains uncertain, despite indicative evidence of valuable information within the dataset. These findings need to be validated in independent datasets. An avenue for potential improvement lies in the exploration of larger datasets to enhance predictive performance and further validate these findings. While our study encompassed a diverse population spanning children, adolescents, and adults, the analysis did not delve into subgroup-specific performance. Consequently, the efficacy of our predictive model across distinct subgroups remains unexplored, potentially subject to interindividual variability. Future investigations could address this limitation by conducting subgroup analyses to elucidate performance variations across demographic or clinical strata. Our findings from patients using closed-loop insulin delivery technology cannot be extrapolated to other treatment regimens without further investigation. A key limitation is that participants only measured ketones during prolonged hyperglycemia, which, coupled with generally low adherence and possible medication influences (eg, sodium-glucose cotransporter-2 inhibitors), may introduce selection bias. Importantly, ketone levels serve as



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surrogate outcomes and do not necessarily predict ketoacidosis events.

## Conclusion

The innovative methodology used in this study for detecting elevated ketone levels among individuals with t1D underscores the potential of integrating CGM and insulin data as a valuable resource for early prediction of patients at risk. Moreover, our findings suggest that such a predictive model holds promise for application in both pediatric and adult populations with T1D, particularly within closed-loop systems.

Future studies are imperative to validate the robustness and reliability of these findings. Furthermore, there is a need for comprehensive investigations to assess the real-world impact of implementing a system based on the proposed prediction model. Such investigations will be instrumental in elucidating the efficacy and practical implications of leveraging predictive modeling in clinical practice for proactive management of diabetes-related complications, including DKA.

## Acknowledgments

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## Disclaimer

The source of the data is the Insulin Only Bionic Pancreas Pivotal Trial (NCT04200313), but the analyses, content and conclusions presented herein are solely the responsibility of the authors and have not been reviewed or approved by the Bionic Pancreas Research Group or Beta Bionics.

## Authors' Contributions

Conceptualization: CB, SC
Data curation: SC
Formal analysis: CB, SC
Methodology: CB, SC
Writing – original draft: SC
Writing – review & editing: CB

## Conflicts of Interest

The research was funded by i-SENS, Inc (Seoul, South Korea) and SC’s involvement with the company did not influence the design, implementation, or interpretation of the study. SC have received research funding from i-SENS, Inc (Seoul, South Korea), which manufactures some of the product types discussed in this paper. However, the study was conducted independently, and the authors declare that their involvement with i-SENS, Inc (Seoul, South Korea) did not influence the findings or conclusions of the study.

Multimedia Appendix 1
SHAP Beeswarm plot
[DOCX File, 184 KB - diabetes_v10i1e67867_app1.docx ]

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## Abbreviations

**AUC:** area under the curve
**CGM:** continuous glucose monitoring
**DKA:** diabetic ketoacidosis
**PR:** precision recall
**ROC:** receiver operating characteristic
**SHAP:** SHapley additive exPlanations
**T1D:** type 1 diabetes
**TRIPOD:** Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis
**XGBoost:** extreme gradient boosting

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Original Paper

# “Now I can see it works!” Perspectives on Using a Nutrition-Focused Approach When Initiating Continuous Glucose Monitoring in People with Type 2 Diabetes: Qualitative Interview Study

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## Abstract

**Background:** Food choices play a significant role in achieving glycemic goals and optimizing overall health for people with type 2 diabetes (T2D). Continuous glucose monitoring (CGM) can provide a comprehensive look at the impact of foods and other behaviors on glucose in real time and over the course of time. The impact of using a nutrition-focused approach (NFA) when initiating CGM in people with T2D is unknown.

**Objective:** This study aims to understand the perspectives and behaviors of people with T2D who participated in an NFA during CGM initiation.

**Methods:** Semistructured qualitative interviews were conducted with UNITE (Using Nutrition to Improve Time in Range) study participants. UNITE was a 2-session intervention designed to introduce and initiate CGM using an NFA in people with T2D who do not use insulin. The intervention included CGM initiation materials that emphasized the continuous glucose monitor as a tool to guide evidence-based food choices. The materials were designed to support conversation between the CGM user and diabetes care provider conducting the sessions. A rapid matrix analysis approach was designed to answer two main questions: (1) How do people who participate in an NFA during CGM initiation describe this experience? and (2) How do people who participate in an NFA during CGM initiation use CGM data to make food-related decisions, and what food-related changes do they make?

**Results:** Overall, 15 people completed interviews after completion of the UNITE study intervention: 87% (n=13) identified as White, 60% (n=9) identified as male, mean age of 64 (SD 7.4) years, mean T2D duration of 7.5 (SD 3.8) years, and mean hemoglobin $A_{1c}$ level of 7.5% (SD 0.4%). Participants fluently discussed glycemic metrics such as time in range (percent time with glucose 70-180 mg/dL) and reported regularly using real-time and retrospective CGM data. Participants liked the simplicity of the intervention materials (eg, images and messaging), which demonstrated how to use CGM data to learn the glycemic impact of food choices and suggested how to adjust food choices for improved glycemia. Participants reported that CGM data impacted how they thought about food, and most participants made changes because of seeing these data. Many of the reported changes aligned with evidence-based guidance for a healthy lifestyle, including prioritizing nonstarchy vegetables, reducing foods with added sugar, or walking more; however, some people reported behavior changes, such as skipping or delaying meals to stay in the target glucose range. A few participants reported that the CGM amplified negative feelings about food or eating.

**Conclusions:** Participants agreed that pairing nutrition information with CGM initiation instructions was helpful for their diabetes care. In general, the NFA during CGM initiation was well received and led to positive changes in food choices and behaviors during a 2-month intervention.



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**KEYWORDS**

diabetic; diabetes mellitus; DM; type 2 diabetes; T2D; endocrinology; nutrition; diet; continuous glucose monitoring; glucose monitor; glucose; glycemic control; time in range; self-care; education; mHealth

# Introduction

## Background

First-line therapy for the management of type 2 diabetes (T2D) is lifestyle modification, which includes following evidence-based nutrition and physical activity guidelines [1]. Food choices can play a significant role in achieving glycemic goals and optimizing overall health for people with T2D [2]. Moreover, continuous glucose monitoring (CGM) has also been shown to improve glycemic outcomes for people with T2D [3]. CGM can provide a comprehensive assessment of the impact of foods and other behaviors on glucose in real time and over the course of time. People with T2D may benefit from using CGM data to guide food choices that help achieve their desired glycemic goals, including time in range (TIR; percent time with glucose levels between 70-180 mg/dL).

However, people with T2D may encounter challenges with knowing how to use CGM data to make food choices, especially making food choices that can maximize TIR and that are good for overall health. In other words, it may not be clear which food choices keep glucose in the desired target range and align with current evidence-based nutrition guidance for people with diabetes [4].

Optimal CGM use requires education, training, and support [5]. Various tools [6], methods [7], and programs [8] have been created to educate CGM users on the effective use of CGM technology and its associated data. However, specific emphasis on evidence-based nutrition guidance has not been embedded into these trainings, and this could have consequences. For example, without nutrition guidance, a continuous glucose monitor could lead its user to regularly choose *less healthy* foods if those foods keep glucose in the target range of 70 to 180 mg/dL (eg, choosing high-fat red meats or highly processed low-carbohydrate snack foods); however, these *less healthy* foods may be detrimental to other aspects of health and lead to unintended consequences.

Research suggests that people who are empowered and skilled to self-manage their diabetes have improved health outcomes [9,10]. Discovery learning is one self-care opportunity, which has been described by Polonsky et al [11] as a time when an individual with diabetes is supported to make use of new information (such as one's own glucose values) to gain insights through personal experience and reflection. Having CGM data available before and after meals can provide a profound opportunity for the user to make connections between a given glucose value and food choices, portions, or circumstances, which, in turn, could promote data-driven behavior changes. Thus, this suggests that evidence-based nutrition recommendations at the time of CGM introduction and initiation could be beneficial.

## This Study

The purpose of this research was to understand the perspectives and behaviors of people who participated in a nutrition-focused approach (NFA) when starting CGM. More specifically, this research in non–insulin-using people with T2D describes the following: (1) How do people who participate in an NFA during CGM initiation describe this experience (ie, intervention receipt)? and (2) How do people who participate in an NFA during CGM initiation use CGM data to make food-related decisions, and what food-related changes do they make (ie, intervention enactment)?

The outcomes of this research can help identify gaps in knowledge regarding how new CGM users understand and use their CGM data to make food-related decisions. This research can also provide the diabetes care community with considerations for how to present or position nutrition messages when initiating CGM in people with T2D.

# Methods

## Study Design

This qualitative study is part of the larger UNITE (Using Nutrition to Improve Time in Range) study (NCT05928572). UNITE is a randomized clinical trial designed to understand if there are differences in glycemia and dietary intake when people with T2D are introduced to CGM using 2 different methods. The 2 CGM initiation methods were an NFA and a self-directed approach (SDA). Participants were randomly assigned to participate in either the NFA or SDA when initiating a Dexcom G7 (Dexcom, Inc) CGM sensor paired with a smartphone app. All UNITE study participants used the G7 sensor and smartphone app continuously for approximately 2 months.

The focus of the NFA was to help CGM users use their CGM data to identify which food choices align with evidence-based nutrition recommendations and help achieve glycemic goals. Development of the NFA has been previously described by Willis et al [12]. In brief, the NFA included the following three components: (1) a 60-minute, in-person CGM initiation session; (2) a 30-minute, remote CGM data review session occurring approximately 14 days after CGM initiation; and (3) nutrition-focused CGM initiation materials designed to support both the CGM user and the diabetes care provider conducting the sessions. The materials included a brief interactive slide presentation containing graphic images and a 1-page CGM nutrition guide. The materials encouraged the CGM user *to know* their glucose goals (including a target glucose range of 70-180 mg/dL and TIR of >70%); *to learn* how their body responds to foods and activity using a *1, 2, 3* approach (a method for following glucose before and after meals and activity to learn the body's response); and to consider how *to adjust* food choices using a *yes/less* framework (a highly simplified version of evidence-based nutrition recommendations). Excerpts of the



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materials and how they were used are published elsewhere [12]. A registered dietitian nutritionist served as the diabetes care provider for both sessions; however, the sessions were not intended to replace medical nutrition therapy (eg, the NFA did not include a full nutrition assessment or diagnosis). While a registered dietitian nutritionist would be an excellent candidate to deliver the NFA, the nutrition-specific content was developed to be general enough that other care providers could be trained to deliver the intervention. An intervention manual was used to keep the content and sessions consistent among all participants in the UNITE study.

A rapid matrix analysis approach with semistructured qualitative interviews [13,14] was designed to describe intervention receipt (this included information about the quality and quantity of information delivered and about the intervention materials, including the interactive slides and the CGM nutrition guide) and intervention enactment (this included thoughts and behaviors related to CGM use and food choices).

A deductive approach (ie, one that uses an existing framework to guide the qualitative coding process) [15] was selected because the National Institutes of Health fidelity framework [16] provided an appropriate a priori coding tree that could be applied to the NFA intervention. Constructs included a description of the participants' diabetes history; intervention receipt, including interventionist and intervention materials; and intervention enactment, including CGM only (no food) and food with or without CGM. The qualitative study was designed and reported following the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines [17].

## Ethical Considerations

All protocols and procedures for this qualitative study were reviewed and approved by the HealthPartners Institutional Review Board (study A22-279) in July 2023; this was approved before contacting participants. Verbal informed consent, as approved by the institutional review board, was obtained from each participant at the time of the interview. Participant confidentiality and privacy were maintained using the following methods: (1) study staff were trained in human subjects research protections and Health Insurance Portability and Accountability Act compliance, (2) any study-related data were collected and stored on password-protected servers behind a firewall to which only study staff had access, and (3) participant information was deidentified, to the extent possible, using numerical IDs. Participants who completed the interview received a US $25 Target gift card.

## Recruitment and Participants

Participants were eligible for the qualitative study if they met inclusion criteria for the larger UNITE study, were randomly assigned to the NFA arm, completed all components of the 2-month intervention, had adequate CGM data at the final postintervention assessment, and were willing to participate in a recorded interview. In brief, eligibility criteria for the UNITE study included being aged ≥18 years; a T2D diagnosis; having a hemoglobin $A_{1c}$ ($HbA_{1c}$) of 7% to 10% at the time of screening; having a stable diabetes medication regimen for at least 30 days excluding any form of insulin, sulfonylureas, meglitinides, or other medications with known hypoglycemia risk; and having no personal CGM use within 90 days before the start of the study.

Individuals who met screening criteria were asked by UNITE study staff via phone if they were interested in participating in a qualitative interview. If so, they were scheduled for a single 30-minute phone call that took place at the clinic after their final UNITE study visit. Only the participant and the interviewer were present during the interview. Participants were informed that they were speaking with a trained health care interviewer and that the purpose of the interview was to learn about their experience in the study to improve CGM initiation options in the future. To increase the likelihood of saturation in qualitative analysis [18], up to 15 interviews were planned, and an effort was made to balance the invitation of participants by gender identity.

## Data Collection

Phone interviews were conducted using an interview guide aligned with the a priori coding tree described earlier, starting with intervention receipt followed by enactment. The guide was developed by the research team (HJW, MMJ, MSGH, and LJZ; all identified as female) following the best practices for semistructured interviewing [19]. Interviews included a series of open-ended root questions with follow-up probes to elicit richer data from participants. The interview started with an easy-to-answer rapport-building question to set the tone and then funneled from broad to more specific questions, ending with a final cool-down question. During the intervention receipt portion of the interview, participants were asked to recall the intervention materials unprompted and were asked to look at copies of the materials to encourage more detailed recall. In the intervention enactment portion, participants were asked to describe how they used CGM data and how the data affected their thoughts about food, food choices, and eating behaviors. Interviewers were encouraged to probe for specific examples. The interview was designed to be completed within 30 minutes. Textbox 1 summarizes the interview questions. The full interview guide can be found in the Multimedia Appendix 1.

Interviews were conducted by trained qualitative interviewers (MSGH and LJZ) with master's degrees in health-related fields and experience conducting interviews with participants in health care–related research studies. The interviewers were involved in previous qualitative research on CGM use by people with diabetes and diabetes care providers. Interviewers also received study-specific interview training from a diabetes researcher (HJW) and conducted practice interviews with diabetes care and education specialists. Ongoing supervision by a qualitative researcher (MMJ) was provided to prevent drift in facilitation over time.



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**Textbox 1.** Interview guide summary, including question purpose, summarized interview questions, and probes.

**Rapport building**

- What do you remember about when you were first diagnosed with diabetes?
  - How did you take care of your diabetes at that time?
  - Did you think about nutrition or food choices at that time?
  - Did you ever talk with a diabetes educator or dietitian? Tell me about that experience.

**Intervention receipt (how do people with type 2 diabetes who participate in a nutrition-focused approach during continuous glucose monitoring [CGM] initiation describe their experience?)**

- What do you remember talking about with your diabetes care provider when you first started using your CGM?
  - What did you think about the nutrition-focused information you received and how it was presented?
  - What did you like (or what could be improved) about the materials that were used to help you learn to use your CGM? (this question was asked unprompted and prompted)
  - Do you think focusing on nutrition (food choices) is a good way to help someone get started using their CGM? Why or why not?

**Intervention enactment (how do people who participate in a nutrition-focused approach during CGM initiation use CGM data to make food-related decisions and what food-related changes do they make?)**

- How did you use your continuous glucose monitor and its data?
  - What information on the app did you use most often?
- How, if at all, did your CGM data affect how you thought about food and the food choices you made?
  - Did seeing your glucose information cause you to change the amount, type, timing, or something else about the foods you ate? What changes did you make? What did you eat more of or less of?
  - Did you try any yes/less choices (Nutrition Guidance) to help reach your glucose targets? Why or why not?
  - What made it hard to use your CGM numbers to make decisions about your food? What would have made it easier to use your CGM to guide your food choices?

**Cooldown**

- What else do you want to share about your experience learning how to use information from your CGM, or about how you now think about food choices with diabetes?

### Qualitative Data Analysis

Interviews were audio-recorded and transcribed using automated transcription software (Microsoft Teams). Interviewers took detailed field notes during the interview and memos [20] after the interview in a field note and memo guide in REDCap (Research Electronic Data Capture; Vanderbilt University) [21], which corresponded with the a priori coding tree. As interviews were completed, a lead qualitative analyst (MMJ) imported recordings, transcripts, field notes, and memos into qualitative analysis software (NVivo version 12; Lumivero). The lead analyst followed a sort-and-sift matrix analysis approach [22] to identify emergent themes within each research question and summarized key findings across interviews, identifying representative quotes. The analysis team (MMJ, HJW, MSGH, and LJZ) met for iterative reviews and to refine key findings. Although the concept of saturation does not directly translate to the rapid sort-and-sift matrix approach used in our study [23], analysts did consider the concept broadly and made note of when no new major themes emerged related to the a priori framework. This was done with issues of reflexivity in mind and to increase the correctness of findings [24]. Finally, a codebook and audit trail were maintained by the analysis team (MMJ, HW, MSGH, and LJZ) to ensure rigor and increase reproducibility.

Qualitative themes within each research question are presented along with representative quotes, which are embedded into the text to aid in the communication and richness of the findings described within each a priori construct in the coding tree [25]. Descriptive statistics, including means, SDs, frequencies, and percentages, are presented where appropriate. Participants did not review transcripts, codebooks, or other findings during or after analysis.

## Results

### Participant and Interview Characteristics

A total of 15 (88%) of the 17 eligible UNITE study participants agreed to participate in the qualitative interviews; 2 (12%) declined due to time constraints. Saturation was believed to be reached, as no new major themes emerged with iterative ongoing analysis. Most (13/15, 87%) interview participants identified as White and male (9/15, 60%). At the start of the UNITE study



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intervention, participants had a mean age of 64 (SD 7.4) years, had T2D for 7.5 (SD 3.8) years, had an $HbA_{1c}$ of 7.5% (SD 0.4%), and had a TIR of 51% (SD 25%; Table 1). Interviews lasted an average of 31 (SD 5) minutes and were conducted between September 2023 and March 2024.

**Table 1.** Descriptive participant data (N=15).

| Characteristics | Values |
|---|---|
| **Self-identified as male, n (%)** | 9 (60) |
| **Age (y), mean (SD)** | 64.2 (7.4) |
| **Racial or ethnic group, n (%)[a]** | |
| African Native; American Indian or Alaskan Native; Asian (including Hmong, Chinese, Asian Indian, Vietnamese, etc); Black or African American; Hispanic or Latino, Latina, or Latinx; Middle Eastern or North African; or Native Hawaiian or Other Pacific Islander | 1 (7) |
| White | 13 (87) |
| Chose not to answer | 1 (7) |
| **Duration since T2D[b] diagnosis (y), mean (SD)** | 7.5 (3.8) |
| **Usual finger stick frequency at baseline, n (%)** | |
| Never or less than once per month | 3 (20) |
| 1-3 times per month | 3 (20) |
| 1-6 times per week | 4 (27) |
| Once per day | 4 (27) |
| 2-4 times per day | 1 (7) |
| **Food secure, n (%)[c]** | 14 (93) |
| **Baseline $HbA_{1c}$[d] (%), mean (SD)** | 7.5 (0.4) |
| **Baseline time in range (%; time with glucose 70-180 mg/dL), mean (SD)** | 51 (25) |

[a]Racial and ethnic groups were merged for data presentation to protect participant confidentiality.

[b]T2D: type 2 diabetes.

[c]Food security was confirmed if there was a positive answer to either of the following two questions: (1) "Within the past 12 months, I worried whether my food would run out before I had money to buy more." (2) "Within the past 12 months, the food I bought just didn't last, and I didn't have money to get more."

[d]$HbA_{1c}$: hemoglobin $A_{1c}$.

## Results of Research Question 1: How Do People Who Participate in an NFA During CGM Initiation Describe This Experience (ie, Intervention Receipt)?

During the first CGM initiation session, the CGM sensor and its data were explained to participants as tools to help guide their food choices. Participants were oriented to the CGM data displayed on the G7 smartphone app and encouraged to know (and remember) their glucose targets.

Approximately 2 months after the original CGM initiation session, the qualitative interviews were conducted, and it was clear that participants understood their CGM data. Participants were able to fluently and easily discuss real-time glucose values and metrics such as TIR and average glucose with their interviewers. While there were nuanced differences in the reported use of the data across participants (described in subsequent sections), these new CGM users seemed to have no difficulty understanding the CGM data, glucose targets, or how to use them.

Most of the participants remembered the nutrition-focused CGM initiation materials, and they generally liked the content and format. They could describe the core concepts presented in the materials (eg, the *1, 2, 3* approach and *yes/less* framework) in simple terms, even if not using the specific terminology. Some participants were able to discuss the materials unprompted, while others needed a brief review of the materials:

> *[After a brief review of the materials] That 1, 2, 3 approach—about checking my glucose before I eat, note what I ate, then note what happened after I ate—that became the real solid basis of my first two or three weeks with the monitor. It really helped me change my diet and I saw some pretty immediate benefits.* [Participant #3]

The nutrition information presented within the materials was recognized by participants as consistent with prior nutrition-related education. This repetition was not seen as negative, and some viewed it as a strength. Several participants commented that the plated food images and the message of "half the plate as vegetables" along with the CGM data were helpful for guiding adjustments to their food intake:



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> *In fact, I was even thinking a little bit about it this morning, the pictures of the plate, the plate method did stick with me. That helped...The actual pictures of plates and having non-starchy vegetables as half and then a quarter protein, that was useful.* [Participant #1]

Many participants specifically noted liking the simplicity of the messages around using CGM data to understand the impact of food choices on their glucose numbers and the utility of having flexible glucose targets (eg, glucose 70-180 mg/dL and >70% TIR). No substantial suggestions to improve the content or format of the nutrition intervention materials were provided. One participant described the materials as "highly polished," and many described the pictures and images as supporting their understanding of what to do with CGM data and food choices:

> *I've made a few PowerPoint presentations in my time, and I'd say these are very good, very, very good...the most educational part of the slide set was about the quantity and choices for what foods to eat; the fact that they talked about it at all, because I don't pay attention to that. I have the foods that I like, and I think I know enough about them to know whether I'm having a good food or not...So, I would say being more aware of high-sugar foods and trying to minimize them [was a helpful message in the slides].* [Participant #6]

Participants described the 2 sessions with their diabetes care provider (the in-person initiation and remote check-in) as positive and useful and described the care providers as pleasant, kind, respectful, clear, knowledgeable, and thorough. One participant described the time with the care provider as feeling "more like a conversation about my health" than being "talked at," and another participant described their care provider as especially helpful in dealing with feelings of guilt and blame related to food and diabetes.

One participant described the content of the discussions with the care provider as consistent with prior experiences but the tone as being distinctly more respectful, positive, and motivating. Another felt part of their success in using the CGM device to guide food choices was due to the consistent messaging from the diabetes care provider throughout the intervention period. However, others suggested that additional planned follow-up sessions with the diabetes care providers would have added benefits (ie, more appointments for CGM data review and discussion):

> *Checking in and reinforcing or affirming more [would have been useful during the program]. Maybe nudging and encouraging more health choices, because there's a lot of emotional and cultural baggage that people have with foods you know, and it's not an easy thing to change.* [Participant #5]

Overall, participants agreed that focusing on nutrition and food choices was a good way to help someone with T2D initiate CGM use and that this approach was beneficial for their diabetes care. Several participants specifically shared their appreciation for both the nutrition-focused intervention materials and the time with the diabetes care provider:

> *[In the past] I saw a nutritionist and it didn't help me—and, I was given a glucose meter and it didn't help me...But, the combination of that real-time glucose and then getting the tips [from the care provider] on what to try...it's like, yes, what they're telling me, now I can see it works!* [Participant #14]

Many described starting to use a CGM and considering their food and nutrition choices as essential. For participants who felt they were knowledgeable about nutrition before the intervention, they presumed they would have naturally thought about food choices when initiating CGM; however, this is challenging to ascertain, especially as it relates to consideration for food choices that align with evidence-based guidelines:

> *Well, nutrition, exercise, and medication is what I would consider to be the triangle. You have to [have these] to be successful...[Use of the CGM without the nutrition guidance] would not have been as good, not as effective...the effectiveness of the control of the blood sugar would have been less.* [Participant #6]

### Results of Research Question 2: How Do People Who Participate in an NFA During CGM Initiation Use CGM Data to Make Food-Related Decisions, and What Food-Related Changes Do They Make (ie, Intervention Enactment)?

All participants described regularly (eg, multiple times per day) using the G7 app to follow their glucose after the initial CGM initiation session. Difficulty using or interpreting CGM data was rarely described. Participants explained using CGM data both retrospectively (ie, the 3 or 14-day TIR) and in real time (ie, the glucose bubble, arrow, and 3-, 6-, 12-, or 24-hour glucose trend lines). Several participants expressed specific appreciation for the new diabetes management concepts, such as CGM-derived average glucose and TIR, and they described using these as guides for their diabetes care:

> *I thought that it was interesting where the time in range was. It helped me understand what you're specifically looking at...I paid attention to it all the time.*" [Participant #4]

Many talked about following glucose levels before and after meals and activity, as recommended by the intervention's *1, 2, 3* approach. However, some described "checking it all the time" or looking at the app "obsessively." Participants described using the CGM data to make decisions in real time, and some described relying on the trend arrows as a way to make decisions about what to eat in the moment:

> *If I'm about to have dinner and [my numbers were near the top of the range] I would make different decisions about either what to eat or how much to eat...I might have a little less, or something that was lower carb, or definitely start with vegetables first. –* [Participant #1]

Many participants described using the recommended techniques (eg, the *1, 2, 3* approach) to learn how various foods and meals affected their glucose. Participants described experimenting to see the impact of *yes* foods (eg, nonstarchy vegetables), and 1 participant described trying various food substitutions to come



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up with a meal plan that worked well for their glucose management:

> *While it's very helpful to see the numbers on your CGM, knowing more about how food impacts those numbers is so helpful...[I can see] if I fill up on vegetables my numbers will stay more consistent and/or lower...and, I swear that I enjoy my salads a lot more now...I found more satisfaction with my vegetables.* [Participant #9]

Many also described experimenting with *less* foods (eg, starchy snacks or sweetened foods) to learn how those foods affected their glucose levels. Some described the results of this type of experimentation as "surprising," specifically noting they learned how long their glucose stayed elevated after eating foods they considered small "cheats" or "slipups." Others also described using experimentation with *less* foods as an "excuse" to eat these foods "guilt free:"

> *I just ate things like a peanut butter and jelly sandwich or chocolate milk and, wow, for me drinking milk really makes the blood sugar go up. That was a sad thing to learn because I love drinking milk.* [Participant #13]

Others described experimenting with the timing and portion sizes of meals, including smaller meals throughout the day, delaying or skipping meals, trying to eat more protein before bed, or adding in physical activity throughout the day, especially right after meals. For most, experimentation with foods led to new perspectives and knowledge about the impact of foods and activity on glucose.

One participant described learning from her CGM data that allowing some feelings of hunger was "safe" for her diabetes management; in other words, she learned that hunger did not mean she needed to eat to prevent low glucose. For some, the increased knowledge and immediate feedback from experimentation led to changes in their perceptions of food, with a few describing a better appreciation for the value of foods. One participant described "losing the craving" for *less* foods because they were not "worth it"; for this participant, they described attaching more value to *yes* foods because they saw the beneficial impact on glucose:

> *[The CGM] helped me appreciate the value of foods. I love carbohydrates and could eat bread and pastry all day long and it will have a bad impact on my blood sugar—an enormously bad impact. And I like sweets. If I indulge in a sweet, it was a real reminder that I may be loving this sensation in my mouth and whatever is going on in my brain chemistry, but I'm not doing my overall health any good...Then, similarly for vegetables, I'm not a real fan of vegetables. But, watching a really high fiber, high vegetable meal have a low impact on my blood sugar, I had a very tangible reminder that these things are actually good for me.* [Participant #3]

Most participants described making at least some dietary changes to positively impact their glucose, and they actively extended experimentation into efforts to maintain improved glycemia or TIR. There were some clear, broad-level changes to food choices or behaviors that emerged as common among participants (eg, eating more nonstarchy vegetables, reducing overall carbohydrates or sugars, and choosing smaller portions); however, these interviews also highlighted that changes to specific foods and other behaviors were nuanced and unique to the individual. Table 2 provides an individual-level summary of some of the main food-related changes and behavior strategies the participants reported using to improve their glucose.

For example, individual participants reported details, such as switching from oatmeal and bananas for breakfast to cottage cheese and strawberries, choosing roasted peanuts in the shell for a snack to slow eating, or relying on cauliflower crust for pizzas. One participant reported making substantial changes to the amount of food consumed, stating that since seeing the CGM data, "I eat about half as much food now." Another reported using their CGM to "guide every decision about food" when first starting with the device and then coming up with a meal plan and using the CGM data to determine when or if more changes were needed.

Not all participants made substantial changes to their food choices or behaviors. Some described a gap between increased knowledge and their perceived or realized ability to make changes. One participant specifically mentioned foods related to holidays, traditions, and culture as being hard to change even when seeing the CGM data. This seemed to pair with a few participants self-describing themselves as "poor eaters" or having negative opinions about their own eating patterns. While infrequent, it is also important to note that some people described CGM as amplifying feelings of needing to "try harder" and noted that CGM added stress because it was hard to avoid seeing the impacts of certain foods when the device "was always measuring me." One person reported not liking the amount of mental energy they spent thinking about glucose and food; therefore, they ended up returning to old food habits:

> *It was always in my head that my blood sugar was always high even when it was at its lowest; it was still too high. So when I ate it would just be way too high...it kinda made me afraid to eat.* [Participant #2]



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**Table 2.** Examples of the individual-level food and behavior changes participants described implementing after seeing their continuous glucose monitoring (CGM) data.

| ID | Food changes | Behavior changes |
|---|---|---|
| 1 | • More: nonstarchy vegetables, other vegetables, and melon<br>• Less: rice | Chose overall lower carbohydrates, ate vegetables before eating other foods, chose smaller portions, chose smaller meals spaced more evenly throughout the day, stopped eating before feeling full, skipped meals, and walked frequently (sometimes as much as every hour) |
| 2 | • More: roasted peanuts in a shell<br>• Less: rice (smaller portions), mini-candy bars, and candy | Chose smaller portions and added activity after meals |
| 3 | • More: cottage cheese and strawberries, large salads, leafy greens, fish, nuts, vegetables, and protein foods<br>• Less: oatmeal and grapes | Chose smaller portions, delayed evening meals, ate very low carbohydrate dinners, and walked in the afternoon |
| 4 | • More: vegetables and homemade nonprocessed foods<br>• Less: fast food; sweets; and chocolate kisses | None noted |
| 5 | • More: salads, peanut butter, sweet potato, and cauliflower crust for pizza<br>• Less: rice, crackers, chips, bread, Italian pasta, and alcohol | Measured portions, chose smaller portions overall (eg, half as much food), chose smaller portions of carbohydrates (eg, 1 piece of bread instead of 2), skipped meals, and walked more (even if only 10 min) |
| 6 | • More: whole-wheat bread, whole-wheat pasta, and white meat<br>• Less: Soda, fruit juices, candy, and chocolate bars | None noted |
| 7 | • More: none noted<br>• Less: cereal and bread | Chose smaller portions and walked more |
| 8 | • More: Green leafy vegetables, other vegetables, fresh fruit, fresh whole foods, and low-sugar yogurt<br>• Less: candy, pure sugar foods, and chips | Chose smaller portions and chose lower carbohydrate options |
| 9 | • More: water, black coffee, vegetables, salads, cucumbers, celery, eggs, popcorn, and protein foods<br>• Less: cereals | Chose smaller portions, reduced carbohydrate-heavy meals, delayed mealtimes, and walked after meals when glucose was high |
| 10 | • More: vegetables and fruit<br>• Less: certain carbohydrates and certain types and amounts of cereals | Measured out servings, chose smaller portions (eg, half bagel instead of whole), and chose overall lower carbohydrate |
| 11 | • More: no specific changes were noted; however, the participant reported confidence in using the CGM data and described examples of food experimentation<br>• Less: nothing noted | None noted |
| 12 | • More: water<br>• Less: sweets | Chose smaller portions |
| 13 | • More: several vegetables<br>• Less: milk | Chose smaller portions, chose overall lower carbohydrate (eg, dropped the bun), and ate a small amount of protein before bed |
| 14 | • More: nonstarchy vegetables (steamer bags), cottage cheese, and protein foods<br>• Less: soda | Chose smaller portions, added more protein to meals, read food labels, and limited sweets and sugars |
| 15 | • More: no changes were noted; however, the participant reported confidence in using the CGM data and reported several examples of current food choices that were reinforced because of seeing CGM data<br>• Less: cereals, pancakes, and baking with regular flour | None noted |

In contrast, many participants described the CGM as finally providing them with a clear understanding of how their food choices influenced their glucose levels and diabetes, which in turn led to potentially more sustainable behavior changes. One participant described the impact of their participation in this NFA as something that helped them make changes in their diabetes management that they had not been able to do for years and another expressed excitement in seeing progress:



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> *It helped me set a different pattern on when I ate, how much I ate, what I ate—those are changes I was unwilling to make until I saw the data.* [Participant #4]

> *This is the first time in 10 years that I've made progress!* [Participant #14]

Similarly, others described the CGM data as "encouraging to see how much control I had" and a way to see the impact of foods with new clarity:

> *I think focusing on nutrition is helpful for someone to get started using a CGM. It hit home that the choices I was making, like in crystal clear clarity, if I eat this, this happens, that happens. With the monitor, it showed it goes up this much.* [Participant #2]

Other participants shared special appreciation for the biofeedback following food choices, with one person describing the feedback loop as a "gamechanger" and another especially liking the immediacy of the data:

> *...many people intellectually understand nutrition, but don't comply—the sensor is an immediate and absolute reminder of the changes and differences that [foods] make.* [Participant #12]

When participants were prompted for suggestions to improve the overall NFA, 1 (7%) of the 15 participants suggested pairing the CGM with structured meal plans, such as instructions for what to try eating for a week for improved glucose. Other suggestions focused more on ideas to improve the CGM app, such as a quick and easy way to record a meal in the app or to overlay their food notes with their glucose values. A participant suggested they would have liked it if the NFA intervention materials "were built into the app" for easier reference:

> *If there was a really convenient way to record what I was eating and have that tied very directly and very visibly to what the CGM app was showing me, that would have been hugely impactful.* [Participant #3]

# Discussion

## Principal Findings

Through these qualitative interviews, we heard that using an NFA during CGM initiation was generally well received and perceived as helpful for people with T2D who do not use insulin. We also found that in this population of people who do not use insulin and who infrequently monitored glucose (with finger sticks), the CGM data were easily understood, regularly viewed, and often used to promote changes in food choices and behaviors during the 2-month study. The nutrition-focused intervention materials and messages were mostly described as supportive and useful for helping participants understand how to use their CGM data to guide food choices.

## Relationship to Prior Work

The results of this research add to existing literature in several ways, including highlighting how the CGM device could potentially be used to specifically encourage evidence-based nutrition recommendations. Research demonstrates that choosing high-quality eating patterns (ie, adhering to evidence-based nutrition recommendations) is linked to better glycemia [26,27] and inversely associated with risk of all-cause mortality, cardiovascular disease, cancer, and neurodegenerative diseases [28]. Therefore, any diabetes technology or care approach that can integrate messages about the importance of diet quality could be of significant benefit. These interviews not only reinforced the notion that there is no one-size-fits-all diet or lifestyle plan that works for everyone with diabetes [2] but also that CGM can be used to help individuals identify which specific foods and behavior strategies work best for them. Findings from this research may also help support the conclusions of previous research, which have suggested that CGM can lead to lifestyle and behavior changes [29-31] but where objective behavior outcomes were not measured or qualitatively assessed.

In addition, this research provides context regarding opportunities for training new CGM users on optimal use of the device. The American Diabetes Association's Standards of Care recommend that education, training, and ongoing support are needed for all diabetes devices, including continuous glucose monitors [5]. Furthermore, Heinemann and Klonoff [32] expanded upon how CGM use in and of itself does not necessarily lead to better outcomes (ie, improved glucose), which may be particularly true for people with T2D who do not take insulin and are less reliant on (or familiar with) glucose testing. At the same time, lack of nutrition guidance and support has also been identified as a prominent barrier to behavior change for people with T2D [33]. Thus, education about how to optimally interpret and use CGM data, specifically to guide food choices that align with evidence-based guidance, seems of benefit. Our interviews suggest that using an NFA during CGM initiation could be a helpful way to both educate on the device and its data and empower new users to use the data to make healthful adjustments to their food choices and behaviors. With this NFA, participants seemed to have little to no difficulty interpreting CGM metrics and using them to guide food choices, which suggests that providing education on both glycemic targets and evidence-based eating principles (at the same time) during CGM initiation is reasonable.

Related to CGM support, it is important to note that this intervention provided to these new CGM users was very brief—just 1 in-person session and 1 remote follow-up session approximately 14 days later. Some participants suggested that more follow-up sessions would have been beneficial. The need for additional follow-up sessions aligns with recommendations for adequate diabetes self-management education [2] and with recent research suggesting that—based on individual circumstances and goals—evolving support is needed to sustain effective CGM use [34]. At this time, it is unclear how often CGM data reviews are needed to support glycemic goal attainment or maintenance, and therefore, further research is needed. Future research should aim to help define best practices for the ideal frequency of health care provider–led CGM data review, for the most efficient ways to systematically and effectively assess and discuss CGM data with users, and for using CGM data specifically as a tool to help sustain long-term lifestyle and behavior change.



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The results of this research provide the diabetes care community with considerations for how to present or position nutrition messages when initiating CGM in people with T2D.

These interviews suggest that using a positive, respectful tone to discuss evidence-based nutrition guidance during CGM initiation was beneficial; however, we also encountered the potential for CGM data to exacerbate negative feelings about oneself or one's relationship with food. Some people described skipping or delaying meals as a means to try and stay in range, which could be acceptable or could be concerning, for example in people with a history of or potential for disordered eating [35]. Others expressed fears and frustration over thinking too much about their CGM data as it related to foods. Taken together, this underscores the importance of ensuring that CGM education includes messaging about how foods and behaviors are only part of what drives glycemia, especially for people who are not using CGM primarily to determine medication doses or adjustments. On the basis of this research, it seems important for diabetes care providers to regularly remind CGM users that sometimes even with the best adherence to nutrition or lifestyle plans, additional medication support may be needed. In other words, diabetes care providers should make it clear that the CGM device is meant to be a support (eg, for positive nutrition and lifestyle changes and medication management), and it should not contribute to negative feelings, stress, or disordered eating. These concepts can be considered further by exploring previous qualitative research describing the psychosocial outcomes [36], quality of life [37], and other attitudes and behaviors [38] of people with T2D using CGM.

## Strengths and Limitations

This research has several strengths and limitations. The first strength is the qualitative assessment of people who underwent a well-defined intervention that was designed specifically for the purposes of using CGM to guide evidence-based nutrition and lifestyle choices. The second strength is the methodology used to design, conduct, and analyze these interviews. Furthermore, the third strength is that this work focused exclusively on CGM initiation in people with T2D who do not use insulin, as people with T2D who do not use insulin and who use CGM is a segment of the diabetes population that has been evaluated less frequently than others.

Regarding limitations, the first limitation is that this research did not assess the perspectives and behaviors of people with T2D who initiated CGM without an NFA (eg, with an SDA). Thus, it is unclear whether people without an NFA during CGM initiation would have similar experiences and report similar changes or whether they would consider the importance of nutrition choices for other aspects of health; future research should consider this. Second, the participants interviewed were predominantly White (13/15, 87%), food secure (14/15, 93%), and identified as males (9/15, 60%) with a lower $HbA_{1c}$ at baseline, which may limit the generalizability of the findings because we cannot account for how the nutrition-focused intervention materials would be received by a more diverse audience (eg, food images and core messaging). It is possible the materials would be more or less applicable based on recipient characteristics, and further research in a more diverse population is needed. Third, while this research describes the participants' reports of their CGM use and their nutrition and lifestyle behaviors over a 2-month period, these behaviors were not objectively measured or connected to the participants' actual glycemic outcomes. However, these objective data will be available with the results of the larger UNITE study.

## Future Research

Future research should assess the experiences and behaviors of people with diabetes who participate in an NFA intervention over a longer period and with more health care provider–led CGM data reviews or could explore factors that may contribute to negative experiences or stress around using CGM data to guide food and lifestyle changes.

## Conclusions

First-line therapy for T2D management is lifestyle modification, which includes following evidence-based nutrition guidelines and increasing physical activity. CGM data can be used to promote or encourage these lifestyle changes. This qualitative study described the experiences and reported behavioral effects of using an NFA during CGM initiation in people with T2D who were not using insulin.

Approximately 2 months after initiating CGM using an NFA (which included 1 in-person and 1 remote follow-up session), participants seemed to clearly understand the meaning and application of CGM data for behavior change. They reported using their real-time and retrospective CGM data regularly, and they agreed that pairing evidence-based nutrition information with CGM initiation instructions was helpful for their diabetes care. Most participants reported making some food and behavior changes that aligned with evidence-based guidance for a healthy lifestyle, such as increasing nonstarchy vegetable intake or decreasing overall sugar intake. At the individual level, participants also noted several unique food or behavior changes, which highlights that no single eating plan works for all people with diabetes but that CGM can likely show which eating plan may work best for an individual. Opportunities exist to further explore best practices for CGM-guided nutrition interventions in people with diabetes.

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## Data Availability

The datasets generated during and analyzed during this study are available from the corresponding author on reasonable request.

## Authors' Contributions

HJW and MMJ designed the research, analyzed data, and wrote the first draft. LJZ and MSGH conducted the research and reviewed and edited the manuscript. HJW had primary responsibility for the final content. All authors read and approved the final manuscript.

## Conflicts of Interest

HJW has received research support from, consulted with, and been on an advisory board for Abbott Diabetes Care and has received research support from and consulted with Dexcom. The employer of HJW, the nonprofit HealthPartners Institute, contracts for her services, and no personal income goes to HJW. MMJ, LJZ, and MSGH declare no potential conflicts of interest.

Multimedia Appendix 1
UNITE (Using Nutrition to Improve Time in Range) study qualitative interview guide.
[DOCX File , 27 KB - diabetes_v10i1e67636_app1.docx ]

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## Abbreviations

**CGM:** continuous glucose monitoring
**COREQ:** Consolidated Criteria for Reporting Qualitative Research
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**NFA:** nutrition-focused approach
**REDCap:** Research Electronic Data Capture
**SDA:** self-directed approach
**T2D:** type 2 diabetes
**TIR:** time in range
**UNITE:** Using Nutrition to Improve Time in Range

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# Young Adults With Type 1 Diabetes and Their Perspectives on Diabetes-Related Social Media: Qualitative Study

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## Abstract

**Background:** Young adults with type 1 diabetes (T1D) often struggle with self-management and achieving target glycemic control, and thus, may benefit from additional support during this challenging developmental life stage. They are also some of the highest users of social media (SM), which may have some benefits to young people with T1D.

**Objective:** Given the potential of SM support for people with diabetes, we sought to use qualitative methods to explore the perceptions of diabetes SM posts to influence self-care and emotional state of young adults with T1D.

**Methods:** A series of Instagram (Meta) posts were selected by a multidisciplinary team of T1D experts. Young adults aged 18 - 25 years with T1D duration of 1 year or more were recruited from the clinic to participate in a 60-minute semistructured videoconferencing interview. First, they were queried about their SM use in general and specific to diabetes. Next, they reviewed 10 posts with the interviewer. For each post, perceptions and reactions were queried. Participants were asked about each post's impact on their emotional state and potential influence on diabetes self-care. Finally, they were asked to comment on what the posts emphasized and how they felt after viewing the posts. Interviews were transcribed and coded using thematic analysis. The participants' diabetes management information was extracted from the electronic health record.

**Results:** There were 26 young adults who completed the study. Their mean (SD) age was 22.6 (SD 2.0) years, T1D duration 12.6 (SD 5.9) years, and glycated hemoglobin ($HbA_{1c}$) 7.6 (SD 1.2%). In this sample, 65.3 were female and 84.6% White. All were using continuous glucose monitors (CGMs) and 80.7% used insulin pumps, 71.4% of which were hybrid closed loop. All participants used SM at least once daily, but most only sometimes or rarely used SM to access diabetes content and rarely or never posted diabetes content themselves. Major themes arising from the interviews centered on the potential for the young adult to connect emotionally through SM, which could be either positive or negative. Overall, for young adults with T1D, SM served to (1) highlight the existence of a community of people with T1D, (2) be a source of new diabetes information, (3) potentially influence diabetes self-management, (4) potentially influence emotional state, and (5) be appealing to the T1D community when the posts possessed certain characteristics (eg, medical accuracy, aesthetically appealing presentation of content).

**Conclusions:** SM has the potential to help young adults with T1D feel a sense of community, seek and share objective and subjective thoughts and feelings about diabetes, motivate diabetes self-care, and positively affect emotional state. However, it may also have the potential to demotivate self-care and exacerbate negative emotional state with regards to diabetes.

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**KEYWORDS**

diabetes mellitus type 1; social media; young adult; self care; qualitative

## Introduction

Young adulthood, generally defined as ages 18 - 25 years, is a time of major transition with increasing developmental autonomy, which can make diabetes self-management more challenging for those people with T1D[1]. Young adults struggle with attainment of target glycemic control, even in the current era of advanced diabetes technologies that generally reduce the burdens of T1D self-care [2]. Young adults often begin to display clinical evidence of long-term renal and ophthalmologic



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complications [3], and frequently experience lower health-related quality of life [4]. Diabetes distress is also common in this group, often attributed to stigma, the rigors of day-to-day diabetes self-care, and financial worries [5,6]. Given these complexities, young adults may benefit from more support during this time of increased transitions and competing obligations. To meet this need for support, creative means have been explored [7-10], and especially following the COVID-19 pandemic, which emphasize use of the virtual and digital environments. One important aspect of this environment is social media (SM).

Given that young adults are some of the highest users of SM [11], it follows that this modality may be a resource for peer support, a creative means to overcome and promote problem solving for to their diabetes challenges, and source for new information. Furthermore, there are known benefits to online support for people with diabetes [12]. One study comparing the SM use of young adults with T1D with those with inflammatory bowel disease showed that those people with T1D were more likely to use SM to share content about their disease, engage in peer support groups, and seek information [13]. Researchers have begun to explore the relationship young adults with T1D have with SM, describe its use to access diabetes medications and supplies [14], and have used SM to recruit young adults with T1D for studies [15].

Investigators have examined existing T1D content created by people with T1D on social media to better understand the virtual diabetes environment.. For example, Tenderich et al [16] used qualitative methods to describe T1D-related content on various SM platforms, having 6 main themes: humor, diabetic pride, getting personal with diabetes tech, tips and tricks, building community, and venting . Holtz and Kanthawala also qualitatively reviewed SM posts, focusing on Instagram (Meta) posts about T1D, finding more positive than negative sentiment in posts, and that self-disclosure of diabetes was associated with increased post engagement [17].

There remains a need to understand the perceived impact of diabetes-specific SM from perspectives of the people with diabetes who view it. This information may be beneficial for clinicians, researchers, and other stakeholders to reach and support young adults with T1D through SM posts in a way that is relevant and useful. In this study, we aimed to use qualitative methods to learn young adult's perceptions of various SM posts, and if how they believed these posts may impact their diabetes self-care and emotional state.

## Methods

### Study Design

A multidisciplinary team (pediatric endocrinologists, psychologists, diabetes educators, and nurse practitioners) determined study design, produced interview questions, and selected relevant SM posts with iterative review through meetings and discussion with young people in the target age group. First, it was decided that posts would be selected from Instagram. Instagram has been reported as the most frequently used platform in those aged 18 - 29 years [18]. Next, research staff members reviewed posts by searching #type1diabetes, #t1d, and related hashtag or accounts to capture themes described by Tenderich et al [16]: humor, diabetic pride, getting personal with diabetes tech, tips and tricks, building community, and venting. Posts were reviewed by the study team, and of the approximately 50 initial posts reviewed, 10 were selected to be discussed in interviews with research participants. Finally, an interview guide was developed to explore participants' reactions to viewing the SM posts, their engagement with content, and potential of the post changing behaviors or emotions.

Eligible young adults were ages 18 to 25 years old, with T1D duration of at least 1 year, and fluent in English. Those with significant developmental, cognitive, or psychiatric disorders (including inpatient psychiatric admissions from the past 6 months) were ineligible. Use of SM use was not a requirement to participate. All eligible participants were seen in the Pediatric, Adolescent, and Young Adult Section of the Joslin Diabetes Center, and recruited through provider referral.

Following provider referral, a study team member contacted interested young adults to schedule a one-time video call over the Health Insurance Portability and Accountability Act (HIPAA)-compliant Microsoft Teams platform. Informed consent was obtained, and electronic signature was provided via REDCap (Research Electronic Data Capture, Vanderbilt University) [19,20] before the start of any study procedures. Consent also detailed permission to access each participant's electronic health record (EHR) to pull specific demographic and diabetes management information (eg, age, sex, diabetes duration, diabetes technology use, and glycated hemoglobin [$HbA_{1c}$]).

Participants engaged in a one-on-one interview with study staff in which the 10 selected posts were viewed and participant experiences, perceptions, and reactions were queried. To reduce likelihood that interpretation of posts could be affected by their placement in the interview, staff members used 4 distinct collections of the same 10 posts in different orders. The semistructured interview guide can be found in Textbox 1. Research staff interrogated the EHR for demographics and diabetes care characteristics as outlined above.



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**Textbox 1.** Interview questions

**Basic social media use questions**

- How often do you use social media?
- How often do you use social media to view others' experiences living with diabetes?
- How often do you use social media to share your experiences living with diabetes?

**Questions asked for each post**

- Can you tell me what you see in this post? What are your initial reactions to this post? What stands out to you about this post? Why?
- How does this post make you feel?
- Do you recognize the person/account that posted this? (If yes) from where?
- Would you "Like" this post? Why or why not?
- Would you share this post with others? Why or why not? (If yes) how? With whom?
- How might this post impact the way you manage your diabetes after you see it? Why/Why not (if appropriate)? How might this post change your willingness to take care of your diabetes? Why/Why not (if appropriate)?

**Concluding questions**

- Now you've seen that each of these posts includes the post itself, the account that posted it, captions, likes, and hashtags. What do you feel like you focused on the most when viewing these posts? Why?
- Now that you have spent some time looking at these posts, how do you feel about living with diabetes?
- How does this compare to how you felt before looking at these posts? Is there anything else you'd like to share with us about diabetes and social media?

An inductive approach to thematic analysis [21] was used to analyze transcripts and elicit new information about young adults' experiences with SM. The primary investigator coded all transcripts individually using NVivo (Lumivera, release 1.5.2, QSR International) to create an initial codebook; this coder had viewed and selected the SM posts. All transcripts were then double-coded by a second team member using the initial codebook; the second coder had not selected or viewed the SM posts. Coders met regularly to discuss discrepancies and revise the codebook accordingly. All coding discrepancies were discussed between coders, and disagreement was brought to a third study team member until consensus was reached [21]. Following coding, study staff further assessed codes by reviewing quotes and documenting the major distinct ideas in the data. These idea units were then further organized into key dimensions that study staff determined to be most relevant to the current study, including participants' initial reactions to posts, knowledge gained, emotional responses, and potential impacts on self-care. Major themes around young adult's perceptions of diabetes-specific SM posts were elicited from this focusing exercise. Basic descriptive statistics of the study sample were performed in Microsoft Excel.

### Ethical Considerations

The study protocol was approved by the Joslin Diabetes Center Committee on Human Subjects (CHS #163). Following the conclusion of the interview, participants were mailed a US $25 Visa gift card for their time. Informed consent was obtained before the start of any study procedures.

## Results

### Sample

There were 26 young adults aged 18 - 25 years with T1D for at least 1 year who completed the study. Participant characteristics can be found in Table 1.



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**Table .** Participant baseline data.

| Participant characteristics (N=26) | Values |
|---|---|
| Age (years), mean (SD) | 22.6 (2) |
| Sex, n (%) | |
| Female | 17 (65.3) |
| Race, n (%) | |
| White | 22 (84.6) |
| T1D[a] duration (years), mean (SD) | 12.6 (5.9) |
| HbA1c[b], % (mean (SD) | 7.6 (1.2) |
| CGM[c] use, %, mean (SD) | |
| Time in range (%) | 100 |
| mean (SD) | 54.5 (19.6) |
| Pump use, n (%) | 21 (80.7) |
| Hybrid closed loop, n | 15 |

[a]T1D: type 1 diabetes.

[b]$HbA_{1c}$: hemoglobin $A_{1c}$.

[c]CGM: continuous glucose monitor.

When asked about their baseline SM use, 100% of participants stated they used SM daily or more. When asked how often they use SM to view others' experiences with diabetes, the most common response was rarely (11, 42.3%), followed by sometimes (9, 34.6%), often (3, 11.5%), daily or more (2, 7.7%), and never (1, 3.8%). When asked how often they use SM to share their own experiences with diabetes, the majority said rarely (14, 53.8%) or never (9, 34.6%). There was one participant each who said daily or more, often, or sometimes (1, 3.8%).

## Themes

Major themes that arose from the data centered around SM as a platform for a range of connections with T1D from positive to negative, as participants discussed how T1D SM could (1) highlight the existence of a community of people with T1D; (2) be a source of new information about T1D; (3) potentially influence diabetes self-management; (4) potentially impact emotional state; and (5) possess aesthetic appeal and relevancy to people with type 1 diabetes.

SM can highlight the existence of the T1D community. The majority of participants endorsed feeling positive toward SM posts that reminded that there are many others with T1D with similar experiences. With this realization, some reported feeling less alone.

> *It's kind of like an instant relation. You can say, "Hey, I've been there." You see that somebody else is going through it. It's not just you. Somebody else is having that same problem, and they're just as upset about it.* [24-year-old man]

However, others experienced negative reactions to posts highlighting the T1D community when they lacked peer support for T1D, describing themselves as feeling jealous and more isolated upon viewing.

> *I was kind of jealous, actually, because I myself don't have a lot of friends with diabetes. You know, I don't really interact with somebody else with diabetes all that often, so I was like a little jealous, like, 'Oh, look at these people. They're hanging out together, and they all share this thing' and I kind of wish I had that.* [21-year-old woman]

SM can provide new information about people with T1D and management.SM can be a source of knowledge for young people with T1D, providing tips and tricks for diabetes management. In particular, some participants posited that certain SM posts could contain helpful knowledge for those new to diabetes.

> *I have only had diabetes for like two years at this point, so I'm still learning a lot, and I did not know that it would be helpful to change your pump site earlier in the day than at night, so it's good for me to see it.* [24-year-old woman]

Some young people felt more motivated to seek out more education and ask specific questions about their diabetes to their medical team.

> *Maybe I'd ask my doctor about like what a pump break would really mean and how I would be able to do that…because like going back to syringes is a whole, another thing, but yeah I would probably be inclined to ask about it.* [21-year-old woman]

Participants also pointed out that posts about T1D could help raise awareness and understanding in the general public.

> *I think anybody could benefit from this information, not just, you know, diabetics because, you know, the more people realize that [cost of insulin] is …a problem in the country, the better for everybody.* [23-year-old man]



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SM can potentially influence diabetes management. Young adults reported a variety of potential influences on T1D management, ranging from positive to negative impact. Some participants noted that a SM post could serve as a helpful reminder to follow through on their diabetes care, and some also reported that the posts triggered them to think about planning for future, upcoming diabetes care tasks.

> *It might just be a reminder to, you know, change my [pump] site. Or on the earlier side, so maybe the next time I change my site it will be a little bit earlier…* [26-year-old woman]

> *I think I would definitely do something different for my diabetes, like, you know, instead of changing before I go to sleep, I would check earlier in the day to see if I need to change it, and then I would do that. Like I think it would help. I would pay attention more to my diabetes.* [21-year-old woman]

Many participants pointed out that seeing others engaged in diabetes care (injections, technology, etc) in a photo might make them more comfortable sharing or managing their own diabetes in public.

> *It might just make me a little less likely to like turn my arm to hide my CGM if someone's taking a picture of me.* [20-year-old woman]

Some participants felt as if the T1D SM content discouraged them from performing their diabetes care.

> *I'm just a stubborn person, but any time someone tells me what to do and not ask, like I kind of have like a sour taste in my mouth, so when it says, 'Immediately change your site,' I'm like, 'No, I'm going to… let it go for another two days.* [25-year-old man]

SM can potentially influence emotional state. Many participants enjoyed seeing people with diabetes thriving and displaying confidence on SM. They appreciated posts reminding them that they are not limited or defined by their diabetes.

> *There's joy, you know, because it's nice to see someone who is like me, experiences the same chronic illness...thriving out there with some really good fashion...and just being able to exist with the illness in the best possible way that can fit into their life.* [19-year-old man]

They expressed appreciation for posts reminding them that they are not limited nor defined by their diabetes, emphasizing a positive identity with diabetes.

> *But like the line in the caption where it's like, 'I'm strong, energetic, positive, passionate, and so much more.' Like sometimes I forget those kinds of ways to describe myself, and I'll be like, oh, I'm a diabetic, you know. When that's not who I am, it's just a part of what I am.* [21-year-old woman]

Participants felt positively about SM posts that encouraged self-compassion. These were posts that served to lighten the burden of diabetes, or to make viewers be more forgiving with themselves with regards to their diabetes care.

> *I think [the post] would encourage me to not be so hard on myself if I have a bad day of high blood sugars.* [20-year-old man]

Certain posts made some viewers feel worse. As stated previously, reminders that an online community of people with diabetes existed was often viewed as positive. However, posts displaying people in a group of others could make the viewers feel jealous and more isolated at times.

> *[It made me feel] a little jealous that they have friends that they can do this with…I mean, I don't have anybody in my life that is also Type I diabetic, so I definitely feel like it would be nice to have friends around my same age who like to do the same stuff as me who can also share that experience of having to deal with their diabetes.* [25-year-old woman]

Some young adults pointed out they did not want to see reminders of diabetes on SM, particularly reminders of negative aspects of living with T1D.

> *I guess it's like social media is where I go usually to get my mind off things like diabetes, and to not think about it, and so if I saw something like this, I'd be like oh man, like back to the real world.* [21-year-old woman]

There are opportunities to make SM more appealing or personally relevant to a young adult. Despite not being asked directly, many participants suggested characteristics of optimal T1D SM content. Participants shared that they appreciated posts that were realistic, relatable, with use of appealing aesthetics such as font and design, and possessing medical accuracy.

Participants commented on the aesthetic appeal of posts, noting that the framing of the information about diabetes matters.

> *It's just a cool photo. It's a good picture, and it's like a cool way of being a diabetes post without being like super like scientific.* [25-year-old woman]

> *I'd be more interested in seeing what [the post] had to say if it was a bit more visually aesthetically pleasing.* [23-year-old woman]

They did not appreciate posts that oversimplified life with diabetes, that tried to be dramatic or disingenuous, and those that attempted to garner pity for having diabetes.

> *It makes me a little annoyed because they're not really acknowledging like the hardness of having diabetes. It feels like someone who doesn't really understand …[and] it is just trying to be encouraging without really acknowledging how hard it is to have diabetes.* [20-year-old woman]

Some participants expressed opinions about medical accuracy of diabetes-focused SM posts.

> *..this is what my doctors say, too, so it seems pretty legit.* [25-year-old woman]

> *…I don't like the idea that like someone might see [the post] and think, 'Oh, I'm just going to go on a pump break without telling my doctor',*

> *[22-year-old man]*



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Finally, some pointed out that certain content would have been more valuable soon after learning of their T1D diagnosis.

> *…this [post] reminds me of something I would have liked when I was newly diagnosed. I think when I was newly diagnosed, I like found comfort in these things, the idea of like making a joke out of diabetes and then finding that joke on the internet.* [22-year-old woman]

# Discussion

## Principal Findings

In this qualitative study of young adults aged 18 - 25 years with T1D, we found 5 overarching themes: SM can (1) highlight the existence of a community of people with T1D, (2) be a source of new diabetes information, (3) potentially influence diabetes self-management, (4) potentially influence emotional state, and (5) be appealing to the T1D community when the posts possessed certain characteristics such as relatability, aesthetic appeal, and medical accuracy.

As far as we know, this is the first study to qualitatively describe young adult's perspectives of diabetes-focused SM posts by querying them as they are viewing the post itself. By acknowledging the unique experiences, interpretation, and internalization of SM posts in young adults, we aim to present balanced observations that highlight the potential positives and negatives of diabetes-specific online content. Our results demonstrate the potential for SM to provide support to young people with T1D and potentially impact their well-being by fostering a sense of community and increasing access to new information about diabetes. We also describe young adult–reported positive and negative potential effects of SM on diabetes self-management and emotional state. Finally, we note suggestions for optimal T1D SM content including realism, relatability, aesthetic appeal, medical accuracy, targeting specific audiences, and avoiding dramatizing or pity regarding life with diabetes.

## Limitations

There are some limitations. First, we selected posts to conform to themes that were identified in the published literature [16,17]. In this preliminary work, we did not include posts with explicitly distressing, false, misleading, commercially-focused, or advertising content. These are all a very real part of the current SM landscape, and their influence likely needs to be assessed in future studies [22]. Next, the study was referred to as the SM study; this may have deterred those who do not regularly use SM from participating. The recruitment method, which relied heavily upon referrals from diabetes providers in clinic, could have introduced bias with a focus on young adults, for example, who were likely more attentive to their self-care. However, interviews continues until saturation in thematic responses was achieved.

As the interviews were conducted via video, there may have been an aspect of social desirability bias, where participants wanted to state observations that were pleasing to the interviewer rather than what was true. However, the interviewer was not a member of the health care team and was, in fact, a young adult with whom the participant could potentially relate. Finally, there were challenges to collecting accurate race, ethnicity, and gender identity data. Initially, the plan was to interrogate the EHR; however, we found that this information was often not provided by patients at registration and did not account for gender identity that may have varied from assigned sex at birth. We attempted to follow up with participants after the interviews but follow-up responses were very limited. In future work, we will plan to ask race, ethnicity, and gender information during study procedures rather than relying on the EHR.

## Comparison With Previous Work

The investigative plan was to probe young adult perceptions of SM in order to assess whether and how SM could provide support to young adults with T1D in their diabetes self-care and how it could affect their emotional well-being. The themes that we generated, specifically around positive influence on emotional state, appear to resonate with literature describing positive outcomes with diabetes identity incorporation [23,24] and self-compassion [25]. Posts making the viewer feel they not being limited or defined by diabetes, and those making the viewer more likely to display their diabetes technology in public, seem to promote the healthy "acceptance" illness identity dimension, which is associated with better psychological functioning and diabetes adherence [23]. Similarly, responses to posts that emphasized feeling community and commonality of diabetes diagnosis, as well as those which seemed to serve to "lighten the load" of diabetes through humor and reminders for sef-kindness, are reminiscent of interventions focusing on self-compassion, which has been associated with decreased diabetes distress [25,26].

Humor has also been demonstrated as beneficial to coping for adults with chronic illnesses [27].

The comments about the importance of accuracy of information from SM are in line with recent SM research, notably concerns about misinformation and its potential effects on young people [28], even specific to diabetes [22]. In this study, our participants seemed appropriately critical of the information in these SM posts, implying strong media literacy [29].

Our conclusion that SM can be a source of camaraderie, and knowledge for young people with T1D was in line with results from descriptive reviews of general T1D SM content itself [16,17]. In terms of comparison with any previously published descriptions of SM content by young adults with type 1 diabetes, we were unable to identify any T1D-focused studies with which to compare our observations. However, there have been some studies of young adults with other chronic illnesses that have queried their perceptions of SM. For example, a qualitative interview of young adults with cancer and their relationship with SM reported that it could be a source of community building, knowledge, and social support, but also that SM could worsen stigma, compromise privacy, and cause emotional distress based on content [30]. Our study results were similar with the exception of stigma; many participants reported appreciating the open display of wearable diabetes technologies in SM posts, with some even suggesting it may make them more comfortable taking care of their own diabetes management needs in public. This perception seems to combat, rather than worsen, stigma for young adults with T1D. Indeed, adults with type 1



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and type 2 diabetes suggested advocating for their chronic disease and its management on SM to reduce diabetes stigma [31].

## Conclusions

SM has the potential to help young adults with T1D feel a sense of community, seek and share information, motivate self-care, and positively affect emotional state. However, it also has the potential to demotivate self-care and exacerbate negative emotional state with regards to diabetes. T1D SM content aimed at young adults should be realistic, relatable, aesthetically appealing, and medically accurate. It should avoid oversimplification or dramatization of life with diabetes. With engagement of the target audience of young adults, and if used judiciously, SM has the potential to positively impact young people with T1D, possibly leading improved biomedical and psychosocial outcomes.

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## Disclaimer

The content is solely the responsibility of the author and does not necessarily represent the official views of the National Institutes of Health.

## Data Availability

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

## Conflicts of Interest

None declared.

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## Abbreviations

**CGM:** continuous glucose monitor
**CHS:** Committee on Human Subjects
**EHR:** electronic health record
**$HbA_{1c}$:** glycated hemoglobin
**HIPAA:** Health Insurance Portability and Accountability Act
**REDCap:** Research Electronic Data Capture
**SM:** social media
**T1D:** type 1 diabetes



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# Toward Personalized Digital Experiences to Promote Diabetes Self-Management: Mixed Methods Social Computing Approach

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## Abstract

**Background:** Type 2 diabetes affects nearly 34.2 million adults and is the seventh leading cause of death in the United States. Digital health communities have emerged as avenues to provide social support to individuals engaging in diabetes self-management (DSM). The analysis of digital peer interactions and social connections can improve our understanding of the factors underlying behavior change, which can inform the development of personalized DSM interventions.

**Objective:** Our objective is to apply our methodology using a mixed methods approach to (1) characterize the role of context-specific social influence patterns in DSM and (2) derive interventional targets that enhance individual engagement in DSM.

**Methods:** Using the peer messages from the American Diabetes Association support community for DSM (n=~73,000 peer interactions from 2014 to 2021), (1) a labeled set of peer interactions was generated (n=1501 for the American Diabetes Association) through manual annotation, (2) deep learning models were used to scale the qualitative codes to the entire datasets, (3) the validated model was applied to perform a retrospective analysis, and (4) social network analysis techniques were used to portray large-scale patterns and relationships among the communication dimensions (content and context) embedded in peer interactions.

**Results:** The affiliation exposure model showed that exposure to community users through sharing interactive communication style speech acts had a positive association with the engagement of community users. Our results also suggest that pre-existing users with type 2 diabetes were more likely to stay engaged in the community when they expressed patient-reported outcomes and progress themes (communication content) using interactive communication style speech acts (communication context). It indicates the potential for targeted social network interventions in the form of structural changes based on the user's context and content exchanges with peers, which can exert social influence to modify user engagement behaviors.

**Conclusions:** In this study, we characterize the role of social influence in DSM as observed in large-scale social media datasets. Implications for multicomponent digital interventions are discussed.

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**KEYWORDS**

digital health communities; diabetes self-management; behavior change; affiliation exposure; social networks; deep learning

## Introduction

Type 2 diabetes (T2D) is responsible for affecting nearly 34.2 million adults, which accounts for 10.5% of the US population [1]. According to a recent report, about US $327 billion was spent on the treatment of diagnosed cases of T2D in the year 2017 alone [1]. In addition to its health and economic burden, T2D also increases the risk of developing other health complications such as heart disease, stroke, kidney failure, and blindness [2]. Modifiable health behaviors such as obesity, physical inactivity, unhealthy eating habits, and tobacco use are major risk factors for developing chronic health conditions such as T2D [2].



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Behavior modification is a core component of diabetes self-management (DSM) programs and provides the much-needed support to improve health-related outcomes in individuals with diabetes [3]. It is a complex process, and research has shown that a range of psychological and social processes influence an individual's engagement in the sustenance of positive health behaviors [4,5]. For example, individuals are more likely to comply with health-related goals and adhere to preventive practices, provided their socially connected peers also engage in similar behaviors by changing their intrapersonal beliefs, attitudes, or knowledge [6,7]. However, the mechanisms underlying such multilevel influences are not fully understood. Such a lack of understanding limits our capabilities to personalize support infrastructure to meet individual needs.

The widespread adoption of digital health technologies, such as mobile apps, wearables, sensors, and digital health communities (DHCs), creates opportunities to design tailored strategies for behavior change [8,9]. These technologies enable in-depth analysis of large-scale individual and population-level trends, providing valuable insights into behaviors, preferences, and social networks. [8,9]. The emergence of various peer-driven health communities has allowed health care consumers to interact with their peers and health care providers to garner social support and gather knowledge on various health-related topics, etc [10-12]. DHCs specific to T2D have been shown to enable their users to seek and receive support and obtain valuable information to improve psychosocial care and health outcomes [13]. These communities provide us with large and invaluable datasets in the form of electronic traces of peer interactions that capture the attitudes and behaviors of large populations in near real time and in natural settings [9]. Analyzing these datasets allows us to understand the individualistic and environmental factors underlying behavior change and develop effective behavior change interventions (BCIs) [14].

Several studies have leveraged peer interactions in DHCs to model human health behavior [15]. Some research studies have explicitly focused on DSM-related DHCs and have analyzed the data generated from these communities to (1) identify the content of peer interactions, such as topics or themes of conversation [16,17], and (2) understand linguistic features of expression among members of DHCs and how that influences social support [18]. However, in a social setting, the content of communication and its context can affect the cognitive state of individuals engaging in a conversation [19,20]. Still, the current research on DSM-related DHCs needs to be more integrative of these components. To develop agile, adaptive, and personalized digital experiences for individuals at risk for T2D or diagnosed with T2D, new approaches are needed that consider multilevel contexts that can influence individual adherence to DSM behaviors. In this paper, we present our methodology using a mixed methods approach that combines qualitative analysis, automated text analysis, and social network analysis (SNA) techniques to characterize the role of context-specific social influence patterns underlying peer-to-peer communication and evaluate how "membership or affiliation" in a specific context is predictive of user engagement in DSM. Such an integrative approach can help us optimize user engagement in digital settings and subsequently leverage these platforms as delivery modalities for DSM.

## Methods

### Ethical Considerations

This study was exempted from human participant ethics review approval by the institutional review board at the University of Texas Health Science Center at Houston (HSC-SBMI-15-0697). We extracted only the messages in the public domain, that is, peer interactions marked public by the community users. To maintain user anonymity, we deidentified the data obtained from the DHC by assigning every community user a unique user identifier. In addition, the researchers had no direct contact with the community users.

### Materials

The American Diabetes Association (ADA) support community is a digital support group for individuals with diabetes (type 1, type 2, or prediabetes) to engage with their peers as well as caregivers [21]. The users of the community interact with one another on a wide variety of topics ranging from medication use, diet, physical activity, and daily monitoring of blood glucose levels. Even though the outcomes among type 1, type 2, or prediabetes are impacted by behaviors (such as lifestyle, medication use, and self-monitoring of blood glucose) that can be heavily influenced by an individual's social infrastructure, for this research, we focused on interactions related to T2D. The dataset used in this research spanned from 2014 to 2021, consisting of 73,543 messages specific to T2D organized into 7619 unique topics posted by 2374 unique community users. The dataset characteristics across all years are presented in Table 1.

Figure 1 captures the overall methodological framework used in this study and is described in detail below.

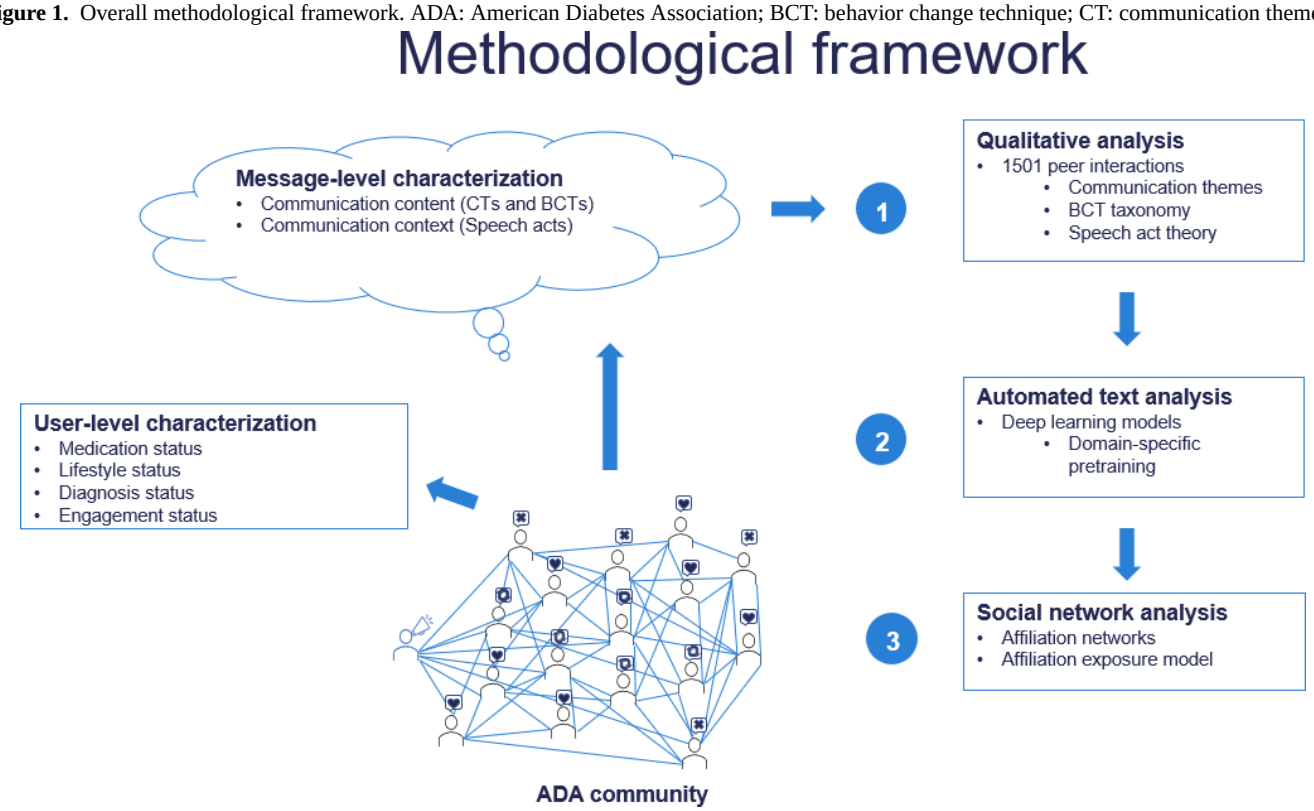


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**Table .** American Diabetes Association dataset characteristics.

| | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 |
|---|---|---|---|---|---|---|---|---|
| Total messages (n=73,543), n (%) | 14,104 (19.2) | 18,311 (24.9) | 16,859 (22.9) | 10,940 (14.9) | 6379 (8.7) | 3805 (5.2) | 2202 (3) | 922 (1.3) |
| Unique topics (n=7619), n (%) | 1337 (17.5) | 1776 (23.3) | 1588 (20.8) | 1028 (13.5) | 746 (9.8) | 587 (7.7) | 501 (6.6) | 234 (3.1) |
| Unique users (n=2374), n (%) | 597 (25.1) | 767 (32.3) | 677 (28.5) | 458 (19.3) | 336 (14.2) | 242 (10.2) | 206 (8.7) | 129 (5.4) |

**Figure 1.** Overall methodological framework. ADA: American Diabetes Association; BCT: behavior change technique; CT: communication theme.




## Characterization of Content and Context Exchanged in Social Ties

### *Qualitative Analysis*

The objective of qualitative analysis was to characterize the nature of communication content and underlying context embedded in peer interactions of the ADA community to gain insights into the meaning of peer conversations and the choice of user expressions that affect DSM behaviors. We randomly selected a subset of 1501 forum messages from the original dataset and manually coded them using directed content analysis techniques along the following three dimensions:

1. Communication themes (CTs): Themes capture the essence or meaning of peer conversations and are derived through inductive analysis using grounded theory techniques [22]. These themes provide insights into the theory-driven behavioral constructs prevalent in digital peer interactions.
2. Behavior change techniques (BCTs): For BCTs, we used the BCT taxonomy [23] to identify manifestations of theory-linked BCTs embedded within digital peer interactions. This taxonomy provides a common vocabulary to understand how sociobehavioral and cognitive constructs of existing behavior change theories have been operationalized in BCIs.
3. Speech acts (SAs): To model the communication context underlying digital peer interactions, we used a modified version of Searle's SA theory [20] to describe how specific content is expressed in human communication using 10 categories of SAs. SA theory can be used to model digital peer interactions to recognize the general attitudes of community users and understand their state of mind by capturing implicit expressions and discourse patterns underlying such peer interactions.

Our qualitative coding schema with definitions of various categories of CTs, BCTs, and SAs can be found in Myneni et al [24] and Singh et al [25].



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### *Automated Text Analysis*

Given our initial experiments with a conventional multiclass, multilabel classification approach (which yielded poor results) and the inherently imbalanced nature of the dataset (see the Results section), we built a classification approach in which multiple models were combined in a cascading manner [26,27] for classification of the 3 communication attributes (CTs, BCTs, and SAs). We implemented the following deep learning models for performing text classification of peer interactions along the 3 dimensions: recurrent neural networks (RNNs), convolutional neural networks (CNNs), and transformer-based models. The labeled dataset was divided into 3 parts: 80% (1201/1501), 10% (150/1501), and 10% (150/1501) for training, validation, and test sets, respectively. For the implementation of RNNs and CNNs, we used the Adam optimization algorithm to find the best values for each parameter [28]. Specifically, we used the AdamW optimizer to implement the Bidirectional Encoder Representations from Transformers (BERT), set the dropout to 0.1 to avoid overfitting, and used a learning rate of $1 \times 10^{-5}$. We also computed class weights for the loss function to assign a higher weight to the loss encountered by the messages associated with infrequent label categories. To mitigate overfitting and increase the models' generalization capacity, the validation loss was monitored at every epoch. We found no further decrease in the value of validation loss after 20 epochs for all models that were trained. Therefore, the models were trained for only 20 epochs. We chose model hyperparameters based on their optimal performance on the validation set. We converted the probabilities into label categories based on a threshold value that was calculated using the validation set. RNNs and CNNs were implemented with Keras (developed by Google LLC) [29], and BERT was implemented using PyTorch (developed by Meta Platforms, Inc) [30]. The detailed implementation methodology can be found in Singh et al [31].

## Characterization of Individual Behaviors: Qualitative Analysis

We extracted DSM behavior persona for a subset of users (92 of a total of 205 unique community users) based on their self-reported forum signatures and assigned them behavior profiles based on their DSM strategies [32] and diagnostic features as follows: (1) medication status—whether or not the users take medications; we further classified the medication use to identify oral medicines only (metformin and glipizide) versus injectable only (Novolog and Lantus) versus using both; (2) diagnosis status—newly diagnosed of diabetes (2018 onward) or had pre-existing diabetes (earlier than 2018); and (3) lifestyle profile—whether the users incorporated lifestyle changes (low-carbohydrate or Mediterranean diet, treadmill, and walking) or they did not incorporate any such changes. An example of a self-reported behavior signature is "Diagnosed: February 2017, I went diet controlled with type 2 diabetes. Meds: metformin 500 mg twice a day," based on which this user was assigned the following behavior persona—medication user, a pre-existing user with T2D, and a user who incorporates lifestyle changes.

## Characterization of Social Ties

### *Overview*

Using the labeled peer interactions from the ADA dataset, we characterized the social networks of the 2 DHCs using content-sensitive user-context affiliation networks. These networks consisted of 2 modesT2D the first one being the community users and the second one being the different SA categories. The ties between them recorded the affiliation of each user with each SA in a given CT. The community users were assigned to a specific CT if they had at least exchanged 1 message belonging to the respective CT. For example, in obstacles CT–based social network (Multimedia Appendix 1), the first community user is affiliated with assertion SA, the second community user is affiliated with commissive SA, and the third community user is affiliated with both SAs, given that these users expressed themselves using these categories of SAs in the given CT. We constructed visual representations of various CT-based affiliation networks between community users and SAs. We used Gephi, an open-source network visualization tool, to create and analyze these networks [33].

### *Affiliation Exposure Model*

We used 2-mode affiliation networks consisting of 2 distinct sets of nodes—the first set of nodes represents the ADA community users (total n=360 - 529, varies by CT), and the second set of nodes represents the various SA categories ($k$=8). We used CT-based social networks, where SAs were further categorized based on community user's communication styles. The two broad communication styles were as follows: (1) the sender of the message has an intention to "push-in" information to the receiver (using SAs—assertion, stance, declarative, directive, and statement) and (2) "interactive turn-taking," where the sender might try to engage their peers by pulling out and pushing in information in the form of question, expressive, or emotion. A community user was considered affiliated with a specific SA category only if that user had exchanged a message with that specific underlying context or SA. The affiliation exposure model (AEM) was used to understand if the affiliation to common SA categories (ie, peers who share similar contexts) within a specific CT is associated with user engagement levels in the ADA community. Affiliation exposure measures the percentage of events in the community, where users coparticipate with other users while embracing a specific behavior [34]. This allows characterization of the role of context-specific social influence patterns underlying peer-to-peer communication in digital communities and simultaneously evaluates the extent to which "membership or affiliation" in a specific SA category is associated with user engagement levels.

In this context, we used the network exposure model [34-37] that assumes that social influence occurs when community users are exposed to a specific behavior by their social network contacts. The 2-mode affiliation networks represented a user (row)-by-SA (column) matrix, where each cell entry recorded the number of times a particular SA ($k$) was expressed by the user ($n$; ie, n × k 2-mode valued matrix) in a given CT. This network was binarized using the median of the counts of SA expressed by all community users in a given theme as a threshold and used for further analysis ($A_{ij}$)=1or 0 for $i$=1, … ,



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529, and $k$=1, … ,8. By multiplying this dichotomized 2-mode affiliation matrix ($A_{ij}$) with its transpose ($A_{ij'}$), the resulting coaffiliation matrix $C$ (=$A_{ij}A_{ij}$) is a symmetric matrix where off-diagonal entries represent the pair of user's coexpression of SAs during peer conversations. The diagonal entries represent the number of SAs expressed by a specific ADA community user (diagonal vector of $C_{ij}$).

The computation of affiliation exposure uses the coaffiliation matrix ($C_{ij}$) and multiplies $C_{ij}$ by each user's attribute $y_j$ (ie, engagement level, which corresponds to the posting frequency of the ADA users). In this scenario, given that $y_j$ represents a continuous variable, affiliation exposure measures the mean $y$ value of all ADA users with whom the ADA user is affiliated through the expression of the same SAs weighted by the shared SAs. The diagonal values of $C_{ij}$; $i$=$j$ were not included in this computation but are included as a control variable for later regression analysis to alleviate the potential underestimation of autocorrelation parameter estimates [34]. The formula used to compute 2-mode affiliation exposure is as follows:

$$F_=\sum j=1Cij\ yj\sum j=1Cij \text{ for } i,j=1,\ldots,N\ i\neq j$$

where $F$ is the affiliation exposure vector, $C_{ij}$ is the coaffiliation matrix that represents a symmetric matrix of community users (user-by-user) with every off-diagonal cell entry recording the number of SAs shared between a pair of ADA users in their peer conversations, and $y_j$ is a vector of user's behavioral attribute (user's posting frequency). In this work, affiliation exposure measures the percentage of SAs that ADA users coexpress while engaging with other community users in a given CT. To account for network autocorrelation, we used the 2-mode version of the network autocorrelation model, which is defined as:

$$y=\rho Wy+X\beta+\gamma D+ \text{ for } \sim n(0,\sigma 2I)$$

where $y$ is the vector of the user's behavioral attribute (user's posting frequency), $Wy$ equivalent to affiliation exposure term F with $W$ being (n×n) coexpression matrix $C$, $X(n\times h)$ is a matrix of values for the $n$ community users on $h$ independent variables with unit row vector for the intercept term, β(n × h) is a vector of regression coefficients, ρ is a scalar estimate of autocorrelation parameter, $D$ represents the number of SAs expressed by each community user, and γ is the corresponding parameter. The covariates were the number of SAs each user expressed (diagonal vector of $C_{ij}$), medication status, diagnosis status, and lifestyle status ($X$s). We used the lnam function from the statnet library in R (R Foundation for Statistical Computing), open-source statistical analysis software for this purpose [38].

# Results

## Characterization of Content and Context Exchanged in Social Ties

### Qualitative Analysis

Regarding the thematic interests of the ADA community users, social support (1128/1501, 75.1%) was the most communicated theme among users. Teachable moments (357/1501, 23.8%) was the second most prevalent theme among ADA community users, using which the users described how positive behavior changes impacted their blood glucose levels. The medication-related conversations centered around insulin, Lantus, metformin, etc, were quite prevalent (pharmacotherapy: 310/1501, 20.7%). Anxiety issues or the inability to manage blood glucose numbers within the desired range were the most commonly expressed obstacles among ADA community users (obstacles: 262/1501, 17.5%). ADA community users shared patient-reported outcomes (232/1501, 15.5%), for example, the impact of β-blockers on blood glucose readings (Multimedia Appendix 2).

For BCTs, feedback and monitoring (659/1501, 43.9%) was the most frequently used among the community users, followed by social support (565/1501, 37.6%), shaping knowledge (518/1501, 34.5%), antecedents (420/1501, 28%), regulation (323/1501, 21.5%), natural consequences (294/1501, 19.6%), goals and planning (246/1501, 16.4%), and comparison of outcomes (185/1501, 12.3%). Community users provided feedback to one another regarding their self-management behaviors toward diabetes. Users also provided support to one another through emotional support or practical guidance. DHC users guide their peers through information on how behavior can be changed or how to restructure or organize physical or social environments to support positive behavior changes. Discussions on regulating positive behavior through medication options such as insulin and metformin were also present. The community users provided examples of social, emotional, and health consequences of changing their behaviors.

Assertion SA (845/1501, 56.3%) was the most prevalent SA embedded within the ADA messages, such as "consider blurry vision as a sign of high blood sugar" or "diet and exercise are the primary tools of defense against diabetes." There was also a high prevalence of statement SA (555/1501, 37%) highlighting health-related practices of community users, such as "since my diagnosis I have cut down carbs, started exercising and taking metformin with the goal of keeping A1C values close to normal." Directive SA (392/1501, 26.1%) highlighting the presence of peer guidance within the community was also prevalent, such as "follow up with your primary care physician to get the medications checked" or "check your blood glucose values at least before every meal in the beginning." Many community ADA users seeking guidance from their peers posted their queries or questions (304/1501, 20.3%) in the forums. Stance SA (260/1501, 17.3%) in the form of "I agree, meds are a source of consternation" or "I disagree with your point" was also prevalent in ADA peer interactions.

### Automated Text Analysis

For the classification of CTs, the performance of BERT (ADA-trained) and BERT-base was comparable for all the categories. For progress CT, BERT (ADA-trained) had a higher $F_1$-score compared to BERT-base, and for obstacles CT, BERT-base had a higher $F_1$-score compared to BERT (ADA-trained; Table 2). RNNs and CNNs performed comparably to BERT models for determining social support and patient-reported outcomes CTs. The average performance of RNNs and CNNs was comparable, while the average performance of BERT (ADA-trained) and BERT-base was the



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same. BERT (ADA-trained) outperformed all other models when predicting community-specific pharmacotherapy and progress CTs within ADA peer interactions. It could be because further pretraining on the ADA corpus helped the model to understand the context of words that pertain to medication uses, such as sugar, swings, insulin, and metformin, as well as understand the context of how these community users report their behavioral progress in terms of $A_{1c}$ values over time, etc.



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**Table .** Category-wise $F_1$-scores of deep learning models for classification of communication attributes in the American Diabetes Association (ADA) dataset.

| Category | | RNN[a] | LSTM[b] | BiLSTM[c] | GRU[d] | CNN[e] | BERT[f]-base | BERT (ADA-trained) |
|---|---|---|---|---|---|---|---|---|
| **Communication themes** | | | | | | | | |
| | Social support | 0.91 | 0.91 | 0.88 | 0.91 | 0.91 | 0.91 | 0.91 |
| | Readiness regulators | 0.70 | 0.76 | 0.79 | 0.72 | 0.78 | 0.81 | 0.80 |
| | Pharmacotherapy | 0.62 | 0.67 | 0.53 | 0.66 | 0.68 | 0.79 | 0.78 |
| | Obstacles | 0.71 | 0.65 | 0.69 | 0.68 | 0.74 | 0.75 | 0.73 |
| | Patient-reported outcomes | 0.81 | 0.81 | 0.82 | 0.79 | 0.79 | 0.81 | 0.81 |
| | Progress | 0.62 | 0.69 | 0.68 | 0.64 | 0.56 | 0.74 | 0.76 |
| | Average performance (SD) | 0.73 (0.11) | 0.75 (0.10) | 0.73 (0.13) | 0.73 (0.10) | 0.74 (0.12) | 0.80 (0.06) | 0.80 (0.06) |
| **Behavior change techniques** | | | | | | | | |
| | Feedback and monitoring | 0.66 | 0.66 | 0.59 | 0.64 | 0.71 | 0.72 | 0.72 |
| | Social support | 0.59 | 0.61 | 0.55 | 0.65 | 0.63 | 0.71 | 0.71 |
| | Shaping knowledge | 0.60 | 0.64 | 0.71 | 0.66 | 0.67 | 0.75 | 0.78 |
| | Antecedents | 0.63 | 0.68 | 0.68 | 0.67 | 0.70 | 0.73 | 0.71 |
| | Regulation | 0.66 | 0.67 | 0.81 | 0.62 | 0.76 | 0.81 | 0.86 |
| | Natural consequences | 0.68 | 0.70 | 0.73 | 0.72 | 0.76 | 0.71 | 0.74 |
| | Goals and planning | 0.78 | 0.73 | 0.78 | 0.76 | 0.79 | 0.79 | 0.79 |
| | Comparison of outcomes | 0.57 | 0.67 | 0.67 | 0.58 | 0.67 | 0.73 | 0.76 |
| | Average performance (SD) | 0.65 (0.07) | 0.67 (0.04) | 0.69 (0.09) | 0.66 (0.06) | 0.71 (0.05) | 0.74 (0.04) | 0.76 (0.05) |
| **Speech acts** | | | | | | | | |
| | Assertion | 0.71 | 0.70 | 0.73 | 0.68 | 0.70 | 0.74 | 0.76 |
| | Statement | 0.49 | 0.53 | 0.54 | 0.47 | 0.60 | 0.69 | 0.71 |
| | Directive | 0.38 | 0.51 | 0.54 | 0.49 | 0.51 | 0.62 | 0.67 |
| | Question | 0.27 | 0.45 | 0.45 | 0.53 | 0.54 | 0.72 | 0.75 |
| | Emotion | 0.62 | 0.60 | 0.65 | 0.68 | 0.63 | 0.63 | 0.72 |
| | Stance | 0.53 | 0.60 | 0.64 | 0.56 | 0.58 | 0.67 | 0.71 |
| | Declarative | 0.69 | 0.70 | 0.71 | 0.59 | 0.72 | 0.67 | 0.76 |
| | Expressive | 0.67 | 0.68 | 0.63 | 0.62 | 0.68 | 0.71 | 0.75 |
| | Average performance (SD) | 0.55 (0.16) | 0.60 (0.09) | 0.61 (0.09) | 0.58 (0.08) | 0.62 (0.08) | 0.68 (0.04) | 0.73 (0.03) |

[a]RNN: recurrent neural network.

[b]LSTM: long short-term memory.

[c]BiLSTM: bidirectional long-short-term memory.

[d]GRU: gated recurrent unit.

[e]CNN: convolutional neural network.

[f]BERT: Bidirectional Encoder Representations from Transformers.



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For BCT classification, BERT (ADA-trained) was better than all other models for classifying various BCT categories, except for the antecedents and natural consequences, for which the BERT-base and CNN had higher predictive performance, respectively. However, the average performance of BERT (ADA-trained) was higher than all other models. The BERT-base model's performance was comparable to that of BERT (ADA-trained) in predicting feedback and monitoring, social support, and goals and planning BCTs. The BERT-based model's average performance was comparable to that of BERT (ADA-trained) in classifying various BCT categories.

In the case of SAs, BERT (ADA-trained) achieved the highest $F_1$-scores for all the categories, ranging from 0.67 to 0.76 (Table 2). The average performance of the model was much higher than that of the other models—BERT-base, CNNs, and RNNs. The $F_1$-score was lowest for identifying directive SA in the ADA dataset, while assertion, declarative, question, and expressive had the highest $F_1$-scores (0.76, 0.76, 0.75, and 0.75, respectively).

## Characterization of Individual Behaviors: Qualitative Analysis

We extracted the behavior persona for 529 (~22.3%) ADA community users (from 2374 community users) who had provided their self-reported behavior signatures. The distribution of different statuses is provided in Table 3; as can be seen, most of the users interacting within the ADA forum used oral medications (237/529, 44.8%), had a long history of diabetes (428/529, 80.9%), and did not provide any information about lifestyle changes (378/529, 71.5%).

**Table .** User-level behavior persona extracted from the American Diabetes Association dataset.

| | | Users (n=529), n (%) |
|---|---|---|
| **Medication profile** | | |
| | Oral only | 237 (44.8) |
| | Injectable only | 63 (11.9) |
| | Both (oral+injectable) | 77 (14.6) |
| | No medications | 52 (9.8) |
| | No information | 102 (19.3) |
| **Diagnosis profile** | | |
| | Pre-existing diabetes | 428 (80.9) |
| | Newly diagnosed | 4 (0.8) |
| | No information | 99 (18.7) |
| **Lifestyle profile** | | |
| | Yes | 153 (28.9) |
| | No | 378 (71.5) |

## Characterization of Social Ties

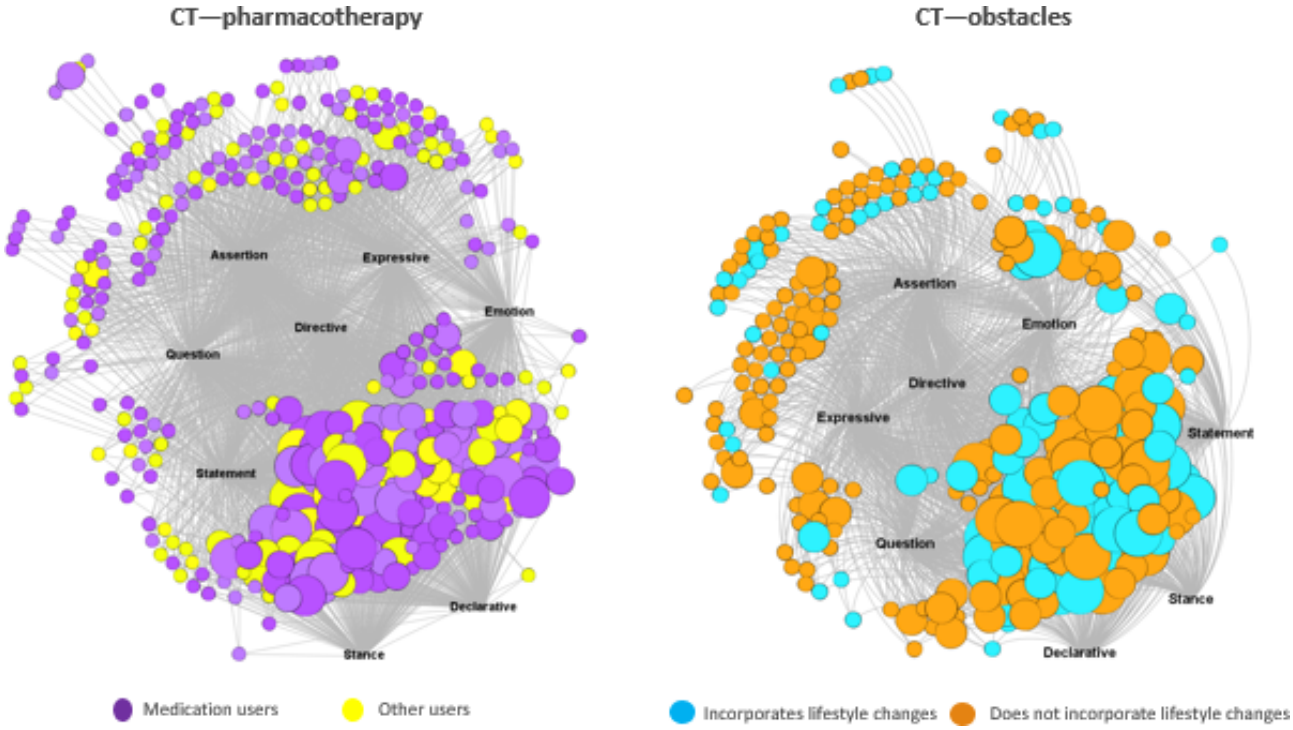
### *Overview*

For illustration purposes, Figure 2 presents the users-by-SA affiliation networks for ADA community users for the 2 CTs—pharmacotherapy and obstacles. In the pharmacotherapy CT–based network, the purple nodes represent the medication users, and the yellow nodes represent the other users. In the obstacles CT–based network, the blue color nodes represent the users who incorporate lifestyle changes, and the orange nodes represent users who did not incorporate lifestyle changes. In both networks, the size of the nodes represents the engagement of the users, where the large-sized nodes represent the power engagement users, medium-sized ones represent the sustained engagement users, and small-sized nodes represent the infrequent engagement users. The different SA categories are represented by their labels, and the affiliation ties represent the SAs the users expressed in their communication using the 2 CTs. These data represent all users' communications from 2012 to 2021, in which the ADA users expressed the 2 CTs given. As seen in the figure, stance and declarative are popular SAs among power engagement users in the pharmacotherapy CT–based network.



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**Figure 2.** Two-mode affiliation networks for American Diabetes Association community users. CT: communication theme.




### *Affiliation Exposure Model*

The overall ADA dataset used for AEM spanned from 2014 to 2021, consisting of 56,993 messages organized into 7232 unique topics posted by 529 community users with self-reported signatures. The distribution of messages by themes is provided in Table 4.

**Table .** Theme-specific affiliation exposure model dataset characteristics.

| Communication themes | Messages (n=56,993), n (%) | Topics (n=7232), n (%) | Users (n=529), n (%) |
|---|---|---|---|
| Social support | 56,952 (99.9) | 7232 (100) | 529 (100) |
| Readiness regulators | 40,233 (70.6) | 6726 (93) | 505 (95.5) |
| Pharmacotherapy | 20,722 (36.4) | 4333 (59.9) | 471 (89) |
| Obstacles | 8204 (14.4) | 2635 (36.4) | 360 (68.1) |
| Patient-reported outcomes | 19,230 (33.7) | 3033 (41.9) | 391 (73.9) |
| Progress | 18,205 (31.9) | 2869 (39.7) | 378 (71.5) |

The effect of affiliation exposure on user engagement was statistically significant for all CTs (ie, social support, readiness regulators, pharmacotherapy, obstacles, patient-reported outcomes, and progress; communication content). The autocorrelation parameter estimates indicated a positive association between exposure to community users through interactive communication style SAs and user engagement. Specifically, community users affiliating with interactive turn-taking communication styles, such as questions, emotions, or expressive statements, were positively linked to higher engagement levels among ADA community users. For example, when a user with a question about morning glucose levels (communication context) interacts with others sharing a similar DSM context within a readiness-regulators–specific network, they are more likely to remain engaged in the digital community. This engagement is reflected in their posting frequency. On the other hand, exposure to community users affiliating with push-in communication style SAs, such as assertions, declaratives, directives, stances, or statements (communication context), was negatively associated with user engagement in the community (Table 5).

The pre-existing users with T2D were more likely to stay engaged in the community when they expressed patient-reported outcomes and progress CTs (communication content) using interactive communication style SAs (questions, emotion, or expressive; communication context). The number of common SAs as manifested in the interactions exchanged between ADA users were significant across all CTs. It indicated that the more SAs a user expressed through peer interactions within the community, the more likely the user would remain engaged with the community for self-managing diabetes-related behaviors (Table 5).



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**Table .** Affiliation exposure among American Diabetes Association users derived from the network autocorrelation model.

| Type of CTs[a] and type of SAs[b] (communication styles) | Affiliation exposure, b (SE) | Medication status, b (SE) | Diagnosis status, b (SE) | Lifestyle status, b (SE) | SAs affiliated, b (SE) |
|---|---|---|---|---|---|
| **Social support (n=529)** | | | | | |
| Push-in CS[c] | −0.012[d] (0.004) | −0.790 (1.415) | 1.682 (1.516) | −1.500 (2.068) | 0.758[d] (0.002) |
| Interactive turn-taking CS | 0.068[d] (0.006) | −0.758 (2.560) | 0.885 (2.747) | 1.787 (3.753) | 0.929[d] (0.004) |
| **Readiness regulators (n=505)** | | | | | |
| Push-in CS | −0.023[d] (0.003) | −0.546 (0.812) | 0.837 (0.865) | −1.222 (1.167) | 0.731[d] (0.001) |
| Interactive turn-taking CS | 0.067[d] (0.006) | −0.825 (1.884) | 0.660 (2.008) | 3.200 (2.707) | 0.885[d] (0.004) |
| **Pharmacotherapy (n=471)** | | | | | |
| Push-in CS | −0.012[e] (0.004) | 0.160 (0.474) | 0.500 (0.504) | −1.003 (0.688) | 0.690[d] (0.002) |
| Interactive turn-taking CS | 0.074[d] (0.007) | −0.391 (1.000) | 0.212 (1.064) | 1.080 (1.452) | 0.871[d] (0.005) |
| **Obstacles (n=360)** | | | | | |
| Push-in CS | −0.017[d] (0.003) | −0.209 (0.147) | 0.049 (0.162) | 0.102 (0.222) | 0.735[d] (0.002) |
| Interactive turn-taking CS | 0.070[d] (0.008) | −0.265 (0.441) | 0.663 (0.488) | 0.164 (0.668) | 0.839[d] (0.006) |
| **Patient-reported outcomes (n=391)** | | | | | |
| Push-in CS | −0.008[e] (0.003) | −0.246 (0.312) | 0.516 (0.340) | −0.313 (0.453) | 0.707[d] (0.001) |
| Interactive turn-taking CS | 0.080[d] (0.006) | −0.590 (0.754) | 1.854[f] (0.823) | 1.208 (1.094) | 0.821[d] (0.004) |
| **Progress (n=378)** | | | | | |
| Push-in CS | −0.009[d] (0.003) | −0.258 (0.313) | 0.512 (0.343) | −0.279 (0.456) | 0.708[d] (0.002) |
| Interactive turn-taking CS | 0.082[d] (0.006) | −0.421 (0.752) | 1.944[f] (0.823) | 0.822 (1.092) | 0.820[d] (0.004) |

[a]CT: communication theme.

[b]SA: speech act.

[c]CS: communication style.

[d]$P<.001$.

[e]$P<.01$.

[f]$P<.05$.

# Discussion

## Principal Findings

### Overview

Studies on social diffusion research underscore social relationships' role in the adoption and spread of behaviors [39]. Ideological proximity increases the likelihood of individuals becoming friends and influences the dynamic of social interactions [40-43]. Characterizing the communication content and context embedded in these social exchanges helps capture the proximity of such ideas. Communication attributes captured via CTs, BCTs, and SAs, along with the structure of social ties in a DHC, can provide us with insights into mechanisms of how communication events lead to specific social actions. One study showed that highly engaged individuals with the diabetes digital community achieve better health outcomes, such as improved glycemic levels, than those who do not engage with such digital platforms [44].

In this paper, we described our attempts to adapt the existing advances in natural language processing techniques and social network modeling approaches to incorporate communication-level attributes (content and context) and individual-level attributes to understand the social influence mechanisms that drive user DSM behaviors from large-scale social media datasets. This study takes an empirically grounded approach to derive communication content- and context-driven network patterns of behavior change that can be translated into the design of adaptive BCIs. The 2-mode affiliation networks allowed us to visualize distinctive patterns of clustering within CT- and BCT-specific networks. The community users in these affiliation networks are interconnected by different SAs, with certain SAs being more popular than others as per user's engagement status, and it also varies by various kinds of CTs



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or BCTs. Another study used affiliation networks to study the impact of affiliation on alcohol use behaviors among adolescents [45]. Young et al [46] investigated how affiliation to certain digital groups within a social network can influence sexual behaviors. Overall, the results from content-sensitive and context-aware SNA conducted in our work reveal multiple significant patterns of expression of specific content and context that can influence users' DSM behaviors.

### *Implications for Design of Digital DSM Interventions*

The results from this study indicate that capturing various communication attributes from digital peer conversations can help us understand users' implicit needs and how providing users with their requirements can positively impact their DSM behaviors. For example, users expressing themselves with specific communication attributes (eg, interactive turn-taking SAs) can form better connections with other community users, which was shown to improve engagement in DSM behaviors [47]. Our results from AEMs show that specific patterns of content and context can exert social influence—for example, ADA community users affiliating with peers who express with interactive turn-taking communication style SAs in the form of question, expressive, or emotion tend to stay engaged in the community. In another study, the AEM was used to understand how affiliation-based peer influence affects alcohol use behaviors in adolescents [48]. Previous studies have shown how user engagement in social media can influence their health-related outcomes [49,50]. Social network interventions using the use of such networks have already been proposed by researchers in the domain of HIV prevention [51] and tackling COVID-19 misinformation spread [52]. The findings from this study suggest new directions in developing network interventions that focus on incorporating communication attributes that are personalized to individuals' latent needs. For example, an intervention in the form of an artificial intelligence Bot Moderator can recommend connections to make structural changes to the existing networks, such as connecting users with similar contexts, for example, a community user asking questions about pharmacological support can be recommended to communicate with other users who have similar questions.

## Limitations

First, in the qualitative analysis, the relatively small sample size was selected for manual annotation, which may have resulted in inaccurate representations of the overall prevalence of different communication attributes. However, the sample of 1501 messages using qualitative research methods was appropriate for the research objectives. For this research, we extracted messages about topics related to T2D, and the extractions were done in 2018 and 2021. While there was a reduction in the number of messages in our dataset between 2018 and 2021, several external factors must be considered, notably the community's transition to a new technology platform and the impact of the COVID-19 pandemic. Research during the pandemic has shown that DSM behaviors were significantly impacted, with many individuals experiencing both positive (adopting healthier eating habits) and negative (decreased physical activity) changes in their management routines due to social isolation, stress, and disruptions in health care access [53,54]. It aligns with what may have occurred within our study community, as they faced the dual challenge of adapting to a new platform and managing the broader societal disruptions caused by the pandemic. Despite these challenges, the dataset remains highly relevant to understanding DSM, as peer interactions are a cornerstone of diabetes self-care. The insights from this dataset contribute to a broader understanding of how peer support can enhance patient engagement in DSM. Thus, while the reduction in message volume is a limitation, the remaining interactions continue to provide valuable insights into the adaptation and resilience of individuals managing diabetes in digital social environments. Second, we only considered some categories of BCTs and SAs for automated text analysis, given the imbalanced nature of the manually annotated dataset. In addition, while applying the finalized model to the unlabeled dataset, we used the threshold values for assigning a particular category of CTs, BCTs, or SAs to the peer messages, which reduced the total number of labeled messages, which might have resulted in missed network ties during our retrospective and SNA. Finally, the AEM analysis was based on the cross-sectional affiliation data obtained from the ADA dataset, which limits our understanding of the potential causality of SA affiliation and dynamic patterns of SA affiliation in various CT-based social networks. Despite this limitation, this work offers empirical insights into users' affiliation to SAs using certain themes or theoretical constructs. Another critical limitation of this study is the potential for bias arising from affiliation exposure, particularly selection bias, autocorrelation bias, and the challenge of distinguishing between causality and correlation [34]. Selection bias may occur if the dataset overrepresents certain affiliations, leading to results that are not fully generalizable. Our methods attempt to address this by ensuring random harvesting of digital interactions. However, our data are limited to individuals participating in these networks. Future works should attempt to include mixed methods recruitment strategies to ensure broader population-level data capture. Autocorrelation bias can inflate behavioral similarities within networks, making it appear that behaviors spread more widely due to social connections rather than inherent trends [34]. Although our AEM helps mitigate these biases by segregating peer and group influences, the difficulty in separating correlation from causality remains. While individuals within certain affiliations may exhibit similar behaviors, it is often unclear whether these behaviors are driven by the affiliation itself or by pre-existing characteristics that led individuals to join those groups. Future research should aim to diversify affiliations in the dataset and incorporate longitudinal data to address these biases better and distinguish between correlation and causality.

We extracted behavioral profiles for only a subset of the community users with self-reported behavior persona; thus, such behavior profiles may not represent the entire community user population. Moreover, this analysis does not consider sociodemographic and cultural factors, which can also result in differences in the expression of various communication attributes. Future work should focus on complementing the current efforts by biobehavioral sensing using commercial wearables (such as continuous glucose monitors), collaborating with community partners, and using data obtained from multiple



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communities for each application domain as has been used by other studies [55]. Such insights will help us understand users' needs and triggers surrounding certain behavioral events (such as fluctuations in blood glucose values) so that the interventions can be customized for that specific behavioral stage of change.

## Conclusions

Ubiquitous internet connectivity has led to the onset of digital health platforms where more and more individuals are engaging with their peers to manage their health-related conditions. Our study demonstrates that real-time digital interactions effectively capture the complexities of DSM-related behaviors and reveal how self-expression within specific contexts influences engagement with digital peers, ultimately affecting DSM. A theory-driven, large-scale analysis of such datasets can provide valuable insights into the underlying processes of DSM, informing the design of highly effective BCIs.

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## Conflicts of Interest

None declared.

Multimedia Appendix 1
Example of affiliation ties in the American Diabetes Association community.
[PNG File, 7 KB - diabetes_v10i1e60109_app1.png ]

Multimedia Appendix 2
Distribution of (A) communication themes, (B) behavior change techniques, and (C) speech acts in the American Diabetes Association community.
[PNG File, 101 KB - diabetes_v10i1e60109_app2.png ]

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## Abbreviations

**ADA:** American Diabetes Association
**AEM:** affiliation exposure model
**BCI:** behavior change intervention
**BCT:** behavior change technique
**BERT:** Bidirectional Encoder Representations from Transformers
**CNN:** convolutional neural network
**CT:** communication theme
**DHC:** digital health community
**DSM:** diabetes self-management
**RNN:** recurrent neural network
**SA:** speech act
**SNA:** social network analysis
**T2D:** type 2 diabetes



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Original Paper

# School-Partnered Collaborative Care (SPACE) for Pediatric Type 1 Diabetes: Development and Usability Study of a Virtual Intervention With Multisystem Community Partners

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## Abstract

**Background:** School-partnered interventions may improve health outcomes for children with type 1 diabetes, though there is limited evidence to support their effectiveness and sustainability. Family, school, or health system factors may interfere with intervention usability and implementation.

**Objective:** To identify and address potential implementation barriers during intervention development, we combined methods in user-centered design and implementation science to adapt an evidence-based psychosocial intervention, the collaborative care model, to a virtual school-partnered collaborative care (SPACE) model for type 1 diabetes between schools and diabetes medical teams.

**Methods:** We recruited patient, family, school, and health system partners (n=20) to cocreate SPACE through iterative, web-based design sessions using a digital whiteboard (phase 1). User-centered design methods included independent and group activities for idea generation, visual voting, and structured critique of the evolving SPACE prototype. In phase 2, the prototype was evaluated with the usability evaluation for evidence-based psychosocial interventions methods. School nurses reviewed the prototype and tasks in cognitive walkthroughs and completed the Intervention Usability Scale (IUS). Two members of the research team independently identified and prioritized (1-3 rating) discrete usability concerns. We evaluated the relationship between prioritization and the percentage of nurses reporting each usability issue with Spearman correlation. Differences in IUS scores by school nurse characteristics were assessed with ANOVA.

**Results:** In the design phase, the partners generated over 90 unique ideas for SPACE, prioritizing elements pertaining to intervention adaptability, team-based communication, and multidimensional outcome tracking. Following three iterations of prototype development, cognitive walkthroughs were completed with 10 school nurses (n=10, 100% female; mean age 48.5, SD 9.5 years) representing different districts and years of experience. Nurses identified 16 discrete usability issues (each reported by 10%-60% of participants). Two issues receiving the highest priority (3.0): ability to access a virtual platform (n=3, 30% of participants) and data-sharing mechanisms between nurses and providers (n=6, 60% of participants). There was a moderate correlation between priority rating and the percentage of nurses reporting each issue (ρ=0.63; *P*=.01). Average IUS ratings (77.8, SD 11.1; 100-point scale) indicated appropriate usability. There was no difference in IUS ratings by school nurse experience (*P*=.54), student caseload (*P*=.12), number of schools covered (*P*=.90), or prior experience with type 1 diabetes (*P*=.83), suggesting



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that other factors may influence usability. The design team recommended strategies for SPACE implementation to overcome high-priority issues, including training users on videoconferencing applications, establishing secure forms for school data reporting, and sharing glucose data in real-time during SPACE meetings.

**Conclusions:** Cross-sector interventions are complex, and perceived usability is a potential barrier to implementation. Using web-based cocreation methods with community partners promoted high-quality intervention design that is aligned with end-user priorities. Quantitative and qualitative assessments indicated appropriate degree of usability to move forward with pilot-testing.

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**KEYWORDS**

type 1 diabetes; user-centered design; school health; collaborative care model; implementation research; pediatric; usability testing; virtual intervention; multisystem community partners; children; youth; diabetes management support; health system partners; psychosocial interventions; quantitative assessments; qualitative assessments

## Introduction

Supportive parent and peer relationships can have a significant impact on diabetes-related behaviors, glycemia, and psychosocial outcomes of children and adolescents with type 1 diabetes [1-4]. For this reason, parent and peer interactions have been the target of numerous community-based interventions [5-7]. There are other natural support systems in the community for children with type 1 diabetes and their families. In particular, schools serve a critical role in the development of children. School success is linked to professional attainment and health in adulthood, making education an important social determinant of health [8]. For children with type 1 diabetes, attendance at in-person schools may benefit diabetes management practices through establishing routines for meal timing and physical activity [9,10]. Children with diabetes are also supported by numerous legal protections to ensure they have appropriate medical care in school and a safe learning environment [11].

Despite the role of schools, there are ongoing challenges with diabetes care there. School nurses have identified gaps in their diabetes training, particularly related to new diabetes technologies [12,13]. This can adversely affect both student and parent experiences with school care [14-16] and may impact health outcomes, as young children with type 1 diabetes have higher blood glucose on average during school as compared to weekends or virtual school days [17]. School nurses have also endorsed difficulty coordinating care with students' medical teams, which can lead to gaps in care [12]. Pediatric diabetes providers understand the importance of school-based diabetes care, though they have similarly reported challenges interfacing with schools due to gaps in school staff education, lack of awareness of specific policies, and poor systems for communication [18]. Interventions to address these challenges in the school setting have been limited in scope and impact [19], and different barriers may hamper joint interventions. At the school level, there may be competing priorities between health and educational initiatives, the confines of the school day, and staffing or resource limitations, driven by state-level policies and funding. Health systems similarly encounter challenges with staffing and resources, which impair the ability to communicate with and train school health staff [18]. Enhancing partnerships through collaborative health service interventions may improve diabetes care in the school setting [20].

To bridge the school-provider practice gap, the objective of this study was to develop a school-partnered collaborative care (SPACE) model for pediatric type 1 diabetes to bring together schools, health care providers, and families into a comprehensive diabetes care team using digital technologies. SPACE was modified from the collaborative care model (CCM), an evidenced-based, integrated care model for pediatric and adult mental health care with several core components [21]. A CCM classically partners multidisciplinary teams with a care manager (core component: patient-centered care team). The team regularly screens candidates for the program (core component: population-based care), develops a shared treatment plan, tracks progress with valid measures (core component: measurement-based treatments to target), and makes treatment recommendations in a stepwise approach (core component: evidence-based care). Originally used in the primary care setting, the CCM has been associated with improved outcomes in youth with depression [22] and in adults with combined depression and chronic illness, including poorly controlled diabetes [23]. The CCM has been adapted for the school setting, as schools are uniquely positioned to identify at-risk students, offer services, and treat co-occurring academic problems [24,25]. The CCM is well-suited for school-based diabetes care, as it could be used to better connect school personnel with diabetes medical teams to overcome barriers in communication and identify and address opportunities to improve diabetes management by integrating a diabetes expert into the school health team.

Translating the CCM to type 1 diabetes required modifications to both content (related to the diagnosis) and contextual factors (local school setting). To accomplish this, we relied on user-centered design (UCD), a field that is relatively new to the health sciences [26], in combination with concepts from implementation science (IS) [27]. The goals of UCD are to promote the development of interventions that are easy to learn, efficient, acceptable, sustainable, and most importantly, fit to the local context [28]. UCD draws from a multidisciplinary background in human-computer interaction, industrial design practices, cognitive psychology, and participatory research [28]. In this application, UCD involves a set of procedures to cocreate interventions with the individuals who will ultimately use them [29]. UCD can be strengthened by combining it with theories, frameworks, and models drawn from IS [27]. Merging methods from UCD and IS can enable investigators to simultaneously



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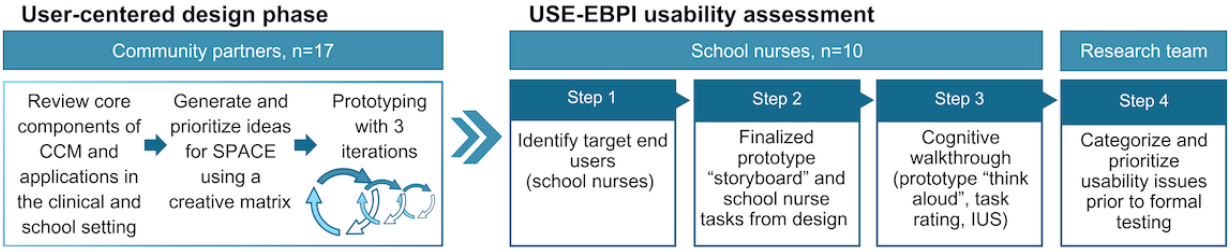
assess multilevel barriers and facilitators which may influence implementation during intervention development. Investigators may also work with design teams to select implementation strategies for future testing or incorporation into clinical practice. In this study, integrating UCD and IS strategies was innovative and essential, as the modifications required navigation of two complex ecosystems, schools, and an academic diabetes medical center. In this paper, we present SPACE design activities and assessments of usability, an indicator of design quality [30], and a determinant affecting intervention feasibility and acceptability [30,31], with target end users (school nurses).

## Methods

### Study Design

We used cocreation methods to design SPACE and assess preliminary usability prior to full-scale implementation [32]. The goal of the SPACE adaptation was to maintain fidelity to the core components of the CCM with the addition and removal of some elements to accommodate the differing content and contextual factors [33]. All modifications were proactive and preplanned prior to full-scale implementation. A summary of processes is depicted in Figure 1. The research team overseeing all activities was comprised of four physicians, a nurse, a psychologist, and a UCD consultant. Together, this team had expertise in type 1 diabetes clinical care, type 1 diabetes school care, school-based health services and research, UCD methods, and IS. All UCD activities were facilitated by a trained investigator in UCD (CAM) with input from other team members. No member of the research team had a diagnosis of or child with type 1 diabetes, though one physician (EM) had a role as the medical doctor for a local school district.

**Figure 1.** Overview of the cocreation methods and usability testing to design the SPACE intervention. In the first phase, we used user-centered design strategies to generate iterative prototypes of the intervention with multisystem community partners. In the second phase, we adopted the USE-EBPI methods to assess usability with target end users (school nurses). CCM: collaborative care model; SPACE: school-partnered collaborative care; IUS: Intervention Usability Scale; USE-EPBI: usability evaluation for evidence-based psychosocial interventions.




### Design Strategies

We iteratively adapted the CCM to create SPACE with a design team of community partners with a vested interest in school-based diabetes care. Roles were identified through stakeholder mapping with an established research advisory board [34]. We recruited partners from three primary groups to represent schools, patients and families, and health systems. School partners included school nurses, educators, and administrators with current working experience with children with type 1 diabetes. Patient and family partners included individuals with type 1 diabetes for ≥6 months, parents of children with type 1 diabetes for ≥6 months, and community advocates. Health system partners included specialists who manage children with type 1 diabetes and paraprofessionals who interact with school systems (eg, nurses, diabetes care and education specialists, and social workers). Partners could identify with more than one role. All partners were required to reside or be employed in our geographic region (Pennsylvania) and participate in English. An established research advisory board served as the foundation for the design team; additional members were recruited through the research team's existing relationships with the Pennsylvania Association of Nurses and Practitioners, our diabetes center, and local branches of national diabetes advocacy organizations. To manage potential power differentials that can exist between these roles [35], we used three strategies: (1) participants completed basic training in ethical research [36], (2) design meetings began by recognizing the importance of each role's unique contributions, and (3) meetings involved a combination of individual and group activities to limit influence from any one person's ideas.

The research team held a series of three monthly 90-minute design meetings. Design meetings were web-based using a videoconferencing platform, Zoom (Zoom Video Communications), which could be accessed by phone, tablet, or computer. The research team met with each community partner either individually or in a group setting to ensure they had access to the videoconferencing platform. All partners were trained on a shared digital whiteboard (Mural Visual Collaboration) to enable active participation in meetings. Two meeting time options were offered each month to increase flexibility and maximize the involvement of all community partners. Partners were provided with meeting agendas in advance, as well as relevant materials to review if able.

Each meeting served as an iterative design cycle for a total of three cycles [37]. The activities generated an intervention prototype and potential strategies for future implementation. The research team provided three assumptions to ground group ideation: (1) the SPACE team must include the school nurse, family, and diabetes medical team at a minimum, (2) the intervention will be geared toward younger children (6 to 13 years of age) who are more likely to rely on a school nurse, and (3) all SPACE activities would be virtual to engage school districts within our broader region and fit within the diabetes medical team's workflow. Each cycle included bidirectional sharing of information between the research team and partners. In the first meeting, we reviewed the core components and



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evidence for the CCM with examples from the literature of the CCM being used in clinical and school settings. Partners independently generated ideas for the adaptation based on the CCM components and roles involved using a creative matrix [38]. In the matrix, the column headings identified the participating role (eg, student, parent, school nurse, diabetes medical team, or other), and the row headings identified important features of SPACE (engagement, structure and content, outcomes, supports and policies, or other). Partners categorized ideas by where they best fit, acknowledging some ideas may bridge between multiple roles or concepts. Following a brief discussion of each idea, partners used a visual voting system to identify first and secondary priorities for the CCM, generating a semiquantitative indicator for each idea. The research team assigned two points for each first-priority vote and one point for each second-priority vote. The total points for each idea were summed.

In the subsequent two cycles, the research team presented increasingly detailed versions of the prototype, with the end goal being a narrative storyboard representing the SPACE intervention. At each stage, the facilitator asked partners to reflect on SPACE to identify strengths, limitations, opportunities for refinement, and areas in need of further clarity. In the final session, partners also discussed the individual tasks school nurses would be responsible for in SPACE to identify which tasks should be targeted for user testing.

### Usability Assessment

We adopted the usability evaluation for evidenced-based psychosocial interventions (USE-EBPI) to evaluate usability, which allows for the discovery and organization of potential barriers and planning for strategies to overcome them [39]. Usability was assessed both quantitatively and qualitatively through cognitive walkthroughs with school nurses (n=10). The USE-EBPI methods outline four steps, including identifying users for testing, defining EBPI tasks, conducting the evaluation, and organizing and prioritizing usability issues. First, we identified that school nurses were appropriate end users for testing (step 1), with the sample size determination based on usability modeling [40,41]. School nurses were recruited through the email listserv of the Pennsylvania Association of School Nurses and Practitioners, which is the state branch of the National Association of School Nurses. School nurses in Western Pennsylvania, where this intervention will be formally pilot-tested, were preferentially recruited. School nurses who participated in the original SPACE design were excluded to allow for a more objective assessment. The prototype and associated tasks for testing were identified through the design process with community partners (step 2). Cognitive walkthroughs were conducted using a videoconferencing platform (step 3). Each session lasted approximately 45 minutes and was attended by two members (CAM and EN) of the research team for facilitation and detailed note-taking. All sessions were audio-recorded to allow for review to ensure all ideas were captured.

Each cognitive walkthrough had two components. First, school nurses were led sequentially through each step of SPACE using the storyboard prototype and asked to think aloud about the intervention. Subsequently, we presented the school nurses with nine case scenarios describing intervention tasks. For each case scenario, school nurses were asked to provide a rating for how likely they would be able to do the task and a justification. Ratings used a 5-point Likert-type response scale with 1 indicating no or very small chance of success and 5 indicating a very good chance of success. Detailed notes were taken throughout the cognitive walkthrough. Subsequently, school nurses completed the Intervention Usability Scale (IUS), a 10-item, validated survey that is used as a benchmark in intervention redesign [42]. The IUS has strong psychometric properties including a two-factor solution (“usable” and “learnable”) and a Cronbach α of 0.83 in a sample of medical professionals [42]. A benchmark IUS score of >70 (range 0-100) corresponds to an acceptable level of usability [43].

### Data Management and Analysis

Qualitative notes from the cognitive walkthroughs were typed, deidentified, and reviewed weekly by two members of the research team (EN and CAM). Usability issues captured from the notes related to both the intervention generally and its specific components, as elicited by the scenarios. The reviewers tallied the number of participants who identified the same issue, adding new usability issues as needed as cognitive walkthroughs continued. Once completed, the reviewers organized the usability issues by type using 13 categories in the UCD literature (step 4) [30]. Two investigators assigned a priority score (1=not important, 2=somewhat important, and 3=very important) for additional adaptations needed to generate a workable intervention. Priority scores were based on the perceived likely impact on future end users, the likelihood that this would be experienced by users, and how critical it is for the success of SPACE [39]. Independent scores were then averaged and sorted from highest to lowest priority. We examined the correlation between the priority rating and the percentage of school nurse participants identifying the issue using Spearman’s correlation. The usability issues and priority rankings were shared with the design team to determine any additional refinements to SPACE.

Quantitative data included case scenario ratings and IUS scores. Ratings for each case scenario and the IUS scores were averaged across participants and presented as a mean and SD. We explored differences in IUS scores using one-way ANOVA among groups with differing characteristics perceived to influence school nurse workload and skill level, including school nursing experience (<10 years vs ≥10 years), caseload (<750, 750-1000, or 1001-1500 students), number of schools covered (1, 2, and more than 2), and students with type 1 diabetes in the past 5 years (<5, 5-10, or >10 students) [44]. A *P* value of <.05 was considered significant. All statistical analyses were completed using StataSE (version 17; StataCorp).

### Ethical Considerations

All design and research activities were deemed exempt by the University of Pittsburgh Institutional Review Board (PRO 23110009). As the study was exempt, we were not required to document written informed consent. All research participants were presented with a consent script describing the purpose of the study, study activities, compensation, risks, and benefits. Verbal consent was obtained. All study data were deidentified



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and linked to private identifiable information using a unique code. Community partners were compensated US $25 per hour (US $37.50 per 90-minute meeting), for a total of US $150. Compensation was provided for partners who could not attend a meeting if they reviewed materials and provided feedback via phone or email. School nurses participating in usability tests were compensated US $30.

# Results

## Overview

We recruited 20 community partners for the design team. Three community partners were unable to attend the meetings due to changes in their family circumstances. The remaining 17 community partners reflected all intended roles (Table 1). The school nurses were employed in rural, urban, and suburban school districts of different sizes. A total of 3 (18%) partners had a personal diagnosis of type 1 diabetes, giving them the additional role as a patient. Monthly attendance ranged from 15 (88%) to 17 (100%) participants. Personal communications were used to follow up with any partner who could not attend a scheduled meeting.

**Table 1.** SPACE[a] design team community partner roles (n=17).

| Type of partner | Value[b], n (%) |
|---|---|
| **School** | 8 (47) |
| School nurse | 4 (24) |
| Administrator or educator | 4 (24) |
| **Patient or family** | 8 (47) |
| Individual with diabetes | 3 (18) |
| Parents | 4 (24) |
| Community advocate | 1 (6) |
| **Health system** | 6 (35) |
| Diabetes specialists | 2 (12) |
| Diabetes care and education specialist | 1 (6) |
| Social workers | 2 (12) |
| School nurse navigator | 1 (6) |

[a]SPACE: school-partnered collaborative care.

[b]Numbers add to more than 17 as partners could identify with more than one role.

## Intervention Design

At the initial design meeting, participants generated 141 ideas for the SPACE redesign, of which 94 were unique. Partners assigned a numeric prioritization to ideas, which were then condensed to create a list of unique ideas (Multimedia Appendix 1). Higher prioritized design ideas by SPACE category and role from the creative matrix are summarized in Table 2. Many focused on flexibility in scheduling, data sharing and communication during and between meetings, multidimensional outcome tracking, and the team approach with other vested stakeholders. Other ideas included having students lead the SPACE discussions if developmentally appropriate (9 points) and having the school nurse identify barriers to the student's diabetes management in school (8 points).

The research team used these ideas to generate an initial concept, functioning as a low-fidelity prototype, summarizing the SPACE intervention (Multimedia Appendix 2). The concept poster summarized the team members and roles, the structure of and topics addressed during SPACE meetings, and potential outcomes to track for the students. Partners provided a critique using individual text responses on the shared whiteboard, followed by group discussion, aligned with four categories in a feedback capture grid (strengths, limitations, opportunities, and questions; Textbox 1). Identified strengths focused on the ability for "everyone to share ideas at the same time" to streamline communication, give the school nurse personalized diabetes advice, and offer the family a team outside of the hospital. Partners also appreciated the flexibility of meeting scheduling and the emphasis on identifying specific goals that are measurable to help the student "feel good and motivated to move forward." Constructive feedback identified potential challenges at the student, school nurse, and parent levels. For students, these may include the impact of meeting attendance on class time and the willingness to share if the team has too many members. For nurses and parents, these included finding a common time for both meetings and communication between meetings. Additional parent challenges included the financial burden of any recommended referrals and the reliance on disclosure to offer resources. To overcome these, the partners suggested maximizing flexibility in scheduling, offering resources to all parents regardless of disclosure, and determining team size based on student comfort level. Partners also suggested the SPACE intervention consider strategies to incentivize less engaged students and reach out to other school staff with educational activities about diabetes. Questions included how



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meetings would be conducted (eg, the virtual platform), follow-up documentation for team members, what to do if the parent or nurse does not come to the meeting, and what if any communication between visits should be required.

**Table 2.** Representative design ideas from the creative matrix exercise for the SPACE[a] adaptation with associated point totals indicating prioritization[b].

| | Student | Parent | School nurse | Medical team |
|---|---|---|---|---|
| Engagement | • Offer the student incentives (n=8)<br>• Establish criteria for student considered high risk and in need of more support (n=2) | • Flexible scheduling (n=8)<br>• Review different parent motivations to participate (n=2) | • Include a school administrator (n=4)<br>• Identify daytime coverage or availability (n=1) | • Screen for social determinants of health (n=2)<br>• Identify patients at medical appointments (n=2) |
| Structure and content | • Choose one thing to work on at a time (n=4)<br>• Address consistent topics (n=2) | • Parent and school nurse communication plan (n=7) | • Check in with student between meetings (n=8)<br>• School nurse contributes data (n=2) | • Identify education needs of the parent, student, and nurse (n=8)<br>• Adjust written care plans (n=3)<br>• Referrals to other services (2) |
| Outcomes | • Time in the classroom (n=11)<br>• Confidence in skills (n=8) | • Communication with school nurse (n=2) | • Assessment of self-management skills (n=7)<br>• Attendance (n=4) | • Glycemia (n=14) |
| Supports and policies | • Cooperation from peers (n=4) | • Family support and collaboration (n=8)<br>• Person-friendly language (n=1) | • Cooperation from teachers (4)<br>• Support from school administration (n=2) | • Diabetes Medical Management Plan (n=6) |

[a]SPACE: school-partnered collaborative care.

[b]Higher numbers indicate greater prioritization from the study team.

**Textbox 1.** Summary of partner critique to the school-partnered collaborative care (SPACE) concept or low-fidelity prototype.

**Strengths**

- Multidisciplinary approach between school, family, and health care system
- Flexibility in scheduling for school and parent
- Focus on tangible outcomes for the student

**Limitations**

- Student concerns: missed class time, comfort with discussing diabetes in the group setting
- Parents: scheduling, reliance on disclosure to identify supportive resources, financial burden of referrals
- School nurses: scheduling, bandwidth to communicate with parents between meetings

**Opportunities**

- Strategies to incentivize students who are less engaged or experiencing burnout
- Parallel education programs for school staff

**Questions**

- Technical aspects (eg, What platform will be used to share information?)
- Follow-up documentation (eg, Who provides the follow-up calls or evaluation?)
- Meeting no-shows (eg, If key members cannot be at meetings, how will the info be communicated?)

We then generated a more detailed prototype of SPACE using a storyboard, narrating the intervention from the initial recruitment of a student through the first SPACE meeting. Partners were given an opportunity to review the prototype independently. During the meeting, partners were split into small groups to go through the prototype together. In addition to minor changes in word choice, this second review generated six areas in need of clarity: a reference to obtaining parental



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permission, the inclusion of teacher support when applicable, clarifying expectations for parental involvement, giving multiple examples for student diabetes goals, modifying language from barriers to factors which may positively or negatively influence diabetes goal attainment, and promoting changes to a 504 or other written accommodations plan. The final storyboard is included in Multimedia Appendix 3.

Partners identified nine scenarios or tasks for school nurse user testing, including securing protected time to participate, identifying candidate students, approaching families about participation, naming potential diabetes-related issues in school and factors contributing to these, selecting and recruiting additional team members, addressing mental health concerns, and listing activities that they can do with the student to work on diabetes habits between meetings. Recommended strategies to foster implementation in schools included leaning on existing programs (eg, the student assistance team in Pennsylvania) and offering incentives to the school district (designation or certification as a "SPACE" school) or school nurse (continuing education credits for participation).

## Usability Testing

We recruited ten school nurses, each from a different school district in Western Pennsylvania, reflecting diverse experiences with diabetes care and school health (Table 3). School nurses identified many positive aspects of the SPACE model and 16 unique usability concerns. School nurses liked that the intervention offered a streamlined process to communicate with parents and health care providers and often found the time commitment to be realistic and manageable. Each usability issue was identified by between 10% and 60% of testers. The issues aligned with eight categories from Munson et al [30] related to intervention complexity, available time, workflow, existing infrastructure and resources, perceived value, trust between families and school nurses, and reliance on technology. Priority scores ranged from 1.0=lowest priority to 3.0=highest priority. Figure 2 visually displays the relationship between priority ratings and the frequency each issue is reported. There was a moderate correlation ($\rho$=0.63; *P*=.01) between priority rating and the percentage of school nurses reporting the issue. Two usability issues had the highest priority (3.0), including accessing the virtual platform and establishing a secure mechanism for data sharing between the school and health care provider (Table 4). Other higher-priority issues included coordinating meetings, nurse availability or health office coverage, and parent engagement. One issue, teacher or other staff engagement, was frequently reported but was deprioritized by the research team as it was less critical to the success of SPACE.



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**Table 3.** Characteristics of school nurse participants (n=10) for usability tests.

| Characteristic | Value |
|---|---|
| Female gender identity, n (%) | 10 (100) |
| Age (years), mean (SD) | 48.5 (9.5) |
| **Highest nursing degree, n (%)** | |
| Bachelor's degree | 5 (50) |
| Master's degree or above | 5 (50) |
| **School nursing experience (years), n (%)** | |
| <10 years | 3 (30) |
| ≥ 10 years | 7 (70) |
| **Number of schools covered, n (%)** | |
| 1 | 4 (40) |
| 2 | 3 (30) |
| More than 2 | 3 (30) |
| **Geographic setting, n (%)** | |
| Rural | 2 (20) |
| Suburban | 7 (70) |
| Urban | 1 (10) |
| **Grades covered[a], n (%)** | |
| Elementary school | 7 (70) |
| Middle school | 6 (60) |
| High school | 8 (80) |
| **Student caseload, n (%)** | |
| <750 students | 3 (30) |
| 750-1000 students | 2 (20) |
| 1001-1500 students | 5 (50) |
| **Students with diabetes in the past 5 years, n (%)** | |
| <5 students | 4 (40) |
| 5-10 students | 4 (40) |
| >10 students | 2 (20) |

[a]School nurses could select more than one choice, so numbers total to greater than 100%.



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**Figure 2.** Relationship between the percentage of school nurses reporting each usability issue (bar chart) and priority ratings from the research team (line).

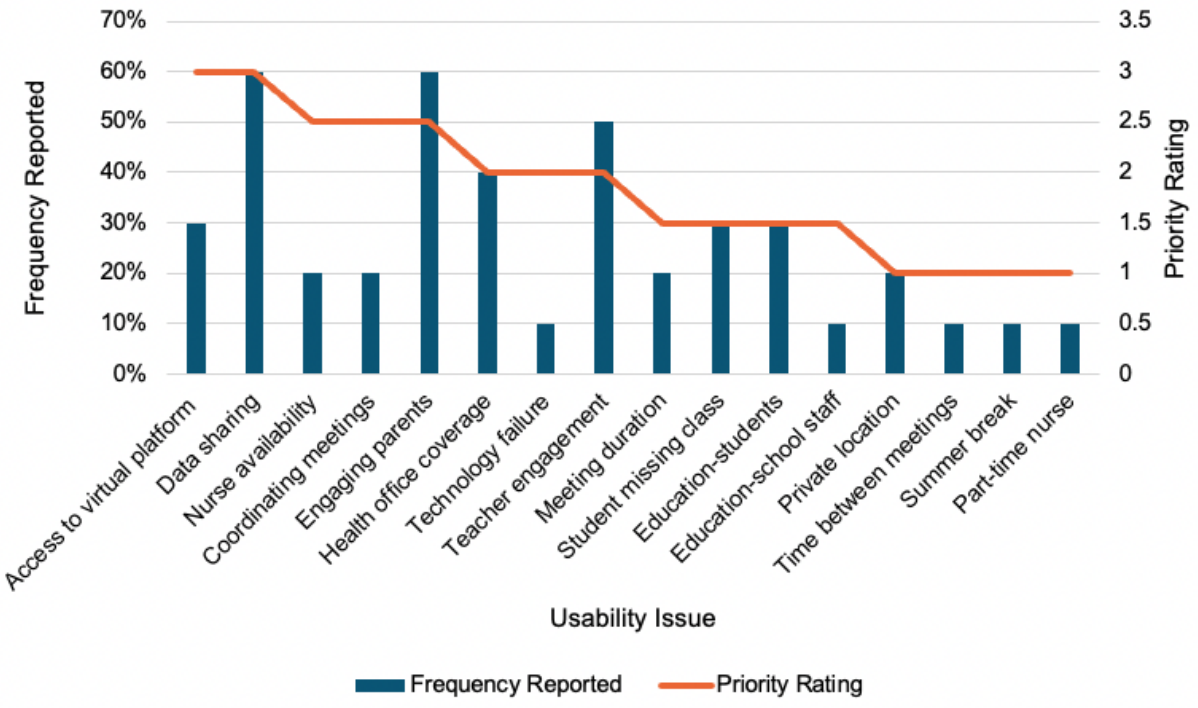



**Table 4.** Summary of case scenario ratings and justifications.

| Scenario | Scenario topic | Rating, mean (SD) | Example comments |
|---|---|---|---|
| 1 | Accommodate SPACE[a] visits in nurse schedule | 4.35 (0.67) | "I can block out time since this would be for a student, so the staff will cover me. The secretary might help with triage and will let teachers know I am busy. The only interruption would be in acute emergencies ... I've done this for students before." [Nurse 1] |
| 2 | Identify students for SPACE | 4.90 (0.32) | "We know our students and can identify who's in need." [Nurse 6] |
| 3 | Discuss SPACE with parents | 4.55 (0.76) | "It's still so new; I need to learn and experience it more to feel comfortable enough to explain it to parents and five all its benefits and value to engage them." [Nurse 7] |
| 4 | Name diabetes-related goals for SPACE | 4.65 (0.47) | "The school nurse is able to look at the medical aspect of blood glucoses, how they're doing, treating, interacting with others, doing at school ... we can look at these areas and set a goal." [Nurse 3] |
| 5 | Identify other school staff to participate | 4.45 (0.69) | "I can look up their schedules and see who teaches the child, who they spend the most time with. I can also check in with the counselors; sometimes they may have a good rapport with the child and their presence would help." [Nurse 2] |
| 6 | Approach other school staff to participate | 4.50 (0.58) | "We're doing it already with 504 plans." [Nurse 9] |
| 7 | Discuss mental health concerns | 4.60 (0.52) | "I'd do it. Mental health is essential." [Nurse 10] |
| 8 | Identify barriers affecting goal attainment | 4.58 (0.55) | "I'd put on a detective hat and go look!" [Nurse 5] |
| 9 | Develop strategies to coach student | 4.38 (0.72) | "That's what I do! This is where I can help educate families about how we do this." [Nurse 4] |

[a]SPACE: school-partnered collaborative care.

School nurses generally indicated a high likelihood of success in the nine case scenarios, with mean Likert scale scores ranging from 4.35 to 4.90 (Table 4). The scenario with the lowest score, scenario 1, related to accommodating the SPACE visits during the school day. Acknowledging the challenge of blocking time for meetings, school nurses identified different workarounds to make time for these meetings, which they commonly use for other types of meetings (eg, for 504 plans). Some suggested having the meeting immediately before or after school, arranging coverage with an administrative assistant or other staff, or



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spacing out visits for different students so they are not on the same day.

IUS scores ranged from 65.0 to 92.5, with an average score of 77.8 (SD 11.1), meeting our predetermined benchmark for acceptable usability [43]. In exploratory analyses, there was no relationship between IUS score and any school nurse characteristics, including years of school nursing experience, student caseload, number of schools covered, or number of students with diabetes in the past five years (Table 5).

**Table 5.** IUS[a] scores by school nurse characteristics.

| Characteristic | IUS score, mean (SD) | *P* value |
|---|---|---|
| **School nursing experience** | | .54 |
| <10 years (n=3) | 74.2 (15.9) | |
| ≥10 years (n=7) | 79.3 (9.5) | |
| **Caseload** | | .12 |
| <750 students (n=3) | 83.3 (15.9) | |
| 750-1000 students (n=2) | 86.3 (1.8) | |
| 1001-1500 students (n=5) | 71.0 (5.8) | |
| **Number of schools** | | .90 |
| 1 (n=4) | 79.4 (12.0) | |
| 2 (n=3) | 75.0 (11.5) | |
| More than 2 (n=3) | 78.3 (13.8) | |
| **Students with diabetes in the past 5 years** | | .83 |
| <5 students (n=4) | 76.3 (9.2) | |
| 5-10 students (n=4) | 80.6 (14.0) | |
| >10 students (n=2) | 75.0 (14.1) | |

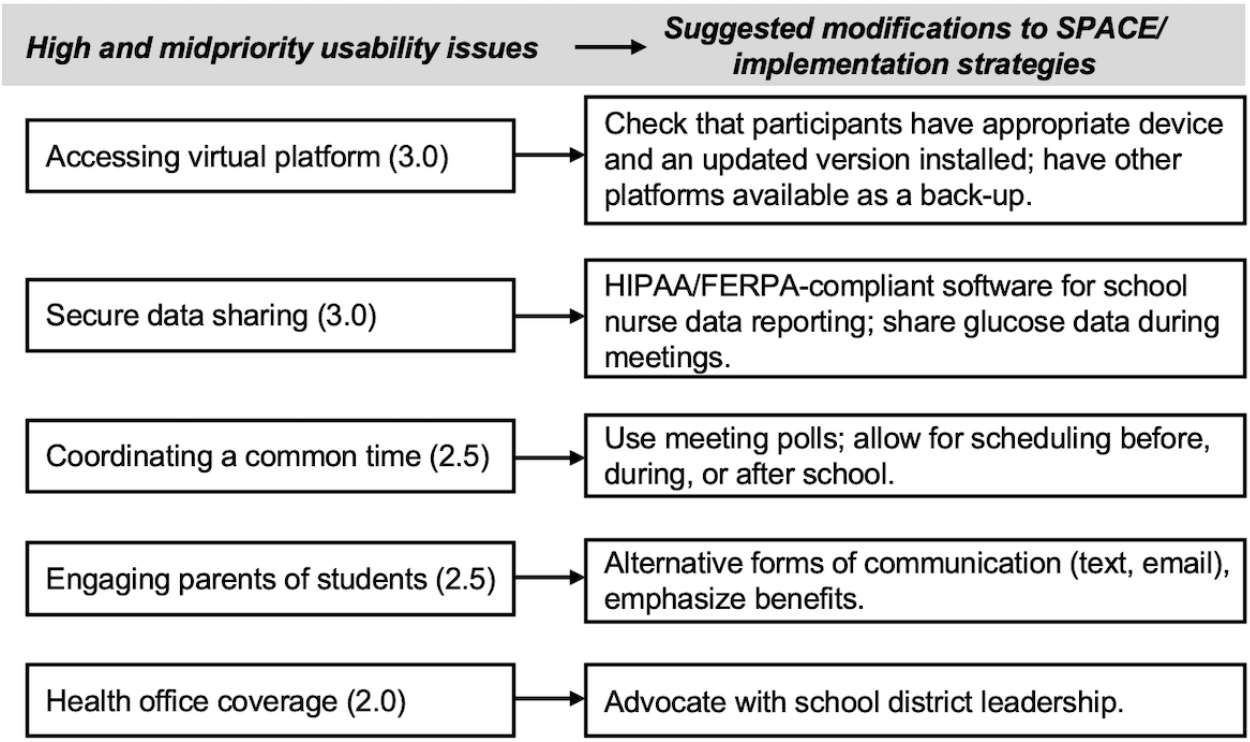
[a]IUS: Intervention Usability Scale.

The usability issues were reviewed by the design team prior to implementation of the SPACE pilot, including high-priority issues (accessing the virtual platform, sharing data) and midpriority issues (coordinating a common time, ensuring health office coverage, and engaging parents). Several suggestions were made by the design team and subsequently implemented in the pilot, including both modifications to the intervention and strategies to implement it. A summary of specific strategies by usability issue is included in Figure 3.



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**Figure 3.** Design team recommendations for SPACE implementation based on high- and midpriority usability issues. FERPA: Family Educational Rights and Privacy Act; HIPAA: Health Insurance Portability and Accountability Act; SPACE: school-partnered collaborative care.




## Discussion

### Principal Findings

School management of diabetes is highly important to the overall care of children with type 1 diabetes, yet school-based or school-partnered interventions remain understudied and underused. Interventions bridging the school and health systems are inherently complex, which may complicate their long-term use [45]. Our proposed modifications exhibited similar complexity, with multiple interacting components that may require organizational or workforce accommodations for implementation [46]. Our process was intended to overcome potential barriers using best practices in UCD [37]. The combination of UCD methods and usability testing with target end users enabled key stakeholders to guide all aspects of intervention design, promoting fitness for the school setting and establishing credibility and trust [27]. Furthermore, our web-based approach, including a shared whiteboard, enabled us to iteratively develop SPACE in a relatively short time with a diverse group of people who often have severe constraints on their time (eg, hospital and school staff). Finally, reviewing the potential usability issues during the design phase helped to refine the prototype in preparation for implementation.

The SPACE model is a fully developed intervention prototype that will bring together the school nurse, parent, and health care provider into a multidisciplinary care team to support students with type 1 diabetes in a structured way. SPACE is based on the CCM for psychosocial interventions, and core components were maintained to the fullest extent possible in the redesign. Patient-centered care was achieved with individualized teams composed of family, diabetes, and school supports. SPACE will allow for multiple referral reasons and sources, in line with population-based care. Measurement-based treatments focused on the evaluation of glycemia, quality of life, self-management skills, and time spent out of class for diabetes management. Finally, evidence-based care was translated to diabetes self-management and education practices.

SPACE is also distinctly unique from the original CCM in the extent to which it accommodates the differing environment (clinic vs school) and diagnosis (depression vs type 1 diabetes). Integrating a CCM into school poses new opportunities to reach a broader network of youth who may be underserved by the health care system. At the same time, there are inherent challenges to medical interventions in school. School health interventions need to consider the educational mission and pertinent outcomes, what medical services may or may not already be in place, and the different needs and wants of students and their parents [24]. Lyon et al [25] proposed key modifications to fit a CCM for the school setting for mental health care, including basing a care manager in school, allowing for flexible entry and treatments for a variety of mental health diagnoses, defining success both academically and medically, and incorporating school-wide supports. We carried these ideas forward to our school adaptation for type 1 diabetes.

Additional modifications to the intervention related to the more "physical" diagnosis of type 1 diabetes, rather than mental health care, though the framework for a school-based CCM nicely aligns with diabetes management. School nurses have frequent contact with these students for day-to-day and emergent care and can easily identify students who may benefit from this additional team support to help them achieve individualized goals [12]. Case management for youth with chronic disease is



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already considered one of the responsibilities of school nursing [47]. In some contrast to the original CCM, we planned for family engagement in SPACE. Parents may be highly involved in diabetes management both at home and at school, particularly for young children. We also allowed for flexible goal identification within SPACE, not solely focused on glycemia. Diabetes treatment is multifaceted, encompassing medication, nutrition, activity, and psychosocial aspects. This lends itself to measuring a variety of school and health-related outcomes to evaluate effectiveness. Our partners felt strongly that diabetes outcomes should include indicators of glycemia, self-management, quality of life, and academics.

The strengths of the SPACE model, identified by the design team and usability tests, focused on the core function of the multidisciplinary team. Having a common space for the student, school nurse, parent, and health care provider to meet was viewed as streamlining communication, giving personalized training to the school nurse, and building trust among all parties. The entirely technology-based SPACE intervention also heightened the perceived usability among school nurses and our design team. With increasing comfort with digital platforms generally, this condition was seen as more feasible for working parents and less intrusive to the school day. The design team had several unexpected suggestions. Some felt strongly the SPACE team should regularly include other school supports, including administrators, who may be less involved in day-to-day care. Others highlighted the role of school nurses to screen for social determinants of health that may influence diabetes management and offer universal resources to families to promote health equity. In usability testing, the SPACE model resonated with school nurses, who frequently described the activities as being within the scope of their role as a medical professional.

Despite the perceived advantages of the SPACE model, our usability testing did identify potential issues to be addressed prior to pilot-testing. The highest priority issues were feasible to address, including preparing school nurses and families to access the virtual platform and organizing secure tools for school nurses to share data with the research team. Other less pressing feedback related to intervention complexity includes coordinating a common time, engaging parents, and ensuring health office coverage. Solutions for these usability issues may need to be customized for different schools to carry out the core components of SPACE. Such an approach is acceptable and often necessary to promote the adoption and sustainability of complex interventions that are appropriately fit to the local context [46]. Though this may result in a tailoring of implementation strategies, adjusting features such as the virtual platform and processes for data collection will not alter the core functions of the intervention.

The iterative design cycles conducted over Zoom contributed to an efficient process, with all activities concluding within 6 months. We used several strategies to promote equitable cocreation practices and foster mutual trust and empathy among the community partners despite the web-based setting [48,49]. We demonstrated equity by including representation from different roles in the school and health system, as well as parents and individuals with type 1 diabetes, and compensating partners for their time and contributions. We addressed potential power imbalances by offering individual and group activities, including asking all parties to vote on ideas to limit the influence of any dominant voices. Applying a web-based format with two meeting options per month lowered barriers to participation like finding childcare, transportation costs, and time needed to participate. We emphasized reciprocity by summarizing and sharing back their comments and how these changed the prototype over time. We hoped to create a personalized and transformative experience by equipping them to participate in research in the future with research ethics training. Among the partners, many agreed to continue serving on a community advisory board, one school nurse volunteered her district to pilot-test SPACE, and a diabetes health care provider agreed to serve as an ongoing study consultant. Finally, we facilitated relationships by learning each other's stories and personal motivations for joining this team.

## Limitations

The SPACE intervention was designed with community partners in a specific geographic area affiliated with our health system. Though this was intentional to ensure fit to our context, this may limit the generalizability of SPACE to other settings where there may be differences in school systems (eg, school health policy, ability to delegate insulin and glucagon, and school health staffing) or health systems (eg, size and resources of the diabetes center). We sought perspectives from nurses in different school districts to get broad representation from our region, though this is still reflective of Pennsylvania, specifically, and state laws may vary. Pennsylvania is one of 35 states with school nursing requirements, and like most states, the delegation of insulin and glucagon to trained lay staff is permitted. Depending on laws in other states, translation of SPACE may require an initial evaluation of the local policy, perceived barriers, and necessary modifications prior to implementation.

A second limitation relates to the composition of our design team. Though we included young adults with type 1 diabetes, we did not rigorously incorporate perspectives of youth with diabetes. Our parent participants did informally discuss the intervention with their children between design meetings, which they shared with us. The SPACE intervention will be piloted with elementary and middle school–aged children (12 years of age or younger), and children in this age group may not have been able to participate in our activities as designed. Older teens were not included as developmentally, their priorities for diabetes management in school will differ from those of younger children who are more reliant on their parents and school nurses.

Finally, the identification of usability issues is inherently a subjective process. It is possible that additional usability issues will arise in future testing. However, a strength of this study was the inclusion of school nurses and other roles from different school districts in our state.

## Comparison With Prior Work

SPACE represents a shift from other school-based diabetes interventions by integrating school nurses into the diabetes medical team with parental support and establishing continuity in that relationship. Prior interventions have focused on school



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nurses alone, including delivering educational tools and curricula, case management, or engaging school nurses to deliver some diabetes tasks (downloading devices and giving long-acting insulin) [50-53]. Other interventions offer visits from diabetes providers in the school setting, such as self-management education and telemedicine [54,55]. Generally, these interventions have improved school nurse's knowledge of diabetes, and some have demonstrated a small improvement in hemoglobin $A_{1c}$ [53,55]. To date, there is limited data on the sustainability or impact of prior interventions, and none are endorsed by leading diabetes organizations as best practices. In contrast, school-based asthma interventions are better studied. Asthma interventions that emphasize care coordination and parent engagement have demonstrated a reduction in hospital admissions and improvements in asthma-related quality of life [56]. A core pillar of the Centers for Disease Control and Prevention–sponsored asthma-friendly schools program is the coordination of school, family, and community efforts to better manage symptoms and reduce absenteeism. The use of UCD methods for co-design, paired with the USE-EBPI, will hopefully enhance the potential reach and impact of SPACE in future testing.

## Conclusions

We present the iterative cocreation of SPACE, a multidisciplinary, goal-directed, school-partnered diabetes intervention based on the evidenced-based CCM for depression management. Relying on UCD methodology, we involved diverse community partners at all phases of the intervention design with the consolidation of ideas on a final prototype that is ready for formal testing. Our use of videoconferencing and shared digital whiteboards enabled diverse participation in a relatively short time interval. The USE-EBPI methods for usability testing helped to evaluate the quality of our design process, establishing a bridge between UCD and IS research. The quantitative indicators suggested a high degree of usability among school nurses of different backgrounds, which was reflected in their comments about how they would operationalize SPACE in their school district. Though cross-sector interventions are by their nature complex, this staged approach to intervention adaptation and preliminary testing may help to overcome barriers and establish a strong foundation for future implementation.

## Acknowledgments

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## Data Availability

The datasets generated or analyzed during this study are available from the corresponding author upon reasonable request.

## Authors' Contributions

CAM was responsible for the conceptualization of the study, methodology, software, formal analysis, investigation, writing (original draft), and funding acquisition. EN was responsible for methodology, investigation, and writing (review and editing). IL, EM, and ARL were responsible for conceptualization, supervision, and writing (reviewing and editing). LS was responsible for supervision and writing (reviewing and editing). CNP was responsible for methodology and writing (reviewing and editing).

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Images representing Mural design activities in session/cycle 1. The first image displays a sample creative matrix with design ideas; the second image adds the priority ranking, represented by the red and blue dots to indicate first and second priority, respectively.
[PNG File , 346 KB - diabetes_v10i1e64096_app1.png ]

Multimedia Appendix 2
Low-fidelity prototype (concept poster) of the SPACE intervention for critique in session/cycle 2. SPACE: school-partnered collaborative care.
[PDF File (Adobe PDF File), 9693 KB - diabetes_v10i1e64096_app2.pdf ]

Multimedia Appendix 3
Narrative storyboard of the "SPACE for type 1 diabetes" prototype used for cognitive walkthroughs to assess usability with school nurses. SPACE: school-partnered collaborative care.
[PDF File (Adobe PDF File), 5077 KB - diabetes_v10i1e64096_app3.pdf ]



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## Abbreviations

**CCM:** collaborative care model
**IS:** implementation science
**IUS:** intervention usability scale
**SPACE:** school-partnered collaborative care
**UCD:** user-centered design


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Original Paper

# The Role of Community Health Workers in Improving Diabetes Device Use Among Youth With Type 1 Diabetes: A Web-Based Qualitative Study Using Human-Centered Design With Clinicians

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## Abstract

**Background:** Inequity in diabetes technology use persists among Black and Hispanic youth with type 1 diabetes (T1D). Community health workers (CHWs) can address social and clinical barriers to diabetes device use. However, more information is needed on clinicians' perceptions to inform the development of a CHW model for youth with T1D.

**Objective:** This study aimed to identify barriers to diabetes technology use and cocreate solutions in collaboration with diabetes and school-based clinicians serving Black and Hispanic youth with T1D.

**Methods:** Using human-centered design, the study team conducted 2-hour web-based workshops with clinicians from a diabetes clinic or school-based clinics at a safety net hospital in the Bronx, New York. The workshops promoted active ideation of barriers and co-design of a CHW intervention prototype to address self-reported challenges. Workshops were analyzed using a qualitative inductive approach.

**Results:** A total of 17 participants completed the human-centered design workshops and surveys. Of these, 11 (65%) were clinicians from the diabetes clinic and 6 (35%) were school-based clinicians from elementary, middle, and high schools in the Bronx. A total of 4 workshops were conducted. The perceived diabetes device barriers for youth with T1D and their families by participants were general health-related social needs (HRSNs) and diabetes technology–specific HRSNs that interfered with technology uptake, such as housing and financial insecurity, as well as digital social needs; and difficulty navigating health care systems, insurance, and pharmacy benefits due to the high level of care coordination required by caregivers. In addition, the participants identified barriers that interfered with their ability to support youth with T1D with diabetes technology, such as limited support for using diabetes technology in school and lack of time and technology support to troubleshoot problems in diabetes clinics. Ways in which a CHW could help mitigate these barriers include (1) identifying and addressing HRSNs by directing patients to appropriate resources; (2) providing peer support for caregivers to navigate diabetes device logistics; (3) acting as a school liaison to improve communication and coordination between caregivers, schools, and diabetes clinicians; and (4) offering administrative support to offload the logistical burden of clinicians.

**Conclusions:** Important needs related to specialized technology support, enhanced care coordination, family-clinician communication, and administrative task shifting were identified by clinicians to inform a CHW model for youth with T1D. Continued co-design and pilot testing are needed to refine the model.



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**KEYWORDS**

diabetes management; diabetes technology; health disparities; type 1 diabetes

## Introduction

### Background

Type 1 diabetes (T1D) is one of the most common chronic illnesses in youth, impacting 304,000 children and adolescents aged <20 years in the United States, most of whom spend the majority of their time in schools [1]. Managing T1D is particularly challenging, as it involves carbohydrate counting, insulin dosage calculations, frequent glucose monitoring, and attention to physical activity [2]. As a result, it is not surprising that 82% of youth with T1D do not achieve the glycemic target of hemoglobin $A_{1c}$ of <7% recommended by national and international guidelines [3-5]. In addition, significant inequity exists in glycemic outcomes among different demographic groups, with non-Hispanic White youth having 1.34 greater odds of achieving hemoglobin $A_{1c}$ <7% compared with Black and Hispanic youth [6].

Diabetes technologies such as insulin pumps, continuous glucose monitors, and automated insulin delivery systems can reduce the burden associated with diabetes management and improve the quality of life in youth with T1D [7-11]. However, Black and Hispanic youth with T1D are less likely to initiate and use them compared with non-Hispanic White youth with T1D, regardless of socioeconomic status [12-15]. Increasing diabetes device use in this population is a potential mechanism to reduce inequity in health outcomes.

Numerous studies have explored social-ecological factors that contribute to lower device uptake among Black and Hispanic youth with T1D [16-20]. Key findings include the impact of longstanding structural inequities, structural racism, physician bias, unmet social needs, barriers at school, and challenges related to care coordination [6,21-23]. Recognizing that these barriers exist at individual, family, and community levels, community-based interventions can be used to address these barriers in the environments where Black and Hispanic youth with T1D spend the majority of their time, such as school settings.

A community health worker (CHW) model is a potential community-based intervention that can address inequity associated with diabetes technology use. CHWs are trusted community members who can provide various services, ranging from basic patient education to social needs support to linking different care sites, such as schools and clinics [24-28]. For example, previous CHW interventions for youth with asthma have demonstrated significant reductions in acute care use, inpatient hospitalizations, days with symptoms, missed school days for children, and missed workdays for caregivers [24,27,29-31]. The success of the CHW model in other chronic childhood conditions suggests that a CHW care model can potentially improve diabetes device uptake and health outcomes in Black and Hispanic youth with T1D.

### Objectives

However, to actualize such a model for youth with T1D, it is necessary to understand how the CHW specialty care model can address specific barriers related to diabetes technology for clinicians, particularly in the clinic and school settings. Garnering perspectives from multidisciplinary clinicians who provide health care to these children in those settings could help fill this gap in the literature. Guided by human-centered design [32] and diabetes technology journey framework [33], this study aimed (1) to identify diabetes and school clinicians' perspectives on barriers to diabetes device use among Black and Hispanic youth with T1D and (2) to help design a prototype of a CHW intervention to address these challenges.

## Methods

### Design

Given that the study aims to explore ways a CHW can address diabetes device barriers at diabetes and school-based clinics, the study was performed from a pragmatist point of view using a general inductive approach. The Standards for Reporting Qualitative Research checklist for qualitative research reporting was used for this report.

### Participants and Setting

The Children's Hospital at Montefiore Einstein (CHAM) is a safety-net hospital in the Bronx, New York, part of the Montefiore Health System. The demographics of patients receiving care at CHAM consist of approximately 30% Black and 55% Hispanic, with most of the patients on public insurance. The New York Medicaid plan covers the majority of the costs associated with diabetes technology. The Montefiore School Health Program (MSHP), a branch of the Montefiore Health System, is the most extensive school-based health program in the United States [34]. MSHP provides coordinated primary care and preventative services (eg, physical examinations, immunizations, dental care, and mental health) as well as urgent care and referrals to subspecialists for school-aged children and adolescents in the Bronx [34]. School-based health programs in New York City have been shown to reduce school absences, parents' time away from work, and hospital visits [35]. Services through the program are performed by physicians, nurse practitioners (NPs), and physician assistants.

Participants were diabetes clinicians employed at CHAM diabetes center (physicians, NPs, certified diabetes care and education specialists, social workers, and psychologists) or clinicians from the MSHP who provide care to Black or Hispanic youth with T1D aged 2-17 years. A staff member from MSHP helped identify potential MSHP clinicians, and CWC identified potential CHAM diabetes clinicians. Participants were recruited via flyers, emails, and word of mouth. Convenience sampling was used. Individuals interested in the study contacted



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the study coordinator (MGM). Participants were recruited from CHAM or MSHP in person at the clinic or over the phone.

### The Research Team

The research team included an early-career pediatric endocrinologist at CHAM (CWC), a senior pediatric endocrinologist (LL), a pediatric endocrinology fellow at CHAM (AJD), a study coordinator at CHAM (MGM), a general pediatrician (MR), and an adult endocrinologist (SA). The research team had extensive experience in all aspects of the study, including human-centered design (CWC, AJD, and SA), qualitative research (CWC, AJD, LL, MGM, MR, and SA), health services research (CWC, LL, MR, and SA), school-based interventions (CWC and MR), and type 1 clinical diabetes research (CWC, AJD, LL, and SA). A few study team members (CWC and AJD) work closely with clinicians from CHAM; however, the research team did not have relationships with clinicians from MSHP. Three study team members performed the workshops, with each workshop including 2 of the 3 personnel (CWC, AJD, and MGM).

### Human-Centered Design Web-Based Workshops

The multidisciplinary research team created the web-based interactive workshop using literature review, advisory boards, and clinical expertise. The human-centered design framework helped inform the workshops. Human-centered design relies on 3 steps: (1) understanding barriers from the target users; (2) analyzing and synthesizing to identify the main obstacles related to the issues; and (3) discussing and co-designing solutions with other attendees to the identified challenges, with specific details discussed such as who would deliver the intervention, when, to whom, and how [32]. This approach has been used previously to elicit perspectives from young adults with T1D [33] and caregivers of youth with T1D [23] on diabetes technology barriers and to cocreate solutions to address these barriers. The workshop materials were created over 2 months and practiced internally through mock sessions before deployment. These sessions helped to provide additional feedback, polish the materials, and effectively deliver the content.

The workshop was divided into 2 main activities. During the first activity, participants were introduced to the diabetes technology journey framework, which is defined as three stages: (1) learning and deciding to get technology; (2) getting and starting to use the technology; and (3) managing problems with technology [33]. Participants were asked to share barriers associated with each step of this process from their perspectives and their patients' experiences.

In activity 2, participants prototyped the CHW intervention to address HRSNs and to support families and clinicians with the challenges identified in the first activity. They were asked to brainstorm specific ways that a CHW could address barriers affecting families of youth with T1D, as well as their barriers to prescribing diabetes devices and supporting families with device use. The participants' real-time responses were shared on the screen to facilitate discussion. The interview guide for activities 1 and 2 from the workshop is shown in Table 1 and Textbox 1.

**Table 1.** Participant interview guide for activity 1.

| Stages | Main questions | Prompting questions |
|---|---|---|
| Stage 1: learning about and deciding to get technology | • What things have parents/guardians shared with you that make caring for diabetes hard?<br>• What has been your experience with diabetes technology so far?<br>• What are things that helped with learning about and deciding to get/prescribe diabetes technology?<br>• What got in the way of learning about and prescribing diabetes technology? | • How did you learn about technology?<br>• What resources were provided to patients to learn about tech?<br>• How could you help patients navigate pros/cons of diabetes technology?<br>• How do you decide to prescribe tech? |
| Stage 2: getting and starting to use technology | • What are things that helped you/your patients get and start using diabetes technology? | • How did patients learn to manage diabetes in a new way?<br>• How did you learn how to use diabetes technology? |
| Stage 3: managing problems and situations with technology | • What are things that helped you/your patients manage and troubleshoot problems after starting diabetes technology?<br>• What are things that got in the way of managing and troubleshooting problems after starting diabetes technology? | • How do you figure out technical problems?<br>• How do you manage social situations?<br>• How do your patients decide to stop or keep diabetes tech?<br>• How has technology changed diabetes care? |

**Textbox 1.** Participant interview guide for activity 2.

**Activity 2: participant perceptions of a community health worker (CHW)**

- What is your perception of a CHW?
- How can a CHW help with social needs?
- How can a CHW help families on their diabetes technology journey?



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### Procedure

Workshops were held on a privacy-protected video platform and video-recorded for analysis purposes. Baseline data on practice location, duration of practice, and demographics (credentials, practice location, and years of practice) were collected using REDCap (Research Electronic Data Capture; Vanderblit University) [36,37] questionnaires completed by participants.

### Ethical Considerations

This exploratory study was approved by the Institutional Review Board of the Albert Einstein College of Medicine (2022-14609). Participants were provided with information about the study. All participants provided written or oral informed consent per institutional review board approval. All study data have been deidentified to protect the privacy and confidentiality of the participants. Sensitive content was redacted from the transcripts to avoid identification. Participants who completed the 2-hour workshop and survey were each provided with a US $100 gift card as compensation.

### Qualitative Analysis

Workshops were recorded, transcribed, and coded in NVivo [38]. Three coders (CWC, AJD, and MGM) analyzed the workshops using a general inductive approach [39]. In activity 1, a coding structure with categories for barriers to diabetes technology use was created. In activity 2, categories for solutions using the CHW intervention were generated. The coding framework was updated with emergent codes, and codes were unified according to similarities. Overlapping concepts were developed into themes, with workshops continuing until thematic saturation was reached [40]. Information was obtained directly from clinicians who interact frequently with Black and Hispanic youth with T1D and their caregivers to ensure credibility. A senior team member reviewed the themes created by the 3 main coders, providing dependability and ensuring the methodology was followed appropriately. An audit trail was kept to track coding decisions.

### Quantitative Analysis

Results from the self-reported questionnaire were analyzed in Microsoft Excel and are presented as the mean (SD) for continuous variables. For categorical variables, frequencies or proportions are reported.

## Results

### Overview

Overall, 17 participants completed the human-centered design workshops and surveys. Of these, 11 (65%) were clinicians from the diabetes clinic and 6 (35%) were school-based clinicians from elementary, middle, and high schools in the Bronx. Descriptive data for participating clinicians are presented in Table 2. A total of 4 workshops, 3 groups with participants from the diabetes clinics and 1 with school-based clinicians, were conducted between September 2023 and December 2023. Each group had 3-6 participants.

In total, 4 key barriers and their corresponding solution themes were identified. Figure 1 represents the cocreated solutions by the clinicians.

**Table 2.** Participant demographics (N=17).

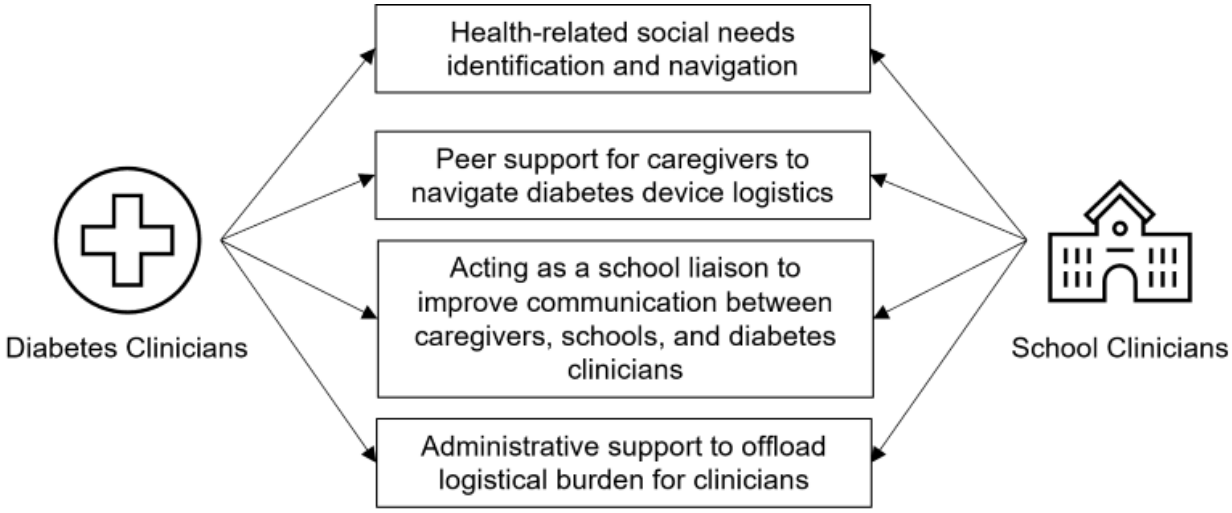
| Demographics | Participants |
|---|---|
| **Participant clinical role, n (%)** | |
| Physician | 9 (53) |
| Nurse practitioner | 6 (35) |
| Psychologist | 1 (6) |
| Social worker | 1 (6) |
| **Practice location, n (%)** | |
| Clinic | 11 (65) |
| School | 6 (35) |
| Licensed CDECS[a], n (%) | 2 (12) |
| Practice duration (y), mean (SD; range) | 10.8 (9.3; 2-34) |

[a]CDECS: certified diabetes care and education specialist.



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**Figure 1.** Cocreated solutions from the human-centered design workshops with diabetes and school clinicians.




Clinicians identified two key barriers to the diabetes technology uptake and use for youth with T1D: (1) general and specific HRSNs interfering with diabetes technology; and (2) difficulty navigating health care systems, insurance, and pharmacy benefits for youth and their families. In addition, clinicians identified barriers that interfered with supporting their patients with diabetes technology, including limited technology support and infrastructure to support diabetes technology use in school and lack of technology support and time to troubleshoot diabetes devices in diabetes clinics.

## Caregiver-Centered Barriers and Solutions From the Clinicians' Perspectives

### *Barrier 1: General and Specific HRSNs That Interfered With Diabetes Technology Uptake*

Most participants (12/17, 71%) recognized that general HRSNs such as housing and financial insecurity presented a major barrier to diabetes device use for youth and their families. For diabetes technology–specific HRSNs, participants (5/17, 29%) acknowledged that digital social needs, such as not having access to a compatible smartphone, impacted whether youth with T1D received the full benefit of the automated insulin delivery system.

> *When we did telehealth, it was like a huge wow! We're seeing into their homes for 30 min or an hour.... That was a big deal, seeing where people were living.... No wonder... they don't care about diabetes.... They're all sleeping on one mattress... that's an issue.* [Diabetes clinician #1]

> *They had to pay out of pocket for... some supplies and insulin, so the mother would ration the insulin...so there were times where he wouldn't come with his pump at all...Nothing would be connected, and...we wouldn't find out till 12-1 o'clock and his sugar be unreadably high.* [School clinician #4]

> *A lot of the Android phones aren't compatible with some CGMs [continuous glucose monitors], like even the newer ones.... And that can play actually into socioeconomics... because the Androids are cheaper than iPhones.* [Diabetes clinician #7]

### *Solution 1: HRSN Identification and Navigation*

When presented with the general CHW model, participants (7/17, 41%) identified how this additional person could ease the diabetes technology journey for caregivers by assisting those with social needs.

> *There is really a need for... a one-on-one connection with someone who is linked to both the medical side and the community side. Because you can just... bang your head against the wall... feeling like you're trying to support people, but they're just running into barrier after barrier... and I can't imagine how they feel, you know.* [School clinician #1]

> *Just being a resource. A lot of times people don't access services because they're not aware that [services] are available.* [School clinician #2]

> *A [CHW] could help direct families on a place to get [the correct type of smartphone] at... low cost or just help them navigate which ones would work [with diabetes devices].* [Diabetes clinician #2]

### *Barrier 2: Difficulty Navigating Health Care Systems, Insurance, and Pharmacy Benefits*

Participants recognized families' challenges with maintaining adequate device supplies (7/17, 41%). Participants from diabetes clinics emphasized the high level of organization that T1D requires from caregivers. Some participants (9/17, 53%) felt that certain families lacked a sense of empowerment or self-efficacy to manage the responsibilities associated with device use.

> *Not knowing what to do if they run out of supplies or knowing how... to manage supplies in general and stuff... that's the biggest issue with technology or diabetes supplies.... They don't understand how to use the system to get supplies...* [Diabetes clinician #1]

Participants (8/17, 47%) described families struggling with care coordination, which hindered the family's ability to facilitate consistent technology use.



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> *Some families are very good about calling in and going over those problems. I think other families kind of have, like a defeatist attitude. And they're like, they can't figure it out...and they just give up and stop working with the technology.* [Diabetes clinician #3]

> *Communication with the pharmacy, because... when they need another refill... the pharmacy, doesn't just automatically send that out. They require that the parent call and sometimes there's confusion if there's... a prior authorization needed, and it needs to be renewed. Some parents are not as comfortable... reaching out to the pharmacy...* [Diabetes clinician #4]

### *Solution 2: Peer Support for Caregivers to Navigate Diabetes Device Logistics*

To address challenges related to maintaining diabetes supplies and health care navigation, most participants (15/17, 88%) thought enhanced care coordination was needed to target issues families experience with pharmacies, insurance, and supply management.

Diabetes clinicians proposed having a "diabetes coach" to review technology education, keep track of appointments and device refills, and empower families to call the clinic, pharmacy, and diabetes device and insurance companies promptly (5/17, 29% overall and 45% of diabetes clinicians).

> *Helping families... make schedules... to like organize medications, know when things are expiring... For the disorganized families who don't pay attention to when refills are due, like helping them kind of develop a strategy so that things don't expire, and that they're not waiting to the last minute for refills.* [Diabetes clinician #3]

> *Calling with the families..., being supportive and allowing the parent to make the phone call but being there with them to help support that.* [Diabetes clinician #4]

> *It's the notion of catching things when they're a small problem before it becomes a big problem.... If you have someone that you can go to, who you feel...you can share and can help to advocate...prevent some major catastrophes.* [School clinician #3]

## Clinician-Centered Barriers and Solutions

### *Barrier 3: Limited Support to Use Diabetes Technology in School*

Participants from the diabetes clinic (5/17, 29% overall and 5/11, 45% of diabetes clinicians) felt burdened with the responsibility of responding to calls from school personnel regarding troubleshooting diabetes devices, educating school personnel on diabetes technology, and completing the required paperwork for diabetes management in school.

> *I still get a lot of calls, because the [school] nurse may not really understand how to use the technology. And, you know they don't feel comfortable...they're not touching the [CGM] or anything.... For some patients that I've worked with has resulted in... missing class, because maybe the monitor is going off or, for example, the pump, if the blood sugar is high...* [Diabetes clinician #4]

> *There's a patient who...it's very frustrating for the parent in terms of what's going on at school...So I think that's a barrier in terms of... miscommunication between school nurses and how to manage diabetes.... And then the burden falls on the parent because they call this parent frequently...* [Diabetes clinician #5]

School-based clinicians reported feeling overwhelmed by the wide varieties of diabetes technologies encountered in school clinics and expressed a lack of familiarity with all available devices (6/17, 35% overall and 6/6, 100% of school-based clinicians). In addition, the school-based clinicians (3/17, 18% overall and 3/6, 50% of school-based clinicians) emphasized the disruptions these diabetes technology malfunctions caused for the student and school-based clinics.

> *My patient has [a CGM] but it doesn't talk to her insulin pump and I... have trouble wrapping my brain around that because I know that there's... closed loop circuits.... One of the things that gets in the way of learning about tech is...there are so many options out there in the market. There's not just like A-B-C, there's just many, many things, and it's always evolving and changing.* [School clinician #4]

### *Solution 3: Acting as a School Liaison to Improve Communication Between Caregivers, School, and Diabetes Clinicians*

Some diabetes clinicians (3/17, 18% overall and 3/11, 27% of diabetes clinicians) endorsed redistributing some of the administrative work associated with diabetes management at school to a CHW. In addition, participants mentioned that CHWs could also help educate caregivers about their rights at school.

> *Helping parents ask for those school medical accommodation (504) meetings. I don't think parents necessarily understand that it's their right to ask for those things even though we try to tell them...* [Diabetes clinician #3]

On their part, school-based clinicians (4/17, 24% overall and 4/6, 67% of school-based clinicians) were enthusiastic about the potential to collaborate with CHWs, and they (6/17, 35% overall and 6/6, 100% of school-based clinicians) expressed a desire for additional training, especially on their students' specific diabetes devices.

> *Let's just say [the CHW] came to the school and educated. It would be a little bit more personalized and tailored to maybe that kid's specific pump because there's so many pumps.... My head spins when they're educating us about a million pumps, so it would be nice if they were able to come to the school.* [School clinician #4]

> *I think that just being a liaison between a parent and whatever they're trying to do, whether it's*



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*pharmacy,... their doctor,... their school... just helping to get that access point.* [Diabetes clinician #1]

### *Barrier 4: Lack of Time and Technology Support to Troubleshoot Problems in Clinic*

Most diabetes clinicians endorsed difficulties troubleshooting diabetes technology and keeping updated with technological advances (4/17, 24% overall and 4/11, 36% among diabetes clinicians). In addition, participants expressed frustration over the time-intensive nature of discussing and troubleshooting diabetes devices (7/17, 41% overall and 7/11, 64% among diabetes clinicians).

*There's so many other things to address/time.... For example, today I feel awful...I had a kid whom I had never met, on a closed loop, and I literally could have done so much more for him...I just had no time.* [Diabetes clinician #6]

*The biggest barrier is like just helping people troubleshoot things at the beginning... when things don't go well at the beginning, I feel like that just leads to long term problems.* [Diabetes clinician #3]

### *Solution 4: Administrative Support to Offload Logistical Burden for Clinicians*

Overall, diabetes clinicians agreed (6/17, 35% overall and 6/11, 55% among diabetes clinicians) that access to a specialized CHW who could provide diabetes device support would save time and improve the diabetes technology experience for both youth with T1D and their clinicians.

*It is nice when we have someone with us in clinic who does have that time to spend.* [Diabetes clinician #3]

*I think having someone who can closely follow... and then also just having time or someone to spend time going over the technology... but it doesn't necessarily, I think, have to be a provider.* [Diabetes clinician #3]

Furthermore, participants (4/17, 24%) emphasized the importance of interactive and hands-on diabetes technology training to feel more confident. Two diabetes clinicians stated that wearing devices themselves greatly enhanced their learning.

## Discussion

### Principal Findings

This study presents the perspectives of diabetes and school-based clinicians on solutions that a CHW can deliver to address barriers associated with diabetes technology use among Black and Hispanic youth with T1D. Four key solutions emerged: (1) HRSN identification and navigation; (2) peer support for caregivers to navigate diabetes device logistics; (3) acting as a school liaison to improve communication between caregivers, schools, and diabetes clinicians; and (4) administrative support to offload the logistical burdens of clinicians.

Regarding HRSNs, previous literature has shown that HRSNs can interfere with diabetes technology use [33,41,42]. However, few studies explored the impact of HRSNs on diabetes device use in school settings. Our study found that school clinicians faced challenges related to both general and diabetes technology–specific social needs. School clinicians often lack the time or support to manage these HRSNs. As a result, HRSNs can disrupt the student's education and increase the workload for school clinicians. Therefore, our participants proposed involving a CHW to perform social care navigation. Although a CHW's core role is to provide social care navigation [43], they can serve as a bridge between schools with hospital systems to address HRSNs [44], making this a compelling solution.

In addition, the participants recognized that many caregivers struggled with the organizational skills required to manage diabetes technology, often leading to inconsistent use. They envisioned a new diabetes team member who could function as a peer mentor to empower families to perform care coordination. Previous studies have employed CHWs to encourage disease self-management using motivational interviewing techniques [45]. CHWs are ideal candidates to be health coaches or deliver motivational interviewing techniques because they are trusted community members [43]. They have the potential to positively impact youth with T1D and their caregivers to manage diabetes technology independently.

Regarding the lack of diabetes support in school, diabetes clinicians also desired someone to help caregivers advocate for their child's rights in the school setting. Despite encouragement from the medical team, caregivers do not always seek school medical accommodations for unclear reasons. While this study did not explore the causes, possible challenges may include mistrust in the health care and education systems, language barriers, low medical literacy, and competing priorities [46,47]. Given their shared experiences with caregivers and ability to foster trust [33,43], CHWs may be more effective in motivating caregivers to seek additional school services (eg, attend medical accommodation meetings).

Regarding troubleshooting diabetes technology, both clinician types requested ongoing education, specifically more hands-on opportunities. While web-based interventions have risen in popularity for diabetes device education [48-51], our study found that clinicians strongly prefer in-person training. In addition, diabetes clinicians emphasized the importance of wearing the technology on their bodies as part of their learning process. The opportunity to wear diabetes devices should also be offered to school clinicians to increase their understanding and confidence in using diabetes technology. In addition, school clinicians desired personalized training tailored to their students' specific devices. While most CHW interventions focus on educating patients, a study found that CHWs were open to collaborating and educating school nurses [52]. Furthermore, our findings suggest that school-based clinicians are receptive to a CHW educating them on diabetes devices, specifically their student's devices. However, there are some reservations from both school and diabetes clinicians regarding the CHWs' level of training in diabetes technology [53].

### Limitations

Our study has several limitations. First, the present analysis was based on the clinicians' perspectives and did not elicit the perspectives of other school personnel, including teachers or paraprofessionals. Future efforts should include these additional



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stakeholders to ensure the feasibility and buy-in of the intervention across all groups. Second, participants were allowed to brainstorm freely without considering the limitations of a CHW role, which was consistent with human-centered design principles [32]. The authors recognize that it may not be possible for CHWs to perform all the solutions presented. However, allowing participants to cocreate solutions without restrictions enabled the study team to fully understand participants' perspectives.

## Conclusions

In conclusion, this study used a novel human-centered design methodology to better understand barriers to diabetes technology use for Black and Hispanic youth with T1D from the perspectives of their diabetes and school-based clinicians. In addition, this workshop encourages CHW intervention prototyping to overcome perceived barriers. Including the perspectives of diabetes and school-based clinicians in the design process may help enhance the feasibility and acceptability of a future T1D CHW care model that aims to connect clinics and schools. The next step is to integrate the perspectives of caregivers and youth with T1D on a T1D CHW specialty care model, as their insights will further enrich the intervention development.

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## Data Availability

Some or all datasets generated during or analyzed during this study are not publicly available but are available from the corresponding author on reasonable request.

## Authors' Contributions

CWC and SA conceptualized the study. CWC, AJD, and MGM performed data collection; reviewed and analyzed the data; and wrote the initial manuscript. MR and LL reviewed and edited the manuscript. SA reviewed and analyzed the data and edited the manuscript. All authors reviewed and approved the manuscript for submission. CWC is the guarantor of this work and, as such, has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

## Conflicts of Interest

None declared.

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## Abbreviations

**CGM:** continuous glucose monitor
**CHAM:** Children's Hospital at Montefiore Einstein
**CHW:** community health worker
**HRSN:** health-related social need
**MSHP:** Montefiore School Health Program
**REDCap:** Research Electronic Data Capture
**T1D:** type 1 diabetes

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# Prevalence and Risk Factors of Metabolic Dysfunction–Associated Steatotic Liver Disease in Patients With Type 2 Diabetes Mellitus at a Tertiary Center in Saudi Arabia: Cross-Sectional Questionnaire Study

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## Abstract

**Background:** The escalating rates of obesity and type 2 diabetes mellitus (T2DM) in Saudi Arabia highlight the impending burden of metabolic dysfunction–associated steatotic liver disease (MASLD) and nonalcoholic steatohepatitis.

**Objective:** This study aimed to identify MASLD among patients with T2DM at King Saud Medical City family medicine clinics, Riyadh, and explore associated factors to facilitate early intervention and prevention strategies.

**Methods:** This cross-sectional study identified patients with T2DM who attended King Saud Medical City, Riyadh, underwent an abdominal ultrasound, and were diagnosed with MASLD. The study data were collected by a peer-reviewed validated data extraction sheet and analyzed by SPSS (version 26.0; IBM Corp).

**Results:** Our study included 292 participants, with 47.3% (n=138) males and 52.7% (n=154) females. Notably, the prevalence of MASLD was 54.5% (n=159). Prevalent comorbidities included dyslipidemia (218/292, 74.7%) and hypertension (209/292, 71.6%). Most participants were nonsmokers (218/292, 74.7%). Higher waist circumference was significantly associated with MASLD (*P*=.02), with >80 cm among females (85/141, 60.3%) and >94 cm among males (60/141, 54.5%) affected across different stages of MASLD. Obesity (BMI>30 kg/m$^2$) also significantly correlated with MASLD (*P*<.001). Individuals taking aspirin had half the odds of MASLD development (odds ratio [OR] 0.523, 95% CI 0.331-0.844; *P*=.007). Biochemical analysis revealed significant associations between MASLD and elevated alanine aminotransferase (*P*=.009), aspartate aminotransferase (*P*=.01), and homeostatic model assessment of insulin resistance (*P*=.001). Total cholesterol (*P*=.01), triglycerides (*P*=.03), and low-density lipoprotein (*P*=.04) were significantly elevated in patients with MASLD. Insulin exhibited a significant positive correlation with MASLD (*r*=0.24; *P*=.001). Glucose levels showed no significant association (*r*=0.03; *P*=.63).

**Conclusions:** Our study highlights significant associations between MASLD and various factors, including waist circumference, obesity, and certain biochemical markers. Furthermore, the protective effect of aspirin against MASLD warrants further investigation. These findings underscore the importance of early intervention and targeted preventive strategies.

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**KEYWORDS**

non-alcoholic fatty liver; type 2 diabetes mellitus; biochemical markers; MASLD; insulin resistance; metabolic dysfunction–associated steatotic liver disease

## Introduction

In the last quarter of 2023, the American Association for the Study of Liver Diseases, the European Association for the Study of the Liver, and the Sur Medical Clinic Foundation jointly released a Delphi consensus statement [1]. These organizations recognized the significant limitations of the current terms, nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH). As a result, a new nomenclature for fatty liver disease was introduced and published in the *Journal*



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*of Hepatology* [2]. The term chosen to replace NAFLD is metabolic dysfunction–associated steatotic liver disease (MASLD) [2]. The changes to the previous terminology will be integrated into this research compilation, while maintaining the original terms as referenced. In addition, the new nomenclature, acronym, and diagnostic criteria received broad support and are expected to enhance awareness and patient identification [2].

Even though NASH was first used in 1989, it required another 10 years for its inclusion in the clinicopathologic spectrum of MASLD, which includes subtypes with varying likelihood for progression [3]. The term MASLD refers to the buildup of fat in the liver, specifically when the amount of fat in the liver exceeds 5% of the hepatocytes [4]. In addition, MASLD is characterized by progressive steatosis and related pathology, such as cirrhosis, hepatitis, or hepatocellular carcinoma. Patients with MASLD can display a diverse range of histological features, including simple steatosis, NALFD, or NASH [5]. Over the years, the prevalence of chronic liver diseases has risen, leading to concerning increases in liver-related morbidity and mortality rates globally [6]. MASLD is one of the primary contributors to chronic liver diseases and has escalated to a worldwide epidemic, impacting approximately 1 in 4 adults, with an estimated prevalence of 25% to 30% [6,7]. This trend seems to correlate with the rising incidence of metabolic syndrome and its associated factors, such as obesity, type 2 diabetes mellitus (T2DM), and dyslipidemia [6].

The diagnostic criteria of MASLD include invasive and noninvasive tests. Noninvasive fibrosis tests should be used to rule out advanced fibrosis in low-prevalence populations and patients at risk of advanced liver fibrosis, such as those with metabolic risk factors or harmful alcohol use. These tests are part of routine investigations in primary care for suspected liver disease. Automatic calculation and systematic reporting of simple noninvasive tests, such as Fibrosis-4, is recommended to improve risk stratification and care linkage [8]. However, liver biopsy continues to be the most reliable method for diagnosing this condition. However, there are a variety of noninvasive methods, such as imaging tests and biomarkers, that are becoming more widely used for the assessment of fibrosis [9].

In Saudi Arabia, the prevalence of MASLD is expected to increase through 2030, parallel to projected increases in the prevalence of obesity and DM. By 2030, there would be a pre-estimated 12,534,000 MASLD cases in Saudi Arabia [10].

It is assumed that 30% of the people aged ≥15 years in 2015 had MASLD. The prevalence of MASLD among older adults in Saudi Arabia is estimated at 24.8% [10]. The prevalence of MASLD continues to rise and is now becoming one of the most frequent causes of cirrhosis (advanced liver disease) and liver transplantation in Europe [11].

Unless patients with MASLD are identified and diagnosed, they are denied the knowledge and opportunity to make the necessary changes. It is important to identify and risk-stratify patients with MASLD in order to implement therapeutic interventions [11]. The latter statements are the major incentives to initiate this research to identify patients with MASLD among T2DM attending King Saud Medical City (KSMC), Riyadh. Patients with MASLD have an increased risk of dying from liver disease, cardiovascular disease, and most causes of cancer, with modeling suggesting that the annual predicted economic burden of MASLD in Europe would be more than €35 billion (approximately US $40) of direct cost and further €200 billion of societal cost [12]. Primary care practitioners are central to the management of patients with NAFLD, but data on the knowledge and attitude of primary care practitioners toward MASLD are lacking. Future guidelines should emphasize strategies for screening vulnerable populations (obese and diabetics) [13].

It has been emphasized in recent relevant literature that MASLD is strongly linked with an unhealthy lifestyle. This is an area where improvement strategies could be designed and implemented in communities, including schools. Another important drive to conduct this research is the close relationship between MASLD and T2DM, and the management of the latter will go far in arresting the progression of MASLD. Family medicine and primary care practitioners are in a central position to provide timely screening and early diagnosis of MASLD and possible reduction in the future prevalence rates, as these practitioners serve as gatekeepers and are the primary health care professionals providing most of the care for these patients. The main aim of this study is to identify patients with T2DM who have MASLD attending KSMC, Riyadh, under the care of Family Medicine Department health care professionals.

## Methods

### Study Design, Setting, and Time Frame

This is an analytical, descriptive, observational, cross-sectional situational analysis survey that identified patients with T2DM, reviewed whether they had a recent ultrasound liver imaging, and ordered this imaging modality for those who are included in the study. The diagnostic criteria of MASLD in this study were based on ultrasound live imaging [4]. The study was conducted at KSMC Riyadh during the study period, as per the research work plan.

### Sample Size Calculation

The sample size was calculated using the formula $z\propto/1(P)(1-P)$ 2 $d2$, where $z$=1.96 (corresponding to a 95% CI value) and the $P$ (the reported prevalence of MASLD among patients with type 2 diabetes in a study conducted in Abha, Saudi Arabia, in 2018) is 72.7% [14]. While the margin of error was indicated as 5%, the final sample size was 309.72. To control for the low response rate, the sample size was increased by 10%. Using Epi-Info with the sample data, the initial sample size was calculated as 310, resulting in a final sample size of 341.

### Sampling Method and Participants

The sampling method was a convenience sampling technique, and the study identified patients with T2DM from the pool of KSMC Riyadh software data. The sample included all the patients who satisfied the criteria for inclusion in the study. The source of the data was the Employee Health Clinic, Chronic Disease Services, and Chronic Disease Refill Clinic. Those who had MASLD reported from a recent radiological order were



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included in the study, ideally within the last 12 months. The included participants were contacted to obtain their consent to be included in the study sample. This process entailed accessing their electronic medical records and reviewing the data available.

### Eligibility Criteria

The inclusion and exclusion criteria are listed in Textbox 1.

**Textbox 1.** Inclusion and exclusion criteria.

**Inclusion criteria**

- All patients with type 2 diabetes mellitus who were more than 30 years of age, regardless of both genders.
- All the patients included must have had a liver ultrasound image within 1 year.
- Patients attending the above-named Family Medicine Clinics.

**Exclusion criteria**

- All pregnant ladies are under obstetrics and gynecology care.
- All patients with type 1 diabetes mellitus.
- All patients with type 2 diabetes mellitus undergoing dialysis.
- All patients with other liver diseases (eg, viral hepatitis and alcohol use).

### *Data Collection Tool*

The study data were extracted from the KSMC database by investigators. The data extraction tool or questionnaire was prepared by collating tools from previous studies, which were adapted by the investigators. This questionnaire (Multimedia Appendix 1) had the following sections:

1. Characteristics of the study subjects (age, gender, marital status, educational level, nationality, medications, vaccination history, duration of T2DM, and smoking history).
2. Anthropometric, biochemical, and ultrasound characteristics (BMI, waist circumference [WC], and blood pressure), lipid profile, liver enzyme level, and hepatic steatosis, identified on ultrasound image and other laboratory indices as stated in the data collection sheet.
3. Associated comorbidities as mentioned in the questionnaire or data extraction tool.

### *Validity*

Face validity of the questionnaire was conducted by expert researchers to ensure the questions were clear and understandable for participants. This process involved reviewing the wording, format, and overall structure of the questionnaire to confirm its appropriateness for the target population. In addition, feedback from pilot testing was used to make any necessary revisions before final administration. The content validity of the questionnaire was assessed through expert review and the use of established measurement techniques. The questionnaire was ultimately deemed appropriate for the target population.

### *Data Variables*

The variables to be measured during the study included dependent and independent variables. The former refers to the diseases to be studied, namely MASLD among patients with T2DM, which represents the outcome. The latter refers to the variables encompassing risk factors that influence the outcome, also called predictors, such as associated comorbidities, anthropometric characteristics, and biochemical indicators. Another detailed classification of the variables and their subdivisions included categorical or qualitative variables. The nominal categorical variables included nationality, marital status, and medications used by the patients. The binary qualitative variable will include gender and vaccination history. The ordinal categorical variables included the educational level and smoking status. The quantitative numerical variables included continuous subgroups such as age, weight, BMI, and laboratory parameters.

### Statistical Analysis

SPSS (version 26.0; IBM Corp) was used to analyze the data. For categorical variables, the results were displayed as numbers and percentages; for continuous variables (such as insulin and glucose levels), they were displayed as mean and SD. Pearson chi-square was used to ascertain whether MASLD and other factors have a significant association. The effects of significant variables, such as gender, WC, obesity, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels, homeostatic model assessment of insulin resistance (HOMA-IR), cholesterol-lowering medications, and aspirin use, on the risk of MASLD were determined using a logistic regression model. Statistical significance was defined as a $P<.05$.

### Ethical Considerations

The study was approved by the Institutional Review Board of King Saud Medical City (protocol code H1RI-07-Mar23-01 and date of approval was May 14, 2023). After identifying the patients to be enrolled in the study, they were contacted by the investigators through the KSMC Riyadh central telephone system, and verbal informed consent was taken from all participants. The researchers ensured the anonymity of the identities of participants. Confidentiality of the collected data and possible publication of the study were acknowledged by the investigators.

## Results

The overall prevalence of MASLD in our study population was 54.5% (n=159). Table 1 provides an overview of the



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sociodemographic and clinical characteristics of the participants in the study, which included 292 individuals. The total response rate was 85%. Of 292 participants, there were 138 (47.3%) males and 154 (52.7%) females. Regarding age groups, the majority of participants fell within the 41 - 59 years category (192/292, 65.8%), followed by those aged 60 years and older (94/292, 32.2%), with a smaller proportion in the 30 - 40 years group (6/292, 2.1%). The vast majority of participants were married (243/292, 83.2%) and had received at least an elementary education (79/292, 27.1%). In terms of physical activity, 30.8% (90/292) reported being physically active. The study population exhibited various comorbidities, with dyslipidemia being the most prevalent (218/292, 74.7%), followed by hypertension (209/292, 71.6%). Other comorbidities included cardiac disease (108/292, 37%), hypothyroidism (32/292, 11%), and bronchial asthma (19/292, 6.5%). The duration of diabetes was relatively evenly distributed, with 28.4% (83/292) having diabetes for less than 5 years and 71.6% (209/292) for 5 years or more. In terms of current treatment for diabetes, the majority were on oral hypoglycemics only (179/292, 61.3%), followed by a combination of oral hypoglycemics and insulin (92/292, 31.5%). In addition, most participants were taking antihypertensive medications (216/292, 74%) and lipid-lowering agents (226/292, 77.4%). However, only 46.9% (137/292) were taking aspirin. The majority of participants were nonsmokers (218/292, 74.7%), with a smaller proportion being current smokers (30/292, 10.3%) or ex-smokers (44/292, 15.1%). Regarding WC, a considerable proportion of males (110/292, 37.7%) and females (141/292, 48.3%) exceeded the recommended thresholds of 94 cm and 80 cm, respectively. Furthermore, the distribution of BMI classifications varied, with the majority falling within the overweight and obese categories (BMI 25 - 39.9 kg/m$^2$).



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**Table .** Sociodemographic and clinical characteristics of participants (N=292).

| Characteristics | Values (N=292), n (%) |
|---|---|
| Sex | |
| Male | 138 (47.3) |
| Female | 154 (52.7) |
| Age (years) | |
| 30-40 | 6 (2.1) |
| 41-59 | 192 (65.8) |
| ≥60 | 94 (32.2) |
| Marital status | |
| Unmarried | 11 (3.8) |
| Married | 243 (83.2) |
| Divorced | 20 (6.8) |
| Widow or widower | 18 (6.2) |
| Duration of diabetes (years) | |
| <5 | 83 (28.4) |
| ≥5 | 209 (71.6) |
| Current treatment of DM[a] | |
| Oral hypoglycemics only | 179 (61.3) |
| Oral hypoglycemic+insulin | 92 (31.5) |
| Insulin only | 18 (6.2) |
| Diet and exercise only | 1 (0.3) |
| Others | 2 (0.7) |
| Antihypertensive medication | |
| Yes | 216 (74) |
| No | 76 (26) |
| Lipid-lowering agents | |
| Yes | 226 (77.4) |
| No | 66 (22.6) |
| Aspirin | |
| Yes | 137 (46.9) |
| No | 155 (53.1) |
| Smoking | |
| Nonsmoker | 218 (74.7) |
| Current smoker | 30 (10.3) |
| Ex-smoker | 44 (15.1) |
| Waist circumference measurement (cm) | |
| Males | |
| <94 | 30 (10.3) |
| >94 | 110 (37.7) |
| Females | |
| <80 | 11 (3.8) |
| >80 | 141 (48.3) |



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| Characteristics | Values (N=292), n (%) |
|---|---|
| BMI classification (kg/m$^2$) | |
| <18 | 1 (0.3) |
| 18.5-24.9 | 38 (13) |
| 25-29.9 | 91 (31.2) |
| 30-34.9 | 99 (33.9) |
| 35-39.9 | 33 (11.3) |
| 40 and more | 30 (10.3) |

[a]DM: diabetes mellitus.

Table 2 presents the laboratory findings of the participants in the study. The majority of participants (251/292, 86%) had normal ALT levels, while a smaller percentage (34/292, 11.6%) had high ALT levels. As for AST, most participants (273/292, 93.5%) had normal levels, with a small proportion (17/292, 5.8%) having high levels. For gamma-glutamyl transferase (GGT), the majority had normal levels (177/292, 60.6%), while some had high levels (22/292, 7.5%). In terms of glycated hemoglobin ($HbA_{1c}$) levels, the largest proportion fell within the range of 6.4 - 10.0 (173/292, 59.2%), followed by >10 (55/292, 18.8%), indicating suboptimal glycemic control in a significant portion of the participants. Regarding triglyceride levels, most participants had normal levels (197/292, 67.5%), while a smaller percentage had borderline high (44/292, 15.1%) or high levels (46/292, 15.8%). Similarly, for low-density lipoprotein (LDL), the majority had normal or optimal levels (184/292, 63%), with smaller percentages in the borderline high, high, and very high categories. Vitamin D levels varied, with a considerable portion of participants having either deficiency (104/292, 35.6%) or insufficiency (71/292, 24.3%). Vitamin $B_{12}$ levels and glucose levels were mostly high (201/292, 68.8% both). Insulin levels were also predominantly normal (171/292, 58.6%), with a notable percentage of participants having high levels (28/292, 9.6%). The HOMA-IR indicated that nearly half of the participants had high insulin resistance (143/292, 49%). Ultrasound reports revealed that the majority of participants had either normal or unremarkable findings (133/292, 45.5%), while 54.5% (159/292) were diagnosed with MASLD based on ultrasound reports.



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**Table .** Biochemical findings of the participants in the study.

| Characteristics | Values (N=292) |
|---|---|
| ALT[a], n (%) | |
| Normal | 251 (86) |
| Low | 5 (1.7) |
| High | 34 (11.6) |
| Not available | 2 (0.7) |
| AST[b], n (%) | |
| Normal | 273 (93.5) |
| High | 17 (5.8) |
| Not available | 2 (0.7) |
| GGT[c], n (%) | |
| Normal | 177 (60.6) |
| High | 22 (7.5) |
| Not available | 93 (31.8) |
| $HbA_{1c}$[d], n (%) | |
| <5.9 | 20 (6.8) |
| 5.9-6.4 | 42 (14.4) |
| 6.4-10 | 173 (59.2) |
| >10 | 55 (18.8) |
| Not available | 2 (0.7) |
| Triglycerides, n (%) | |
| Normal | 197 (67.5) |
| Borderline high | 44 (15.1) |
| High | 46 (15.8) |
| Very high | 2 (0.7) |
| Not available | 3 (1) |
| LDL[e], n (%) | |
| Normal or optimal | 184 (63) |
| Near optimal | 42 (14.4) |
| Borderline high | 30 (10.3) |
| High | 25 (9.6) |
| Very high | 8 (2.7) |
| Not available | 3 (1) |
| Vitamin D, n (%) | |
| Deficiency | 104 (35.6) |
| Insufficiency | 71 (24.3) |
| Normal | 61 (20.9) |
| High | 29 (9.9) |
| Not available | 27 (9.2) |
| Vitamin $B_{12}$, n (%) | |
| Low | 6 (2.1) |
| Normal | 71 (24.3) |



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| Characteristics | Values (N=292) |
|---|---|
| High | 201 (68.8) |
| Not available | 14 (4.8) |
| Glucose, mean (SD) | 8.53 (3.7) |
| Low, n (%) | 6 (2.1) |
| Normal, n (%) | 71 (24.3) |
| High, n (%) | 201 (68.8) |
| Not available, n (%) | 14 (4.8) |
| Insulin, mean (SD) | 95.59 (79.3) |
| Low, n (%) | 6 (2.1) |
| Normal, n (%) | 171 (58.6) |
| High, n (%) | 28 (9.6) |
| Not available, n (%) | 87 (29.8) |
| HOMA-IR[f], n (%) | |
| Low | 5 (1.7) |
| Normal | 47 (16.1) |
| High | 143 (49) |
| Not available | 97 (33.2) |
| Ultrasound report, n (%) | |
| Normal or unremarkable | 133 (45.5) |
| Fatty liver grade I | 82 (28.1) |
| Fatty liver grade II | 66 (22.6) |
| Fatty liver grade III | 8 (2.7) |
| Cirrhosis | 3 (1) |
| MASLD[g] prevalence based on ultrasound reports, n (%) | |
| Yes | 159 (54.5) |
| No | 133 (45.5) |

[a]ALT: alanine aminotransferase.

[b]AST: aspartate aminotransferase.

[c]GGT: gamma-glutamyl transferase.

[d]$HbA_{1c}$: glycated hemoglobin.

[e]LDL: low-density lipoprotein.

[f]HOMA-IR: homeostatic model assessment of insulin resistance.

[g]MASLD: metabolic dysfunction–associated steatotic liver disease.

Table 3 presents the association using the chi-square test between sociodemographic and clinical characteristics and MASLD stages among the study participants. There were no significant associations observed between MASLD stages and age groups, gender, physical activity, hypertension, dyslipidemia, hypothyroidism, bronchial asthma, cardiac disease, stroke, epilepsy, depression, kidney disease, treatment of diabetes mellitus, or antihypertensive medications. However, a significant association was found between high WC and MASLD, with 60.3% (85/141) of females and 54.5% (60/110) of males with WC greater than the normal range having MASLD ($P$=.02), as well as a significant association regardless of gender ($P$=.003). In addition, obesity (BMI >30 kg/m²) was significantly associated with MASLD ($P$<.001), as well as increased BMI, where higher BMI categories showed higher prevalence of MASLD ($P$<.001). These findings suggest that factors such as WC, obesity, and BMI may play crucial roles in the development of MASLD among patients with T2DM.



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**Table .** Association of sociodemographic and clinical characteristics and stages of metabolic dysfunction–associated steatotic liver disease.

| Variables | Stages, n (%) | | | | | *P* value |
|---|---|---|---|---|---|---|
| | No MASLD[a] | 1 | 2 | 3 | 4 | |
| Age (years) | | | | | | .23 |
| 30-40 | 4 (66.7) | 0 (0) | 2 (33.3) | 0 (0) | 0 (0) | |
| 41-59 | 78 (40.6) | 60 (31.3) | 47 (24.5) | 6 (3.1) | 1 (0.5) | |
| >60 | 50 (53.2) | 23 (24.5) | 17 (18.1) | 2 (2.1) | 2 (2.1) | |
| Sex | | | | | | .01 |
| Female | 59 (38.3) | 52 (33.8) | 36 (23.4) | 5 (3.2) | 2 (1.3) | |
| Male | 73 (52.9) | 31 (22.5) | 30 (21.7) | 3 (2.2) | 1 (0.7) | |
| Physically active | | | | | | .80 |
| No | 91 (45) | 54 (26.7) | 49 (24.3) | 6 (3) | 2 (1) | |
| Yes | 41 (45.6) | 29 (32.2) | 17 (18.9) | 2 (2.2) | 1 (1.1) | |
| Waist circumference (cm) | | | | | | |
| Female | | | | | | .022[b,c] |
| <80 | 4 (36.4) | 3 (27.3) | 3 (27.3) | 0 (0) | 1 (9.1) | |
| >80 | 56 (39.7) | 47 (33.3) | 33 (23.4) | 4 (2.8) | 1 (0.7) | |
| Male | | | | | | .022[b,c] |
| <94 | 22 (73.3) | 4 (13.3) | 3 (10) | 0 (0) | 1 (3.3) | |
| >94 | 50 (45.5) | 29 (26.4) | 27 (24.5) | 4 (3.6) | 0 (0) | |
| BMI (kg/m$^2$) | | | | | | <.001[b,c] |
| <18 | 1 (100) | 0 (0) | 0 (0) | 0 (0) | 0 (0) | |
| 18.5 - 24.9 | 24 (63.2) | 7 (18.4) | 5 (13.2) | 1 (2.6) | 1 (2.6) | |
| 25 - 29.9 | 59 64.8 | 20 (22) | 11 (12.1) | 0 (0) | 1 (1.1) | |
| 30 - 34.9 | 34 (34.3) | 34 (34.3) | 28 (28.3) | 2 (2) | 1 (1) | |
| 35 - 39.9 | 8 (24.2) | 11 (33.3) | 12 (36.4) | 2 (6.1) | 0 (0) | |
| >40 | 6 (20) | 11 (36.7) | 10 (33.3) | 3 (10) | 0 (0) | |

[a]MASLD: metabolic dysfunction–associated steatotic liver disease.

[b]*P* values were calculated by chi-square test.

[c]*P*<.05 denotes statistical significance.

Table 4 provides insights into the association using the chi-square test between biochemical findings and MASLD stages among the study participants. High levels of ALT were significantly associated with MASLD, with 41.2% (14/34) of participants in stage 2 having high ALT levels. Similarly, high AST levels were significantly associated with MASLD, with 29.4% (5/17) of participants in stage 2, and 11.8% (2/17) in stage 4 having high AST levels. However, there was no significant association between GGT levels and MASLD. Regarding insulin resistance markers, high HOMA-IR levels were significantly associated with MASLD, with 31.5% (45/143) of participants in stage 2 having high HOMA-IR levels. However, no significant associations were found between MASLD and $HbA_{1c}$ levels, total cholesterol, triglycerides, albumin, LDL levels, vitamin D levels, and vitamin $B_{12}$ levels. When comparing the mean (SD) values of glucose and insulin according to stages, no significant differences were observed with glucose levels according to MASLD stages (*P*=.69), whereas significantly higher insulin levels were observed among patients with stage 2 and 3 compared with patients without MASLD (*P*=.008).



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**Table .** Association of biochemical findings and MASLD stages. "Not available" values were excluded from the analysis.

| Biomarker[a] | Stages | | | | | *P* value |
|---|---|---|---|---|---|---|
| | No MASLD[b] | 1 | 2 | 3 | 4 | |
| ALT[c] | | | | | | .009[d] |
| High | 9 (26.5) | 8 (23.5) | 14 (41.2) | 1 (2.9) | 2 (5.9) | |
| Low | 2 (40) | 3 (60) | 0 (0) | 0 (0) | 0 (0) | |
| Normal | 121 (48.2) | 70 (27.9) | 52 (20.7) | 7 (2.8) | 1 (0.4) | |
| AST[e] | | | | | | .01[d,f] |
| High | 5 (29.4) | 4 (23.5) | 5 (29.4) | 1 (5.9) | 2 (11.8) | |
| Normal | 127 (46.5) | 77 (28.2) | 61 (22.3) | 7 (2.6) | 1 (0.4) | |
| GGT[g] | | | | | | .38 |
| High | 7 (31.8) | 5 (22.7) | 9 (40.9) | 1 (4.5) | 0 (0) | |
| Normal | 82 (46.3) | 47 (26.6) | 40 (22.6) | 6 (3.4) | 2 (1.1) | |
| $HbA_{1c}$[h] | | | | | | .78 |
| <5.9 | 13 (65) | 3 (15) | 4 (20) | 0 (0) | 0 (0) | |
| 5.9 - 6.4 | 22 (52.4) | 8 (19) | 10 (23.8) | 1 (2.4) | 1 (2.4) | |
| 6.4 - 10 | 71 (41) | 54 (31.2) | 41 (23.7) | 6 (3.5) | 1 (0.6) | |
| >10 | 26 (47.3) | 17 (30.9) | 10 (18.2) | 1 (1.8) | 1 (1.8) | |
| Total cholesterol | | | | | | .06 |
| Borderline | 10 (24.4) | 11 (26.8) | 19 (46.3) | 1 (2.4) | 0 (0) | |
| Desirable | 106 (50.2) | 56 (26.5) | 40 (19) | 6 (2.8) | 3 (1.4) | |
| High | 11 (36.7) | 14 (46.7) | 4 (13.3) | 1 (3.3) | 0 (0) | |
| Low | 3 (60) | 0 (0) | 2 (40) | 0 (0) | 0 (0) | |
| Normal | 0 (0) | 0 (0) | 1 (100) | 0 (0) | 0 (0) | |
| Triglyceride | | | | | | .45 |
| Borderline high | 16 (36.4) | 13 (29.5) | 12 (27.3) | 3 (6.8) | 0 (0) | |
| High | 15 (32.6) | 17 (37) | 13 (28.3) | 1 (2.2) | 0 (0) | |
| Normal | 98 (49.7) | 51 (25.9) | 41 (20.8) | 4 (2) | 3 (1.5) | |
| Very high | 1 (50) | 1 (50) | 0 (0) | 0 (0) | 0 (0) | |
| LDL[i] | | | | | | .88 |
| Borderline high | 8 (26.7) | 12 (40) | 8 (26.7) | 2 (6.7) | 0 (0) | |
| High | 7 (28) | 8 (32) | 9 (36) | 1 (4) | 0 (0) | |
| Near optimal | 22 (52.4) | 12 (28.6) | 7 (16.7) | 0 (0) | 1 (2.4) | |
| Normal | 2 (50) | 1 (25) | 1 (25) | 0 (0) | 0 (0) | |
| Not available | 2 (66.7) | 1 (33.3) | 0 (0) | 0 (0) | 0 (0) | |
| Optimal | 88 (48.9) | 46 (25.6) | 39 (21.7) | 5 (2.8) | 2 (1.1) | |
| Very high | 3 (37.5) | 3 (37.5) | 2 (25) | 0 (0) | 0 (0) | |
| Vitamin D | | | | | | .93 |
| Deficiency | 49 (47.1) | 30 (28.8) | 21 (20.2) | 3 (2.9) | 1 (1) | |
| High>100 | 11 (37.9) | 7 (24.1) | 10 (34.5) | 1 (3.4) | 0 (0) | |
| Insufficiency | 32 (45.1) | 18 (25.4) | 18 (25.4) | 2 (2.8) | 1 (1.4) | |
| Normal level | 26 (42.6) | 21 (34.4) | 12 (19.7) | 2 (3.3) | 0 (0) | |
| Insulin | | | | | | .27 |



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| Biomarker[a] | Stages | | | | | *P* value |
|---|---|---|---|---|---|---|
| | No MASLD[b] | 1 | 2 | 3 | 4 | |
| High | 8 (28.6) | 8 (28.6) | 11 (39.3) | 1 (3.6) | 0 (0) | |
| Low | 5 (83.3) | 1 (16.7) | 0 (0) | 0 (0) | 0 (0) | |
| Normal | 73 (42.7) | 49 (28.7) | 43 (25.1) | 4 (2.3) | 2 (1.2) | |
| Not available | 41 (56.9) | 18 (25) | 10 (13.9) | 2 (2.8) | 1 (1.4) | |
| HOMA-IR[j] | | | | | | <.001[d,f] |
| High | 43 (30.1) | 48 (33.6) | 45 (31.5) | 5 (3.5) | 2 (1.4) | |
| Low | 3 (60) | 2 (40) | 0 (0) | 0 (0) | 0 (0) | |
| Normal | 36 (76.6) | 5 (10.6) | 6 (12.8) | 0 (0) | 0 (0) | |

[a]Total may vary from 292, since analysis was done on patients with results only.

[b]MASLD: metabolic dysfunction–associated steatotic liver disease.

[c]ALT: alanine aminotransferase.

[d]*P* values calculated by chi-square test.

[e]AST: aspartate aminotransferase.

[f]*P*<.05 denotes statistical significance.

[g]GGT: gamma-glutamyl transferase.

[h]$HbA_{1c}$: glycated hemoglobin.

[i]LDL: low-density lipoprotein.

[j]HOMA-IR: homeostatic model assessment of insulin resistance.

Table 5 provides insights into the association between sociodemographic characteristics and MASLD regardless of severity among the study participants. Variables including age groups, marital status, and educational level did not show significant associations with MASLD. However, when grouped by sex, females showed a significantly higher prevalence of MASLD compared with males (94/154, 61% vs n=65/138, 47.1%). Similarly, there were no significant associations between MASLD and physical activity. However, a significantly higher proportion of patients with high WC have MASLD (146/253, 57.7%) compared with those with normal WC (13/39, 33.3%). In addition, BMI showed a significant association with MASLD, with higher proportions of MASLD observed among patients with BMI 30-34.9 kg/m² (64/99, 64.6%), 35 - 39.9 kg/m² (25/33, 75.8%), and >40 kg/m² (24/30, 80%).



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**Table .** Association of sociodemographic characteristics and metabolic dysfunction–associated steatotic liver disease. "Not available" values were excluded from the analysis.

| Characteristics[a] | MASLD[b] | | *P* value[c] |
|---|---|---|---|
| | No MASLD | With MASLD | |
| Age (years) | | | .05 |
| 30 - 40 | 4 (66.7) | 2 (33.3) | |
| 41 - 59 | 78 (40.6) | 114 (59.4) | |
| >60 | 51 (54.3) | 43 (45.7) | |
| Sex | | | .017[d] |
| Female | 60 (39) | 94 (61) | |
| Male | 73 (52.9) | 65 (47.1) | |
| Physically active | | | >.99 |
| No | 92 (45.5) | 110 (54.5) | |
| Yes | 41 (45.6) | 49 (54.4) | |
| Waist circumference (cm) | | | .004[d] |
| Normal | 26 (66.7) | 13 (33.3) | |
| High | 107 (42.3) | 146 (57.7) | |
| BMI (kg/m$^2$) | | | <.001[d] |
| <18 | 1 (100) | 0 (0) | |
| 18.5-24.9 | 24 (63.2) | 14 (36.8) | |
| 25-29.9 | 59 (64.8) | 32 (35.2) | |
| 30-34.9 | 35 (35.4) | 64 (64.6) | |
| 35-39.9 | 8 (24.2) | 25 (75.8) | |
| >40 | 6 (20) | 24 (80) | |

[a] Total may vary from 292, since analysis was done on patients with results only.

[b]MASLD: metabolic dysfunction–associated steatotic liver disease.

[c]*P* values calculated by chi-square test.

[d]*P*<.05 denotes statistical significance.

Figure 1 shows the relationship between various clinical characteristics and MASLD among the study participants. Results indicate no significant association between MASLD and hypertension, dyslipidemia, hypothyroidism, bronchial asthma, cardiac disease, stroke, epilepsy, depression, kidney disease, and smoking history. However, there was a significant association between MASLD and obesity (*P*<.001), with a higher proportion of patients with obesity (113/162, 69.8%) exhibiting MASLD compared with those without obesity (46/130, 35.4%). In addition, patients on lipid-lowering medications (*P*=.047) and those taking aspirin (*P*=.006) showed significant associations with MASLD, with higher proportions of MASLD among those not taking these medications. Furthermore, no significant association was found between MASLD and the duration of diabetes or the use of antihypertensive medications.

Categorical variables were represented as numerical variables, and collinearity diagnostics were performed by calculating the variance inflation factor and tolerance. Variance inflation factor for ALT was 1.36, AST was 1.36, HOMA-IR was 1.04, lipid-lowering drugs was 1.14, aspirin was 1.16, gender was 1.11, and WC was 1.08. This signifies that there was a moderate correlation, but it was not severe enough to warrant corrective measures.



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**Figure 1.** Association of clinical characteristics and metabolic dysfunction-associated steatotic liver disease.

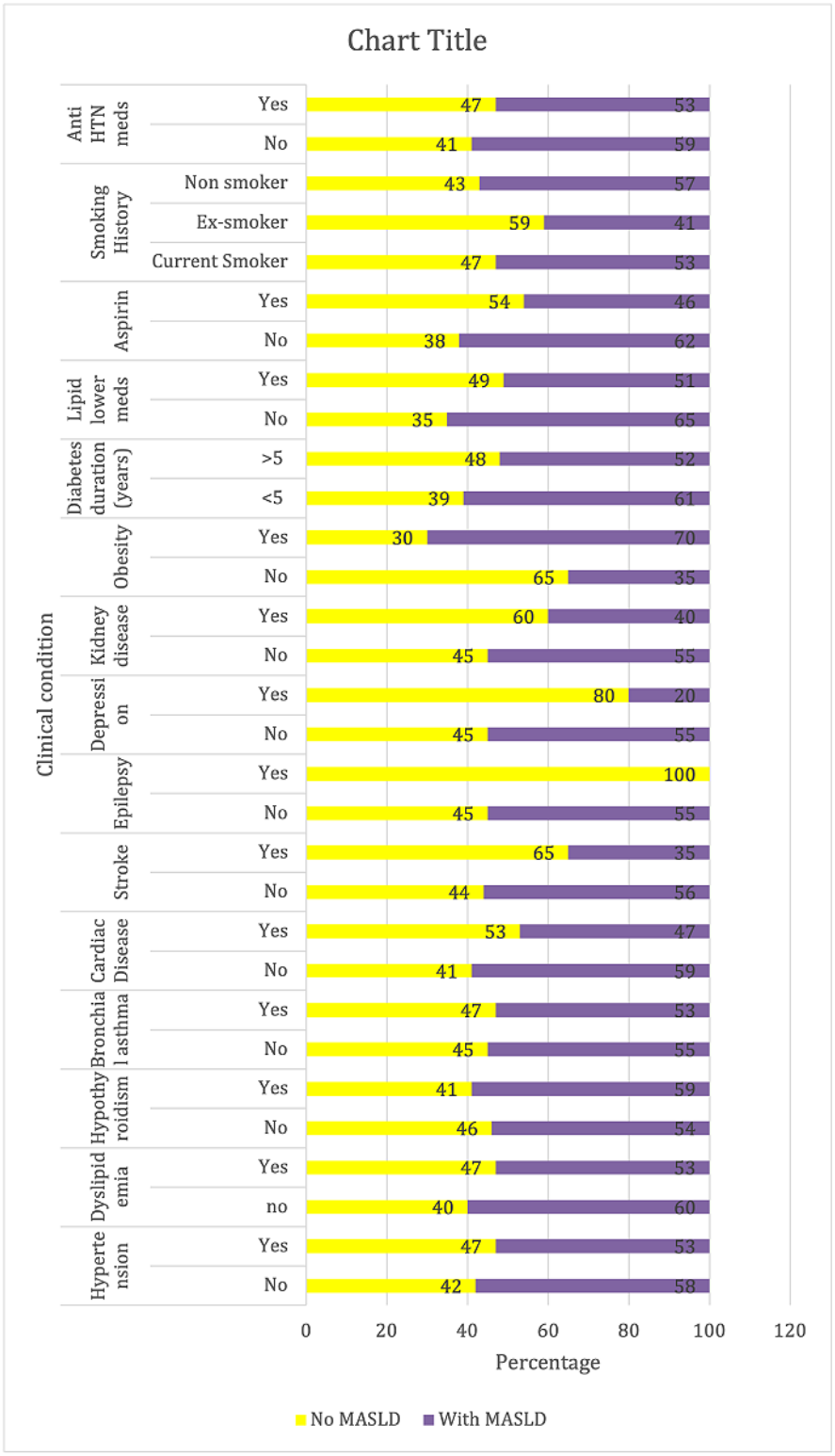



Table 6 shows the series of sequential logistic regression models. Unadjusted logistic regression showed a significantly increased risk associated with male sex, high WC, presence of obesity, high ALT, and high HOMA-IR on MASLD, and with a significantly decreased risk associated with MASLD for patients who used insulin (refer to OR in Table 6). When adjusted for age, gender, and obesity, high ALT and high HOMA-IR remained to significantly increase the risk for MASLD (model 2). When adjusted for age, gender, obesity, and the use of lipid-lowering drugs and aspirin, high ALT and high HOMA-IR remained significant risk factors for MASLD (model 3).



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**Table .** Series of sequential logistic regressions of risk factors for metabolic dysfunction–associated steatotic liver disease.

| Factors | UOR[a] (95% CI) Model 1 | *P* values | AOR[b] (95% CI) Model 2 | *P* values | AOR (95% CI) Model 3 | *P* values |
|---|---|---|---|---|---|---|
| Sex | | | | | | |
| Male | Reference | —[c] | — | — | — | — |
| Female | 1.759 (1.105 - 2.802) | .02 | — | — | — | — |
| Waist circumference (cm) | | | | | | |
| Normal | Reference | — | Reference | — | Reference | — |
| High | 2.33 (1.178 - 4.618) | .02 | 0.95 (0.43 - 2.07) | .90 | 0.94 (0.43 - 2.06) | .89 |
| Obesity | | | | | | |
| No | Reference | — | — | — | — | — |
| Yes | 4.21 (2.576 - 6.885) | <.001[d] | — | — | — | — |
| ALT[e] | | | | | | |
| Normal | Reference | — | Reference | — | Reference | — |
| High | 2.44 (1.091 - 5.462) | .03 | 3.23 (1.30 - 8.06) | .01 | 3.37 (1.33 - 8.48) | .01 |
| AST[f] | | | | | | |
| Normal | Reference | — | Reference | — | Reference | — |
| High | 1.88 (0.637 - 5.567) | .25 | 1.64 (0.48 - 5.5) | .42 | 1.55 (0.45 - 5.30) | .48 |
| HOMA-IR[g] | | | | | | |
| Normal | Reference | — | Reference | — | Reference | — |
| High | 7.61 (3.545 - 16.339) | <.001 | 7.41 (3.19 - 17.2) | <.001 | 8.11 (3.42 - 19.25) | <.001 |
| Lipid-lowering agents | | | | | | |
| No | Reference | — | Reference | — | — | — |
| Yes | 0.57 (0.326 - 1.023) | .06 | 0.53 (0.28 - 1.00) | .05 | — | — |
| Aspirin | | | | | | |
| No | Reference | — | Reference | — | — | — |
| Yes | 0.52 (0.331 - 0.844) | .008 | 0.61 (0.36 - 1.03) | .07 | — | — |

[a]UOR: unadjusted odds ratio.

[b]AOR: adjusted odds ratio.

[c]—: not applicable

[d]*P*<.05 denotes statistical significance.

[e]ALT: alanine aminotransferase.

[f]AST: aspartate aminotransferase.

[g]HOMA-IR: homeostatic model assessment of insulin resistance.

In addition to the associations mentioned, the analysis reveals several other noteworthy findings regarding the relationship between biochemical findings and MASLD. When MASLD was compared with ALT, AST, GGT, $HbA_{1c}$, and albumin levels (regardless of stage), no significant associations were found (*P*>.05). However, a higher proportion of patients with MASLD had significantly elevated levels of total cholesterol (*P*=.01), triglycerides (*P*=.03), and LDL (*P*=.04). In addition, there was no significant association between MASLD and vitamin D (*P*=.92) or vitamin $B_{12}$ (*P*=.92) levels. Furthermore, HOMA-IR exhibited a significant association with MASLD, with many patients with high HOMA-IR having MASLD compared with those with normal or low HOMA-IR (*P*<.001). The analysis also showed that glucose level was not significantly associated



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with MASLD (correlation coefficient $r$=0.03, $P$=.63). However, insulin level exhibited a significant positive correlation with MASLD ($r$=0.24; $P$=.001), indicating that as insulin levels increased, the likelihood of having MASLD also increased.

## Discussion

### Principal Results and Comparison With Prior Work

MASLD poses a global health concern, with rising prevalence linked to obesity and diabetes [12]. Soto et al [15] show that it is a widespread contributor to chronic liver disease globally. In Saudi Arabia, MASLD cases are projected to surge to more than 12 million by 2030 [16]. A study by Alswat et al [10] shows that by 2030, the estimated MASLD cases in Saudi Arabia and the United Arab Emirates would be 12,534,000 and 372,000, respectively. Lack of diagnosis denies patients crucial interventions. MASLD increases mortality risk, with significant economic burdens. According to Eskridge et al [17], MASLD severity correlates with mortality risk; after 20 years, excess risk ranges from 10.7% (simple steatosis) to 49.4% (cirrhosis). There is a need for better identification and management, particularly by primary care practitioners, emphasizing screening in high-risk populations, such as the obese and diabetics. Our study elucidates associations between MASLD and T2DM, offering insights for clinical intervention. Comparison with existing literature enhances understanding and identifies avenues for further research.

Our study reported that the prevalence of MASLD is 54.5%. Previous studies conducted in Saudi Arabia showed the prevalence of MASLD to be 47.8% (2015) in Jazan [18], 72.7% (2018) in Abha [14]. A recent analysis reported that the MASLD prevalence in Saudi Arabia from 2012 to 2019 was 28% to 33% [16], where older adults (older than 20 years) have an increased prevalence of MASLD from 41% to 44% [16]. The Middle East and North Africa regions have been identified as a primary source of MASLD, with prevalence rates exceeding 40% in most Middle East and North African countries [19,20]. Yemen, Turkey, and Kuwait had the lowest age-standardized disability-adjusted life years rates in 2021, whereas Egypt, Qatar, and Saudi Arabia had the highest rates. According to the 2019 Global Burden of Disease data, the high prevalence of obesity and diabetes in Egypt and Saudi Arabia is responsible for the high burden of chronic liver diseases, including MASLD [21]. This pattern is consistent with this information. According to Alenezi et al [22], Saudi Arabia had one of the highest rates of MASLD in the Middle East and North African region due to its obesity rate surpassing the global average. These geographic disparities are likely to be influenced by lifestyle patterns, socioeconomic factors, and access to health care.

Notably, the sociodemographic profiles of the study participants reflect a typical distribution seen in populations with T2DM, with a slight predominance of females (154/292, 52.7%) and a majority in the middle to older age groups (41 - 59 years old; 192/292, 65.8%). In contrast, previous studies by Meo et al [23] and Kautzky-Willer et al [24] showed that the prevalence is higher in males at 11.2% as compared with females at 9.19%. Globally, men are 40% more likely to have MASLD than 26% of women [25]. This could be due to men and women storing fat differently, with women storing more fat subcutaneously and men having more visceral fat. This excess fat exacerbates liver damage. Estrogen, which protects against NAFLD, may also contribute to these differences, making men and postmenopausal women more susceptible to liver damage [5].

The high prevalence of comorbidities, such as dyslipidemia (218/292, 74.7%) and hypertension (209/292, 71.6%), underscores the multifactorial nature of T2DM and its associated complications. Similarly, Katundu et al [26] showed that dyslipidemia with low-density lipoprotein cholesterol derangement was highly prevalent, especially in individuals with both diabetes mellitus and hypertension. Likewise, some studies have reported that the prevalence of hypertension in individuals with MASLD was 40% - 60% [3]. In contrast, a previous study conducted in Saudi Arabia shows lower prevalence of hyperlipidemia (41.7%), T2DM (35.3%), and hypertension (28.4%) [5]. These findings suggest that the comorbidities are increasing in the Saudi population; however, longitudinal studies are needed to confirm the relationship.

Interestingly, while most participants were nonsmokers, a significant proportion exhibited abdominal obesity and overweight or obesity, highlighting the importance of lifestyle factors in metabolic health. Comparing these findings with previous studies, the prevalence of comorbidities aligns with established literature on the burden of cardiometabolic diseases in populations with T2DM [26]. However, the relatively high proportion of individuals with abdominal obesity warrants further investigation into the impact of visceral adiposity on liver health, particularly in the context of MASLD. Kuang et al [27] showed that there is increased MASLD risk in females with abdominal obesity phenotypes.

Notably, laboratory findings revealed a mixed metabolic profile among participants, with varying degrees of liver enzyme abnormalities, glycemic control, lipid levels, and insulin resistance. While elevated liver enzymes were associated with MASLD, other traditional markers of liver function, such as GGT, did not show significant associations. Huang et al [28] showed that participants with MASLD and elevated liver enzymes were younger, more often they were males, smokers, and had higher metabolic markers.

In our study, we found that insulin resistance, as measured by HOMA-IR, emerged as a significant predictor of MASLD, indicating the intricate interplay between insulin sensitivity and liver fat accumulation. According to new diagnostic criteria, the HOMA-IR is included as a diagnostic feature for T2DM in patients with MASLD [29]. A study by Fujii et al [30] shows that HOMA-IR was an independent predictor of advanced fibrosis. Thus, comparing these results with existing literature, the association between insulin resistance and MASLD aligns with the pathophysiological mechanisms of MASLD [31]. Insulin resistance promotes hepatic lipid accumulation by impairing insulin-mediated suppression of lipolysis and promoting de novo lipogenesis, contributing to the development and progression of MASLD.

Furthermore, several sociodemographic and clinical factors were investigated for their association with MASLD, with WC and obesity emerging as significant predictors of MASLD risk



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and cardiovascular disease [32]. These findings underscore the central role of adiposity in the pathogenesis of MASLD, highlighting the importance of weight management interventions in patients with T2DM at risk of liver disease. In addition, gender disparities in MASLD prevalence were observed, with females exhibiting a higher risk compared with males ($P$=.02), consistent with previous studies. Similarly, a study by Lonardo et al [33] showed that MASLD is more prevalent in men than women. Male gender and metabolic factors independently predict MASLD. Menopause also increases the risk of MASLD. Comparing these results with existing literature, the association between obesity and MASLD is well-established, with visceral adiposity driving insulin resistance, hepatic lipid accumulation, and inflammation [33]. However, the observed gender disparity in MASLD prevalence warrants further investigation into the underlying hormonal and metabolic factors contributing to sex-specific differences in liver disease susceptibility.

Thus, our study aligns with existing literature on MASLD risk factors in T2DM, showing that obesity, insulin resistance, and dyslipidemia are predictors of MASLD. While our findings were consistent with previous findings, some results, like the insignificance of certain biomarkers, indicate the necessity for further investigations.

### Limitations

Several limitations include the reliance on cross-sectional data, which precludes causal inference, and potential selection bias due to the study's hospital-based design. In addition, the lack of longitudinal follow-up limits the assessment of disease progression, and the study's sample size may restrict generalizability to broader populations. During the data extraction, we did not extract actual values of the laboratory tests, except for glucose and insulin. The laboratory tests were categorized during data extraction based on predefined thresholds. It is therefore considered that converting continuous variables into categories has limitations, impacting statistical power and bias risk. Maintaining continuous variables offers a nuanced understanding of nonlinear relationships.

## Conclusions

Our study contributes to our understanding of the epidemiology and pathophysiology of MASLD in populations with T2DM. By comparing these findings with existing medical literature, we enhanced our knowledge of the risk factors and clinical implications of MASLD, guiding future research and clinical practice in the prevention and management of liver disease in patients with T2DM. The findings of our study have important clinical implications for the management of patients with T2DM at risk of MASLD. Health care providers should prioritize screening for liver disease in individuals with abdominal obesity, insulin resistance, and dyslipidemia, as these factors are strongly associated with MASLD risk. Multidisciplinary approaches that integrate diabetes care with liver health monitoring and interventions are warranted to optimize patient outcomes and reduce the burden of liver disease in populations with T2DM. Future research should focus on elucidating the mechanistic pathways linking metabolic dysfunction, adiposity, and liver injury in patients with T2DM. Longitudinal studies are needed to assess the impact of lifestyle interventions, pharmacotherapy, and metabolic surgery on MASLD progression and clinical outcomes. In addition, exploring the role of genetic, epigenetic, and environmental factors in MASLD pathogenesis may yield novel insights into disease mechanisms and therapeutic targets.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Questionnaire used for data collection.
[DOCX File, 17 KB - diabetes_v10i1e77772_app1.docx ]

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## Abbreviations

**ALT:** alanine aminotransferase
**AST:** aspartate aminotransferase
**GGT:** gamma-glutamyl transferase
**$HbA_{1c}$:** glycated hemoglobin
**HOMA-IR:** Homeostatic Model Assessment of Insulin Resistance
**KSMC:** King Saud Medical City
**LDL:** low-density lipoprotein
**MASLD:** metabolic dysfunction associated steatotic liver disease
**NAFLD:** nonalcoholic fatty liver disease
**NASH:** nonalcoholic steatohepatitis
**T2DM:** type 2 diabetes mellitus
**WC:** waist circumference

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# Correction: Toward Personalized Digital Experiences to Promote Diabetes Self-Management: Mixed Methods Social Computing Approach

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**KEYWORDS**

digital health communities; diabetes self-management; behavior change; affiliation exposure; social networks; deep learning

In "Toward Personalized Digital Experiences to Promote Diabetes Self-Management: Mixed Methods Social Computing Approach" (JMIR Diabetes 2025;10:e60109) the authors made one addition.

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Corrigenda and Addenda

# Correction: Glycemic Control, Renal Progression, and Use of Telemedicine Phone Consultations Among Japanese Patients With Type 2 Diabetes Mellitus During the COVID-19 Pandemic: Retrospective Cohort Study

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**Related Article:**

Correction of: https://diabetes.jmir.org/2023/1/e42607

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In "Glycemic Control, Renal Progression, and Use of Telemedicine Phone Consultations Among Japanese Patients With Type 2 Diabetes Mellitus During the COVID-19 Pandemic: Retrospective Cohort Study" (JMIR Diabetes 2023;8:e42607) the authors made one addition.

The equal contribution footnote (marked by *) was added for the authors Akiko Sankoda and Yugo Nagae. The final authorship list appears as follows:

*Akiko Sankoda[1]*, Yugo Nagae[1*], Kayo Waki[1,2,3], Wei Thing Sze[2], Koji Oba[4], Makiko Mieno[5], Masaomi Nangaku[6], Toshimasa Yamauchi[3], Kazuhiko Ohe[1,2]*

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The correction will appear in the online version of the paper on the JMIR Publications website on March 6, 2025, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.



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Corrigenda and Addenda

# Correction: Enhancing Health Equity and Patient Engagement in Diabetes Care: Technology-Aided Continuous Glucose Monitoring Pilot Implementation Project

Madhur Thakur[1], MBBS, PHIT; Eric W Maurer[2], MHA, MHI; Kim Ngan Tran[2], PharmD; Anthony Tholkes[3], MS; Sripriya Rajamani[1,4], MBBS, MPH, PhD; Roli Dwivedi[2,5], MD

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**Related Article:**

Correction of: https://diabetes.jmir.org/2025/1/e68324

***(JMIR Diabetes 2025;10:e72689)*** doi:10.2196/72689

In Enhancing Health Equity and Patient Engagement in Diabetes Care: Technology-Aided Continuous Glucose Monitoring Pilot Implementation Project" ([JMIR Diabetes 2025;10:e68324]) the authors noted two errors.

In the Ethical Considerations section, the sentence:

> *Patients who were not able to afford the CGM sensor were provided with Libre Pro CGM sensors, which were donated to the CUHCC by the Abbott Fund.*

Has been revised to:

> *Patients who were not able to afford the CGM sensor were provided with Libre Pro CGM sensors, which were donated to the CUHCC by Abbott.*

In the Acknowledgement section, the sentence:

> *The authors express their gratitude to Abbott Fund for donating the Libre Pro sensors for participants, as well as the Abbott Fund's ongoing support of digital health programs at the Community-University Health Care Center (CUHCC).*

Has been revised to

> *The authors express their gratitude to Abbott for donating the Libre Pro sensors for participants, as well as the Abbott Fund's ongoing support of digital health programs at the Community-University Health Care Center (CUHCC).*

The correction will appear in the online version of the paper on the JMIR Publications website on March 20, 2025, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.



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# Toward a Clinically Actionable, Electronic Health Record–Based Machine Learning Model to Forecast 90-Day Change in Hemoglobin A1c in Youth With Type 1 Diabetes: Feasibility and Model Development Study

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## Abstract

**Background:** Clinicians currently lack an effective means for identifying youth with type 1 diabetes (T1D) who are at risk for experiencing glycemic deterioration between diabetes clinic visits. As a result, their ability to identify youth who may optimally benefit from targeted interventions designed to address rising glycemic levels is limited. Although electronic health records (EHR)–based risk predictions have been used to forecast health outcomes in T1D, no study has investigated the potential for using EHR data to identify youth with T1D who will experience a clinically significant rise in glycated hemoglobin ($HbA_{1c}$) ≥0.3% (approximately 3 mmol/mol) between diabetes clinic visits.

**Objective:** We aimed to evaluate the feasibility of using routinely collected EHR data to develop a machine learning model to predict 90-day unit-change in $HbA_{1c}$ (in % units) in youth (aged 9 - 18 y) with T1D. We assessed our model's ability to augment clinical decision-making by identifying a percent change cut point that optimized identification of youth who would experience a clinically significant rise in $HbA_{1c}$.

**Methods:** From a cohort of 2757 youth with T1D who received care from a network of pediatric diabetes clinics in the Midwestern United States (January 2012-August 2017), we identified 1743 youth with 9643 $HbA_{1c}$ observation windows (ie, 2 $HbA_{1c}$ measurements separated by 70 - 110 d, approximating the 90-day time interval between routine diabetes clinic visits). We used up to 5 years of youths' longitudinal EHR data to transform 17,466 features (demographics, laboratory results, vital signs,



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anthropometric measures, medications, diagnosis codes, procedure codes, and free-text data) for model training. We performed 3-fold cross-validation to train random forest regression models to predict 90-day unit-change in $HbA_{1c}$(%).

**Results:** Across all 3 folds of our cross-validation model, the average root-mean-square error was 0.88 (95% CI 0.85 - 0.90). Predicted $HbA_{1c}$(%) strongly correlated with true $HbA_{1c}$(%) ($r$=0.79; 95% CI 0.78 - 0.80). The top 10 features impacting model predictions included postal code, various metrics related to $HbA_{1c}$, and the frequency of a diagnosis code indicating difficulty with treatment engagement. At a clinically significant percent rise threshold of ≥0.3% (approximately 3 mmol/mol), our model's positive predictive value was 60.3%, indicating a 1.5-fold enrichment (relative to the observed frequency that youth experienced this outcome [3928/9643, 40.7%]). Model sensitivity and positive predictive value improved when thresholds for clinical significance included smaller changes in $HbA_{1c}$, whereas specificity and negative predictive value improved when thresholds required larger changes in $HbA_{1c}$.

**Conclusions:** Routinely collected EHR data can be used to create an ML model for predicting unit-change in $HbA_{1c}$ between diabetes clinic visits among youth with T1D. Future work will focus on optimizing model performance and validating the model in additional cohorts and in other diabetes clinics.

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**KEYWORDS**

adolescent; AI, artificial intelligence; clinical decision support; EHR, electronic health records; glycemic control; HbA1c, hemoglobin A1c; machine learning; pediatric; population health; prediction; real-world data; T1D, type 1 diabetes; youth

## Introduction

### Background

Type 1 diabetes (T1D), an immune-mediated chronic disease that affects more than 1 in 300 youth in the United States, is characterized by significant to near-total loss of endogenous insulin production [1,2]. Given insulin's critical role in maintaining glucose homeostasis, the most immediate and pervasive downstream effect of insulin deficiency is persistent, life-threatening hyperglycemia that must be identified through frequent glucose monitoring and managed with lifelong administration of exogenous insulin [1].

Youth with T1D attend routine (often quarterly) diabetes clinic visits where clinicians use glycated hemoglobin ($HbA_{1c}$) testing to assess glycemic status [3,4]. Considered the gold standard for monitoring long-term glycemia in diabetes, $HbA_{1c}$ testing provides an objective measure of an individual's mean blood glucose during the previous 2 - 3 months [3,5]. To achieve glycemic goals, youth with T1D are increasingly being encouraged to adopt sophisticated diabetes technologies, such as hybrid closed-loop insulin pumps and continuous glucose monitoring (CGM) systems [6,7]. Concurrent with the rising availability of these technologies and a strong research base linking $HbA_{1c}$ with the development of diabetes complications, the American Diabetes Association has incrementally lowered its recommended $HbA_{1c}$ goals for youth with diabetes [4,8].

Despite increased adoption of advanced diabetes technologies over time, data from the T1D Exchange indicated that between 2010 - 2012 and 2016 - 2018, mean $HbA_{1c}$ in US youth with T1D rose from 7.8% (62 mmol/mol) to 8.4% (68 mmol/mol); and in 2016 - 2018, only 16% (686/4346) of youth were meeting the American Diabetes Association's (then) recommended $HbA_{1c}$ goal of <7.5% (<58 mmol/mol) [6]. A separate analysis of 2015 - 2016 data indicated that fewer than 20% (1817/9685) of US youth with T1D less than the age of 18 years had an $HbA_{1c}$<7.5% (58 mmol/mol); and fewer than 10% (690/9685) of youth had an $HbA_{1c}$<7% (53 mmol/mol) [9]. Previous research has shown that 1 in 5 youth with T1D experience an increasing $HbA_{1c}$ trajectory between the ages of 8 and 18 years [10].

Through a phenomenon known as "metabolic memory," periods of hyperglycemia are known to increase risk for diabetes-related microvascular and macrovascular complications for >10 years following initial exposure [11]. A similar—but beneficial—legacy effect is observed in individuals with T1D who are exposed to near-normal glycemia and later experience more favorable long-term diabetes outcomes, even when glycemic levels later rise [11,12]. These findings point to a critical need to optimize the early identification of youth who are candidates for targeted interventions to improve deteriorating glycemia.

The increasing availability of real-world clinical data housed in electronic health records (EHR) is generating opportunities to investigate population-level health outcomes, develop classification and risk prediction models to augment clinical decision-making, and accelerate diagnostic and therapeutic discovery [13-15]. Machine learning (ML) has been used to meaningfully advance understanding of numerous clinical outcomes in individuals with diabetes [16-18], and EHR-based risk predictions have been leveraged to generate insights across the health-disease spectrum, including T1D [19-21].

Given the multifactorial etiology of rising glycemic levels in youth with T1D, it remains difficult to identify youth who are at the highest risk of experiencing increased $HbA_{1c}$ between routine diabetes clinic visits. To date, no study has investigated the feasibility of or potential for using EHR data to develop a predictive model to identify youth with T1D who will experience a clinically significant rise in $HbA_{1c}$ between clinic visits. Such a model could augment clinical decision-making and facilitate initiation of interventions that increase behaviors known to improve glycemia in high-risk youth.



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### Objective

We sought to evaluate the feasibility of using ML to identify youth (aged 9 - 18 y) with T1D who were candidates for behavioral and care delivery interventions designed to reduce or prevent a predicted rise in $HbA_{1c}$. To do so, we used routinely collected EHR data to develop an interpretable and clinically actionable ML model to forecast unit-change (ie, increase or decrease, in % units) in $HbA_{1c}$ in 90 days. We then evaluated the ability of our model to augment clinical decision-making by identifying a percent-change cut point that optimized identification of youth who experienced a clinically significant rise in $HbA_{1c}$ at their subsequent diabetes clinic encounter.

## Methods

### Study Design

We applied the random forest (RF) regression algorithm to longitudinal EHR data to develop a model to forecast 90-day unit-change in $HbA_{1c}$ (in % units). We used RF due to its utility for constructing accurate, noise-resilient ML models from high-dimensional data [22,23]. To evaluate our model's ability to identify youth who, based on predicted rise in $HbA_{1c}$, were true candidates for intervention, we evaluated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of predicted versus actual change in $HbA_{1c}$ at several cut points: ≥0.3%, ≥0.4%, ≥0.5%, and ≥0.6% (approximately 3 mmol/mol, 4 mmol/mol, 5 mmol/mol, and 7 mmol/mol, respectively).

### Source Data and Study Cohort

Using data extracted from Oracle Health EHR (formerly Cerner Millenium Electronic Medical Record System; Nashville, Tennessee) [24], we used diagnosis code and laboratory data to identify a cohort of 2757 youth with T1D who received care from a network of pediatric diabetes clinics in the Midwestern United States between January 2012 and August 2017. Criteria used to identify this T1D cohort are provided in Multimedia Appendix 1.

### $HbA_{1c}$ Measurements and Observation Windows

For youth with T1D, we identified health encounters that were associated with $HbA_{1c}$ measurements (ie, laboratory and point-of-care $HbA_{1c}$ measurements) and $HbA_{1c}$ observation windows that met inclusion criteria. Each $HbA_{1c}$ observation window comprised 2 documented $HbA_{1c}$ measurements (from a single individual) separated by a time interval of 70 - 110 days. The 70 - to 110-day time interval was selected to approximate the 3-month (ie, 90-day) time interval between regularly scheduled diabetes clinic visits.

Certain encounters with $HbA_{1c}$ data were excluded from consideration and therefore not included in any $HbA_{1c}$ observation windows. $HbA_{1c}$ values documented at or shortly after T1D diagnosis tend to be more extreme than those documented at subsequent time points (ie, after an individual with T1D begins receiving regular insulin injections) [25,26]. As such, each youth's first-documented encounter with an $HbA_{1c}$ value was excluded under the assumption that a youth's first $HbA_{1c}$ measurement may have been obtained at the time of T1D diagnosis. We also excluded data from encounters where youth were <9 years old, as the incidence of clinically significant rise in $HbA_{1c}$ is less common in this age group [6,27].

We excluded observation windows associated with $HbA_{1c}$ measurements that were separated by <70 days or >110 days, as well as those where the first encounter for a given $HbA_{1c}$ observation window (ie, the index encounter) was associated with an $HbA_{1c}$ of >12% (>108 mmol/mol). The latter exclusion criterion was used because individuals with an $HbA_{1c}$ of >12% (>108 mmol/mol) were already considered ideal candidates for intervention. Encounter-level data from all $HbA_{1c}$ observation windows that met inclusion criteria were included in our final dataset, which could include data from multiple $HbA_{1c}$ observation windows per individual.

### Outcome Definition

The forecasted outcome was unit-change in $HbA_{1c}$ (in % units) at the end of 90 days. After predicting each youth's percent change in $HbA_{1c}$ in 90 days (ie, at the time of the follow-up encounter), we used various thresholds to determine an $HbA_{1c}$ percent rise cut point that optimized identification of individuals who were true candidates for intervention at the time of their index encounter: ≥0.3%, ≥0.4%, ≥0.5%, and ≥0.6% (approximately 3 mmol/mol, 4 mmol/mol, 5 mmol/mol, and 7 mmol/mol, respectively). We considered these cut points to be clinically relevant and actionable, given that a long-term decrease of ≥0.3% (3 mmol/mol) in $HbA_{1c}$ is associated with reduced risk of long-term diabetes complications [28].

### Data Extraction

We used SQL queries to comprehensively extract up to approximately 5 years (January 2012-August 2017) of structured and unstructured EHR data for each youth with index and follow-up encounter data for at least 1 qualifying $HbA_{1c}$ observation window. These data included demographics, laboratory results, vital signs, anthropometric measures, encounter locations, medications, diagnosis codes, procedure codes, structured clinical vocabulary codes, and free-text data from diabetes- and non–diabetes-related clinical notes, messages, and reports.

Demographic data included sex (female, male), age, ethnicity (non-Hispanic, Hispanic), race (White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Pacific Islander, and other), primary language (eg, English or Spanish), health plan type; and postal code (3- and 4-digit postal code prefixes). Additional extracted data included up to approximately 5 years of all available laboratory test results, clinical event and observation data, vital signs (heart rate, respiratory rate, oxygen saturation, and blood pressure), anthropometric measures (weight, height, and BMI), and medications (mapped to standard generic drug names [29]). We also extracted diagnosis codes (ie, *ICD-9* [*International Classification of Diseases, Ninth Revision*], ICD-10 [*International Statistical Classification of Diseases, Tenth Revision*], and Systematized Nomenclature of Medicine Clinical



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Terms [SNOMED CT] codes), procedure codes (ie, Current Procedural Terminology [CPT] codes); and other structured clinical vocabulary codes (ie, SNOMED CT).

We chose not to include data generated by diabetes devices (eg, automated insulin delivery and CGM systems). Early on, we observed that $HbA_{1c}$ was easiest to predict in youth who used diabetes devices that generate diabetes data (eg, glucose levels) in real time. However, since most diabetes centers do not have broad or ready access to device data in near-real time, we sought to evaluate the potential of using only EHR data to predict $HbA_{1c}$.

### Feature Engineering

We engineered features using data documented during all available historical encounters, as well as during $HbA_{1c}$ observation window index and follow-up encounters. Processes used to transform variables into features for ML varied by data type. In all, our feature engineering processes generated 17,466 input features for model fitting.

### Numeric Variables

For numeric variables (eg, laboratory results, weight, and vital signs), we created features by calculating summary metrics (ie, mean, slope, and SD). In general, we created 2 sets of features for each numeric variable, based on proximity of the measurements to the $HbA_{1c}$ observation window's index encounter. One set of features was created using data documented during the 12 months preceding (and at) the index encounter. A second set was created using all available EHR data documented before (and at) the index encounter. For example, we created 2 features for mean $HbA_{1c}$: one calculated using the previous 12 months of $HbA_{1c}$ data (up to and including the index encounter), and the other calculated using all available $HbA_{1c}$ data (up to and including the index encounter). Given the intrinsic insensitivity of RF to numerical outliers, we did not alter or drop outliers from the data. Once all numerical features were created, missing numerical values were imputed using the population median.

Each youth's diagnostic (ie, first) $HbA_{1c}$ result was included as a separate feature, as was the $HbA_{1c}$ result documented at the observation window's index encounter. Because research suggests that youth with T1D can be grouped into one of several $HbA_{1c}$ trajectory clusters [10], we created an $HbA_{1c}$ trajectory feature by using k-means clustering [30] to assign youth to 1 of 4 clusters based on their quarterly $HbA_{1c}$ measurements.

### Categorical Variables

We used data documented at the observation window's index encounter to create features from demographic data (eg, age, race, ethnicity, primary language, health plan type, and postal code). For each categorical demographic variable, we used the StringIndexer feature transformer to convert the categories associated with each variable into numeric indices, thus creating a single feature for each of these variables [31].

We used Clinical Classification Software Revised (CCSR), developed by the Agency for Healthcare Research and Quality, to group *ICD-10* codes into meaningful categories [32]. Thereafter, each CCSR category and each *ICD-9*, *ICD-10*, SNOMED CT, and CPT code was treated as a separate variable. We created 2 sets of features for each of these separate variables, based on how many times each had been assigned to the individual relative to the observation window's index encounter. One set of features was created by calculating the frequency that each had been assigned to the individual during the 12 months preceding (and at) the index encounter. The second set was created using all available EHR data documented before (and at) the index encounter. Absence of diagnosis, procedure, or structured clinical vocabulary codes was presumed to reflect true absence, rather than missingness, of these data variables.

Medication variables were similarly transformed into 2 sets of features based on how often each medication had been prescribed relative to the index encounter. One set of features was created by calculating the frequency that each medication had been prescribed to the individual during the 12 months preceding (and at) the index encounter. The second set was created using all available medication data documented before (and at) the index encounter. Encounter frequencies were similarly calculated and included as separate features. Absence of medication and encounter data was presumed to reflect true absence of these data.

### Natural Language Processing

We used term frequency–inverse document frequency (TF-IDF) vectorization, a natural language processing technique, to process free-text data from clinical notes, messages, and reports. In TF-IDF vectorization, words (ie, tokens) are first converted into a matrix of token counts [33]. The matrix is then transformed into a normalized TF-IDF representation that most heavily weights tokens that occur infrequently across the entire corpus of available text [33]. As such, TF-IDF is used to assign the highest weight to words that have the most discriminating power. After ranking by weight, we constrained the total number of features generated via TF-IDF vectorization to 250 single-word terms and 250 two-word terms, each of which had to be present in at least 5 documents.

### Model Development and Evaluation

RF uses bootstrap aggregation and random feature sampling to independently train a series of uncorrelated decision tree regressors, known as "weak learners" [22,23,34-36]. Predictions from this ensemble of weak learners are averaged to produce a single "strong learner" with improved prediction accuracy [23]. Relative to many other ML methods, the RF algorithm presents several key advantages, including decreased risk of overfitting, straightforward calculation of the degree to which individual input features contribute to model predictions, and robustness to missing data [22,34].

After randomly splitting the entire dataset into 3 nonoverlapping data subsets, we used 3-fold cross-validation to recursively fit RF regressors to 2 of the 3 subsets and then evaluate model performance on the third, held-out subset. We used 3-fold (rather than 5- or 10-fold) cross-validation due to the large number of $HbA_{1c}$ observation windows included in our analysis, as well as our desire to reduce variance in the estimated performance of our model. Hyperparameters used for model fitting are



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presented in Table 1. Model performance was evaluated by averaging the mean absolute error (MAE) and the root-mean-square error (RMSE)—the SD of the residuals [37]—across all 3 cross-validation models.

**Table .** Hyperparameter values used for random forest regressor model training. A complete list of hyperparameter keys accepted by the random forest regressor algorithm and definitions of each can be found on the web [38]. Hyperparameters not listed below were set to default values.

| Hyperparameter | Value used | Default value |
|---|---|---|
| NumTrees | 40 | 20 |
| MaxDepth | 7 | 5 |
| MaxBins | 128 | 32 |
| MinInstancesPerNode | 8 | 1 |
| FeatureSubsetStrategy | “onethird” | “onethird” |
| Impurity | “variance” | “variance” |
| MinInfoGain | 0.0 | 0.0 |
| MinWeightFractionPerNode | 0.0 | 0.0 |
| SubsamplingRate | 1.0 | 1.0 |

Decision tree regressors are grown by recursively splitting on features to maximize impurity reduction [39]. Feature splits that reduce impurity by maximally reducing variance are considered important; thus, the features that are split to maximize reduction in variance are also deemed important [39,40]. We evaluated feature importance by calculating and ranking the mean reduction in variance associated with only those features that were used by all 3 of our cross-validation models to forecast $HbA_{1c}$.

We used Python (version 3) and Scala (version 2; Programming Methods Laboratory at École Polytechnique Fédérale de Lausanne) to clean and transform the data. ML analyses were conducted using the Apache Spark MLlib (version 2) ML library [41].

### Statistical Analysis

Pearson *r* correlations were used to assess the strength and direction of the relationship between actual and predicted $HbA_{1c}$ values. We also used sensitivity, specificity, PPV, and NPV as clinical performance metrics to aid in identifying a predicted $HbA_{1c}$ percent rise threshold that would facilitate optimal capture of youth who would experience a clinically significant rise in $HbA_{1c}$ in 90 days.

Summary statistics, correlations, RMSE, MAE, and sensitivity, specificity, PPV, and NPV metrics were assessed using Stata/SE (Stata standard edition) software (version 18.5; StataCorp) [42].

### Ethical Considerations

Clinical and model output data were collected and coded in an institutional review board–approved research data repository at Children’s Mercy Kansas City (Kansas City, Missouri; IRB #11120355) that met the requirements for a waiver of written informed consent as outlined in 45 CFR 46.116.

## Results

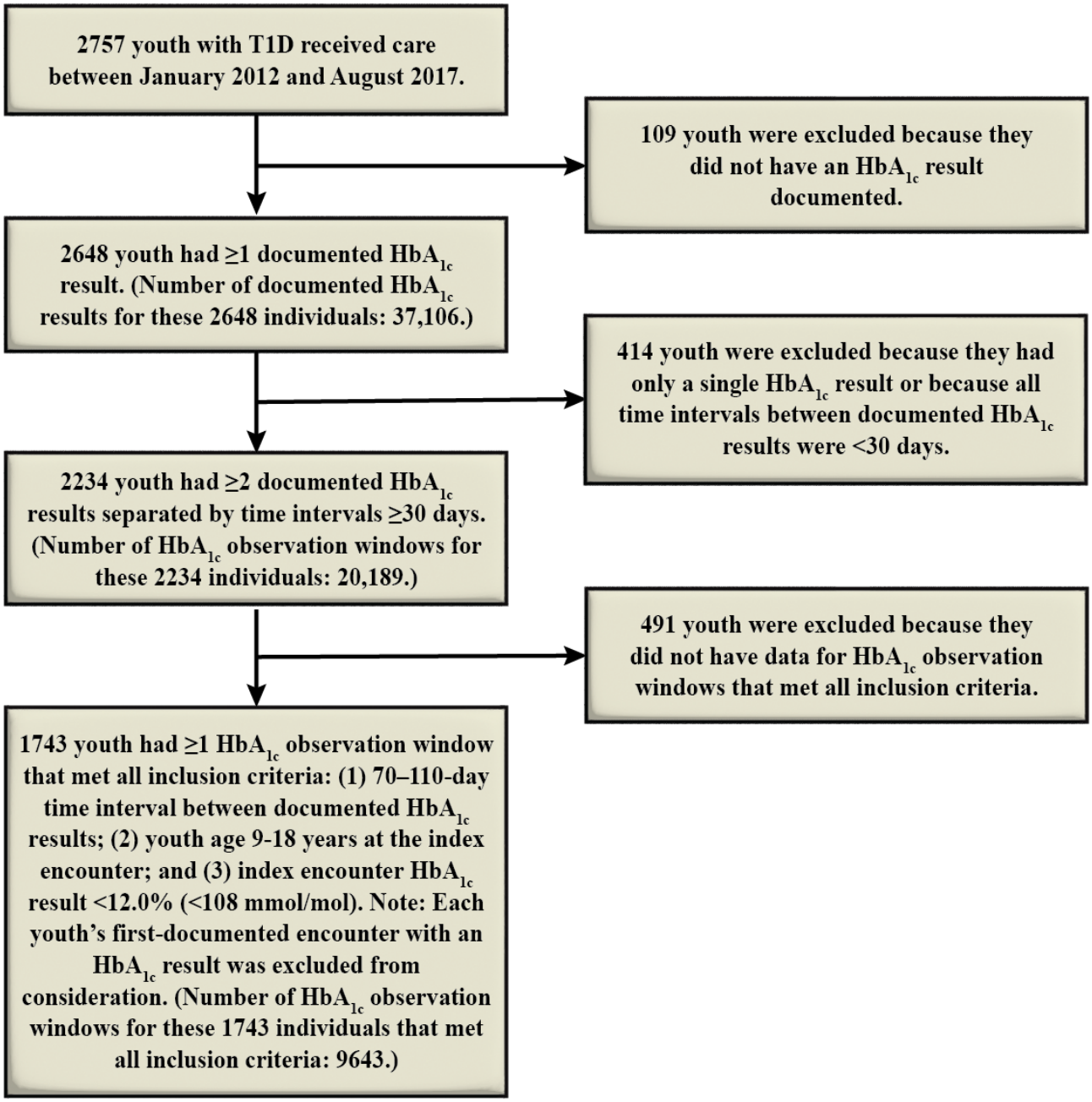
### Overview

Out of 2757 youth with T1D, 1743 youth (63.2%) had one or more $HbA_{1c}$ observation windows (n=9643) that met inclusion criteria (Figure 1).



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**Figure 1.** Flowchart depicting inclusion and exclusion criteria for the study cohort and for glycated hemoglobin observation windows. Abbreviations: $HbA_{1c}$: glycated hemoglobin; T1D: type 1 diabetes.




Characteristics of the entire cohort that met inclusion criteria are summarized in Table 2. The observed frequencies that youth experienced a rise in $HbA_{1c}$ that exceeded each percent change cut points (≥0.3%, ≥0.4%, ≥0.5%, and ≥0.6% [approximately 3 mmol/mol, 4 mmol/mol, 5 mmol/mol, 7 mmol/mol]) were 40.7%, 35.6%, 30.8%, and 26.5%, respectively. Characteristics of observations included in each nonoverlapping K-fold are summarized in Table 3.



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**Table .** Demographic and clinical characteristics of 1743 youth with glycated hemoglobin observation windows that met inclusion criteria.

| Demographic and clinical characteristics | All $HbA_{1c}$[a] observation windows (n=9643) | Index encounter of each youth's first $HbA_{1c}$ observation window (n=1743) |
|---|---|---|
| Age (y), mean (SD) | 13.8 (2.6) | 12.9 (2.7) |
| Sex, n (%) | | |
| Female | 4599 (47.7) | 844 (48.4) |
| Male | 5044 (52.3) | 899 (51.6) |
| Unknown | 0 (0) | 0 (0) |
| Race, n (%) | | |
| White | 8196 (85) | 1449 (83.1) |
| Black or African American | 616 (6.4) | 133 (7.6) |
| Asian | 53 (0.5) | 12 (0.7) |
| American Indian or Alaska Native | 42 (0.4) | 8 (0.5) |
| Native Hawaiian or Pacific Islander | 8 (0.1) | 3 (0.2) |
| Other | 63 (0.7) | 10 (0.6) |
| Unknown | 665 (6.9) | 128 (7.3) |
| Ethnicity, n (%) | | |
| Non-Hispanic or non-Latino | 8978 (93.1) | 1620 (93.0) |
| Hispanic or Latino | 656 (6.8) | 121 (6.9) |
| Unknown | 9 (0.1) | 2 (0.1) |
| $HbA_{1c}$ at index encounter (%), mean (SD) | 8.6 (1.3) | 8.5 (1.5) |
| $HbA_{1c}$ at index encounter (mmol/mol), mean (SD) | 70 (14.2) | 69 (16.4) |
| Change in $HbA_{1c}$[b] (%), median (IQR) | 0.1 (–0.4 to 0.6) | 0.1 (–0.4 to 0.7) |
| Change in $HbA_{1c}$[b] (mmol/mol), median (IQR) | 1 (–4 to 7) | 1 (–4 to 8) |
| $HbA_{1c}$ increase, n (%) | | |
| ≥0.3% | 3928 (40.7) | 763 (43.8) |
| ≥0.4% | 3435 (35.6) | 662 (38) |
| ≥0.5% | 2966 (30.8) | 580 (33.3) |
| ≥0.6% | 2552 (26.5) | 498 (28.6) |

[a]$HbA_{1c}$: glycated hemoglobin.

[b]Change in $HbA_{1c}$: ($HbA_{1c}$ at the observation window's follow-up encounter)–($HbA_{1c}$ at the observation window's index encounter).



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**Table .** Demographic and clinical characteristics of youth with glycated hemoglobin observation windows included in each K-fold subset.

| Demographic and clinical characteristics | $HbA_{1c}$[a] observation windows: fold 1 (n=3151) | $HbA_{1c}$ observation windows: fold 2 (n=3129) | $HbA_{1c}$ observation windows: fold 3 (n=3363) |
|---|---|---|---|
| Youth, n (%) | 1291 (41.0) | 1288 (41.2) | 1381 (41.1) |
| Age (y), mean (SD) | 13.9 (2.6) | 13.8 (2.6) | 13.8 (2.6) |
| Sex, n (%) | | | |
| Female | 1534 (48.7) | 1488 (47.6) | 1577 (46.9) |
| Male | 1617 (51.3) | 1641 (52.4) | 1786 (53.1) |
| Unknown | 0 (0) | 0 (0) | 0 (0) |
| Race, n (%) | | | |
| White | 2690 (85.4) | 2658 (85.0) | 2848 (84.7) |
| Black or African American | 174 (5.6) | 206 (6.6) | 236 (7.0) |
| Asian | 14 (0.4) | 16 (0.5) | 23 (0.7) |
| American Indian or Alaska Native | 17 (0.5) | 13 (0.4) | 12 (0.4) |
| Native Hawaiian or Pacific Islander | 3 (0.1) | 3 (0.1) | 2 (0.1) |
| Other | 17 (0.5) | 21 (0.6) | 25 (0.7) |
| Unknown | 236 (7.5) | 212 (6.8) | 217 (6.4) |
| Ethnicity, n (%) | | | |
| Non-Hispanic or non-Latino | 2911 (92.4) | 2928 (93.6) | 3139 (93.3) |
| Hispanic or Latino | 236 (7.5) | 197 (6.3) | 223 (6.6) |
| Unknown | 4 (0.1) | 4 (0.1) | 1 (0.1) |
| $HbA_{1c}$[a] at index encounter (%), mean (SD) | 8.6 (1.3) | 8.6 (1.3) | 8.6 (1.3) |
| $HbA_{1c}$ at index encounter (mmol/mol), mean (SD) | 70 (14) | 70 (14) | 70 (14) |
| $HbA_{1c}$ increase ≥0.3%, n (%) | 1255 (39.8) | 1293 (41.3) | 1380 (41) |

[a]$HbA_{1c}$: glycated hemoglobin.

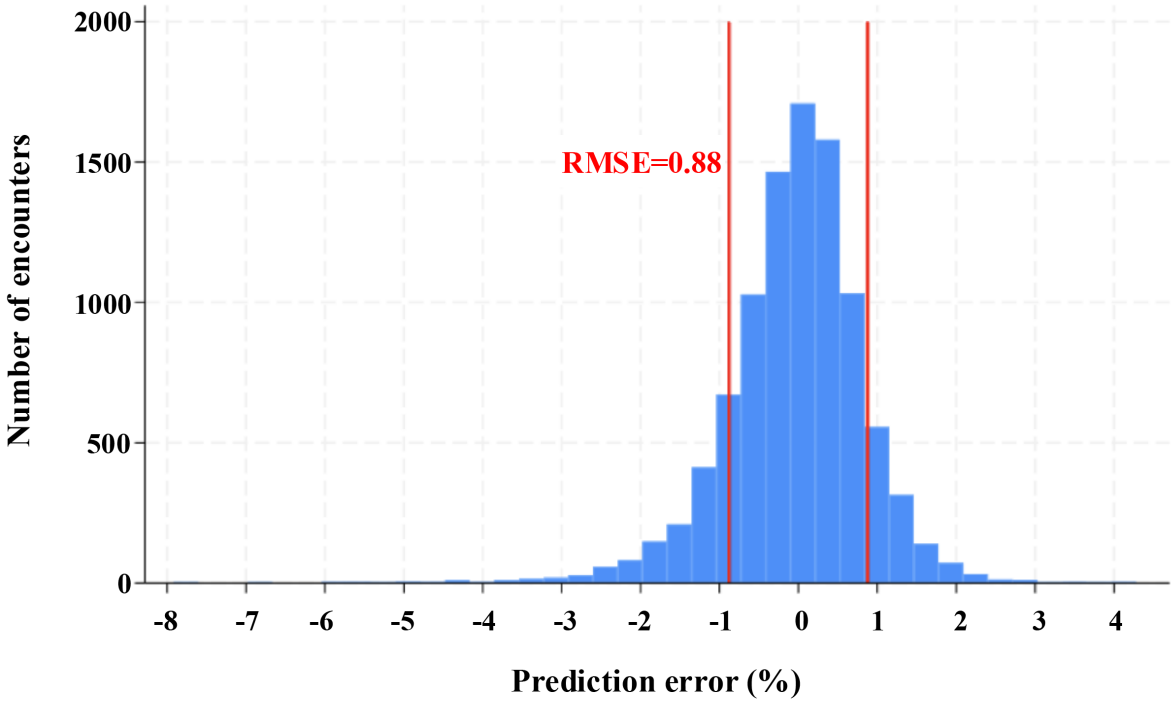
## Model Performance

Across all 3 folds of our cross-validation model, average RMSE was 0.88 (Figure 2). Thus, in 68% (6557/9643) of cases (representing one SD), our predictions were within ±0.88% (95% CI 0.85 - 0.90) of the true percent change in $HbA_{1c}$. The average MAE across all 3 folds was 0.64 (95% CI 0.63 - 0.65). Predicted $HbA_{1c}$(%) strongly correlated with true $HbA_{1c}$(%; $r$=0.79; 95% CI 0.78 - 0.80).



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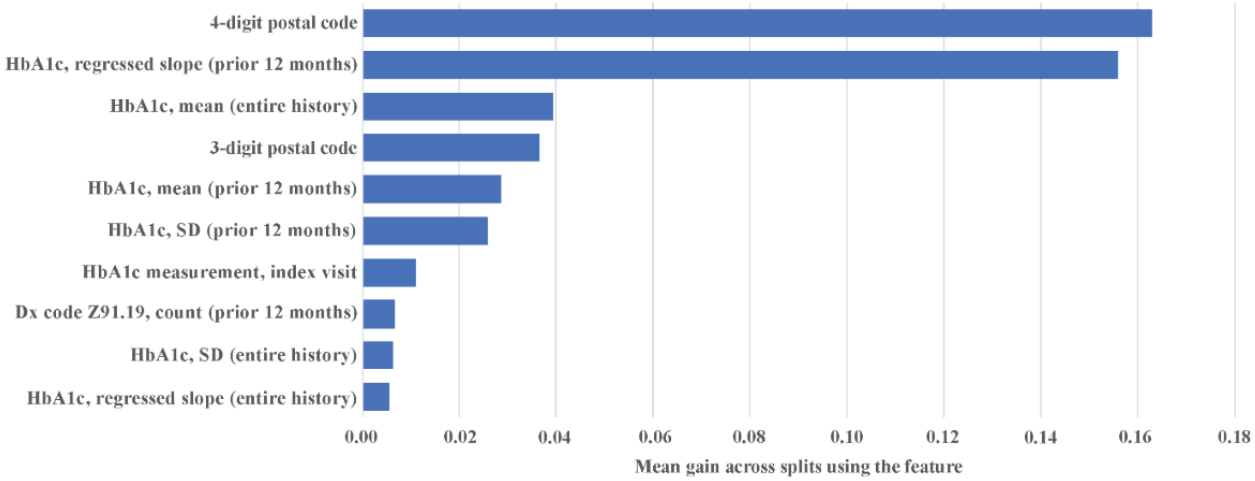
**Figure 2.** Distribution of the prediction error (ie, residuals) across all 3 cross-validation K-folds. Root-mean-square error is equal to the SD of the prediction error. RMSE: root-mean-square error.




## Feature Importance

Across all 3 folds of our cross-validation model, the top 10 features identified as having the greatest impact on model predictions included postal code, various metrics related to $HbA_{1c}$, and the number of times that the individual had been assigned a diagnosis code indicating difficulty with treatment engagement (Figure 3). The top 30 most important features used to predict percent change in $HbA_{1c}$ are in Multimedia Appendix 2.

**Figure 3.** Top 10 most important features for predicting 90-day percent change in glycated hemoglobin, assessed via gain-based feature importance. In random forest regression, gain is a feature importance measure that reflects, for a given feature, the mean increase in node purity (ie, mean reduction in variance) that the feature contributes across all splits in which it is used. Z91.19 is a diagnosis code from the *ICD-10* (*International Classification of Diseases, Tenth Revision*), that is used to code for nonadherence to, or noncompliance with, medical treatment. Dx: diagnosis; $HbA_{1c}$: hemoglobin $A_{1c}$.




## Percent Change Cut Points

Our cross-validation model's ability to accurately predict change in $HbA_{1c}$ at various percent change cut points is illustrated in Table 4. At each percent change cut point (≥0.3%, ≥0.4%, ≥0.5%, and ≥0.6% [approximately 3 mmol/mol, 4 mmol/mol, 5 mmol/mol, 7 mmol/mol]), PPV was 60.3%, 56.4%, 52.7%, and 53.1%, respectively, indicating an approximately 1.5- to 2-fold enrichment (relative to the observed frequency of each outcome [Table 1]) for identifying youth who would experience a clinically significant rise in $HbA_{1c}$. Sensitivity and PPV improved when predictions involved smaller changes in $HbA_{1c}$,



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whereas specificity and NPV improved when predictions involved larger changes in $HbA_{1c}$. Sensitivity, specificity, PPV, and NPV metrics for each K-fold are in Multimedia Appendix 3.

**Table .** Sensitivity, specificity, positive predictive value, and negative predictive value of predicted versus true percent change in $HbA_{1c}$ across all 3 cross-validation K-folds.

| Model metrics at each percent change cut point | Estimate, % (95% CI) |
|---|---|
| Predicted $HbA_{1c}$[a] % change: ≥0.3% | |
| Sensitivity (True $HbA_{1c}$% change: ≥0.3%) | 28.7 (27.3-30.2) |
| Specificity (True $HbA_{1c}$% change: ≥0.3%) | 87 (86.1-87.9) |
| PPV[b] (True $HbA_{1c}$% change: ≥0.3%) | 60.3 (58.1-62.5) |
| NPV[c] (True $HbA_{1c}$% change: ≥0.3%) | 64 (62.9-65) |
| Predicted $HbA_{1c}$% change: ≥0.4% | |
| Sensitivity (True $HbA_{1c}$% change: ≥0.4%) | 17.4 (16.1-18.7) |
| Specificity (True $HbA_{1c}$% change: ≥0.4%) | 92.6 (91.9-93.2) |
| PPV (True $HbA_{1c}$% change: ≥0.4%) | 56.4 (53.3-59.4) |
| NPV (True $HbA_{1c}$% change: ≥0.4%) | 66.9 (65.9-67.9) |
| Predicted $HbA_{1c}$% change: ≥0.5% | |
| Sensitivity (True $HbA_{1c}$% change: ≥0.5%) | 10 (8.9-11.1) |
| Specificity (True $HbA_{1c}$% change: ≥0.5%) | 96 (95.5-96.5) |
| PPV (True $HbA_{1c}$% change: ≥0.5%) | 52.7 (48.4-56.9) |
| NPV (True $HbA_{1c}$% change: ≥0.5%) | 70.6 (69.6-71.5) |
| Predicted $HbA_{1c}$% change: ≥0.6% | |
| Sensitivity (True $HbA_{1c}$% change: ≥0.6%) | 6.1 (5.2-7.1) |
| Specificity (True $HbA_{1c}$% change: ≥0.6%) | 98.1 (97.7-98.4) |
| PPV (True $HbA_{1c}$% change: ≥0.6%) | 53.1 (47.2-58.9) |
| NPV (True HbA1% change: ≥0.6%) | 74.4 (73.5-75.3) |

[a]$HbA_{1c}$: glycated hemoglobin.

[b]PPV: positive predictive value (it is the probability that the cases predicted to experience clinically significant rise in $HbA_{1c}$ [at or above each percent rise threshold] did experience that outcome).

[c]NPV: negative predictive value (it is the probability that the cases not predicted to experience clinically significant rise in $HbA_{1c}$ [at or above each percent rise threshold] did not experience that outcome).

## Discussion

### Principal Findings

We used routinely collected EHR data, including both structured and unstructured data, to establish the feasibility of constructing an interpretable ML model for predicting unit-change in $HbA_{1c}$ (in % units) between quarterly diabetes clinic visits among youth (aged 9 - 18 y) with T1D. For those predicted to experience a ≥0.3% (approximately 3 mmol/mol) rise in $HbA_{1c}$ during the following 3 months, PPV was 60.3%, indicating a 1.5-fold enrichment (relative to the observed frequency [40.7%] of this outcome) for identifying youth who would experience a clinically significant rise in $HbA_{1c}$. This finding, which suggests that EHR data may be useful for identifying youth who will experience rising glycemic levels, is clinically relevant given that a long-term increase of ≥0.3% (3 mmol/mol) in $HbA_{1c}$ is associated with increased risk for long-term complications of diabetes [28].

Another key finding was that our model's sensitivity and PPV were higher when the predicted percent rise threshold was lower (eg, ≥0.3% vs ≥0.4%), whereas specificity and NPV were increased at higher predicted percent rise thresholds (eg, ≥0.4% vs ≥0.3%). We hypothesized that using a higher percent rise threshold would decrease the likelihood of false positives (ie, identifying a youth as someone who would experience a corresponding rise in $HbA_{1c}$ when they did not), and the data supported this conclusion. On the other hand, using a lower percent rise threshold reduced the likelihood of missing those who would experience a clinically significant rise in $HbA_{1c}$. If confirmed in future studies, these findings suggest that using



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the lowest clinically significant threshold may be useful for guiding clinical decision-making and subsequent initiation of interventions designed to mitigate rising glycemic levels.

We also evaluated our model's ability to augment clinical decision-making by using PPV and NPV to identify a percent-change cut point that optimized identification of youth who experienced a clinically significant rise in $HbA_{1c}$ at their subsequent diabetes clinic encounter. Although PPV and NPV are considered the metrics of choice for clinical decision-making at the level of an individual person, the selection of desirable PPV and NPV values in a particular use case depends on numerous factors. These factors include considerations about short- and long-term burdens and costs related to over- or undertreatment, associated psychological impacts on individuals receiving care, and short- and long-term costs imposed on the health care system (eg, for increased staffing resources) [43]. Therefore, before implementing this model clinically, it would be important to allow clinicians to provide feedback about the most appropriate thresholds for defining clinically significant rise in $HbA_{1c}$, along with associated PPV and NPV values. For this work, we propose using the ≥0.3% cut-point to maximize capture of high-risk youth who are candidates for behavioral and care delivery interventions designed to reduce or prevent predicted rise in $HbA_{1c}$.

The top features impacting our model's predictions (ie, postal code, numerous metrics pertaining to $HbA_{1c}$, and history of low treatment engagement) have been shown in previous studies to be associated with elevated glycemic levels. Ample evidence suggests associations between geographic location and geographically linked measures of socioeconomic status (eg, area deprivation, social deprivation, and child opportunity indices) and T1D outcomes, including glycemic levels and diabetic ketoacidosis [44-47]. Previous $HbA_{1c}$ measurements have also been shown to significantly impact ML-based predictions of future $HbA_{1c}$, but previous investigations have only examined this in adults with type 2 diabetes (T2D) [48]. Finally, lower treatment engagement has been shown to have a substantial impact on $HbA_{1c}$ in youth with T1D [49,50]. This evidence collectively underscores the critical need for members of the diabetes care team to partner with affected youth and families to identify resources and tailored strategies for optimizing diabetes self-management behaviors.

Given the widespread use of EHRs in clinical care, as well as the growing volume and availability of these data, there exists tremendous potential for using EHR data to identify and personalize care pathways for improving health outcomes in T1D. Previous work has applied ML to EHR data, for example, to predict the onset of T1D in youth [51], as well as diabetic ketoacidosis in both youth and adults with T1D [19,20,52]. Recent research has focused on applying numerous ML classifiers to medical encounter data to predict $HbA_{1c}$ in individuals with T2D [48]. The area under the receiver operating curve for each of the top 5 best-performing classifiers in the aforementioned study was extremely high (>0.95). Of note, however, these model predictions were binary (ie, $HbA_{1c}$ <7% [<53 mmol/mol] vs ≥7% [≥53 mmol/mol]) rather than continuous and were evaluated in a primarily adult Chinese cohort diagnosed with T2D, limiting generalizability to other populations. Our approach is designed to predict unit change in $HbA_{1c}$ and to give clinicians a simple output (ie, $HbA_{1c}$ will or will not increase by ≥0.3%) for interpretation. This study is the first to use EHR data to predict a clinically significant rise in $HbA_{1c}$ in youth with T1D.

Recent efforts have also explored the use of ML classifiers that use 2 weeks of CGM data to forecast 90-day $HbA_{1c}$ in youth with T1D [53]. The first of these studies used a nested, ensemble learning approach to iteratively predict $HbA_{1c}$ in stages: (1) $HbA_{1c}$ ≤7.5% (58 mmol/mol) or >7.5% (stage 1), (2) $HbA_{1c}$ ≤9% (75 mmol/mol) or >9% (stage 2, after stage 1 was complete), and (3) $HbA_{1c}$ ≤12.5% (113 mmol/mol) or >12.5% (stage 3, after stage 2 was complete) [54]. A subsequent study used few-shot learning followed by K-nearest neighbors to classify transformed images of CGM time series data into multiclass $HbA_{1c}$ intervals [55]. Generalizability of these $HbA_{1c}$ prediction efforts is limited, however, by these methods' dependence on CGM data and by racial disparities in the relationship between CGM metrics and $HbA_{1c}$ [56].

Currently, CGM systems are neither accessible to nor used by all individuals with T1D. Recent data from the T1D Exchange Quality Improvement Collaborative suggest that only 40% - 50% of US youth with T1D currently use CGM systems [57,58]. Reasons for this are multifactorial and can include reluctance to use CGM technologies, financial constraints, lack of insurance coverage, device-related skin complications, CGM alarm fatigue, and sociodemographic and racial or ethnic disparities in access that adversely impact use of diabetes technologies [58-62]. At this time, CGM data also remain notably absent from most EHRs, are distributed across multiple proprietary commercial software, and are difficult for health systems to access. Although efforts to integrate CGM data into the EHR remain ongoing [63,64], large-scale implementation of these efforts will hinge on the development of CGM-related data standards and a data architecture that supports this integration [65].

In contrast, EHR data are routinely collected on every person receiving care from a given health care institution. These data thus provide a rich, longitudinal source of individual- and population-level health data that can be leveraged in near real-time for ML-driven clinical decision support [13,66]. Even so, the potential for integrating EHR-based ML-driven analytics in health care remains largely unrealized. A 2020 systematic review evaluating the number of clinical prediction models that have been embedded into EHRs noted that fewer than 45 such examples have been published [67]. Of note, only 36% (16/45) of model implementations occurred in outpatient settings, and none of the embedded models were specific to individuals affected by diabetes [67]. These findings highlight a critical gap, as well as opportunity, for leveraging real-world EHR data to facilitate real-time risk prediction and improve diabetes-related health outcomes.



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## Limitations and Strengths

A strength of this study is its use of longitudinal EHR data to predict 90-day unit-change in $HbA_{1c}$ in a large cohort of youth with T1D. The scale and granularity of these data facilitated the creation of thousands of data features that we simultaneously analyzed as potential predictors for suboptimal glycemic outcomes. Additional strengths of this study include its use of explainable ML methods for evaluating model predictions and our use of a clinician-led, postmodeling decision analysis to enhance clinicians' understanding and uptake of model predictions. The relevance of our model is underscored by its ability to forecast 90-day change in $HbA_{1c}$ for all youth receiving care through our regional clinic network, and not only for those using CGM systems.

Several limitations also warrant consideration. The data used in this study originated from a regional network of diabetes clinics in the Midwest United States and may not generalize to other geographic locations or health care settings, to future cohorts using rapidly evolving diabetes treatment technologies, or to more racially or socioeconomically diverse cohorts. External validation of the geographic and demographic "transportability" of this and future iterations of our model will hinge on ensuring that data from different clinical settings are collected in similar ways and standardized according to a common data model. Examples of such data standards include the Observational Medical Outcomes Partnership Common Data Model [68] and the T1D Exchange Quality Improvement Collaborative data specification [69]. As well, EHR data are subject to data entry errors and missing data that inadvertently occur as a part of routine clinical care. EHRs are also characterized by data fragmentation and reflect biases in clinical data collection, documentation, and decision-making [13]. Therefore, results from this and all models constructed using EHR data must be interpreted carefully, given both known and unknown biases that impact model predictions.

Model generalizability could be enhanced by using standardized geographic-based features (eg, an area deprivation index or the Child Opportunity Index [45,47]) rather than zip code, as well as by creating a final prediction model that includes only a limited number of the "top-N features identified via cross-validation. Using additional data preprocessing methods (eg, one-hot encoding) when transforming categorical demographic features (eg, race and ethnicity) for ML would facilitate interpretability of model results pertaining to those features. Model performance may improve with additional hyperparameter tuning. This model's predictive utility could also be compared with that of models constructed using other ML methods, including other explainable AI methods and deep learning models. Finally, for youth who adopt diabetes technologies, such as CGM and automated insulin delivery systems, the inclusion of diabetes device data would likely significantly augment our model's predictions.

We acknowledge that translation of this work into clinical practice will be accompanied by various logistical and practical challenges. This study was designed as an "initial step" to evaluate the feasibility of using EHR data to predict change in $HbA_{1c}$. As previously described, additional research is needed to address issues related to model refinement, validation (using data from external organizations, as well as future EHR data collected from our network of diabetes centers), and deployment in clinical settings. Future work can, for example, evaluate whether a limited set of standardized features may be useful for developing a more parsimonious model that can be readily disseminated to other institutions. Once deployed, ongoing monitoring of model performance will also be needed.

Furthermore, we acknowledge that refining and successfully incorporating this approach into clinical and decision workflows will hinge on the collection of additional evidence from future studies with even larger and more diverse patient cohorts, as well as buy-in and trust from both clinicians and patients. Although, in this iteration, our modeling approach yielded a nontrivial number of false positives, we note as well that our model's performance represents a substantial improvement over existing capabilities. Compared, for example, with initiating interventions randomly or initiating interventions at every diabetes clinic visit (to address youths' rising glycemic levels, which occurred 40.7% of the time in our cohort), our modeling efforts facilitated pre-emptive identification of rising glucose levels three-fifths of the time. The 1.5-fold risk enrichment demonstrated in this work represents a meaningfully improved opportunity for more targeted initiation and delivery of interventions designed to lower youths' glucose levels.

## Conclusions

Using EHR data to develop an ML-based prediction model to identify youth who will experience a clinically significant rise in $HbA_{1c}$ between diabetes clinic visits is both timely and feasible. Future research should aim to further optimize model performance, as well as evaluate model performance in racially or ethnically, socioeconomically, and geographically diverse cohorts. Future work is also needed to evaluate whether model results vary by duration of diabetes, use of technology (eg, CGM system users vs nonusers), and insulin delivery modality. Findings from this study may help to inform risk stratification and resource allocation efforts and serve as a catalyst for future quality improvement efforts focused on developing and evaluating personalized strategies and supports for optimizing diabetes self-management behaviors.

## Acknowledgments

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## Data Availability

The datasets generated and analyzed for this study are not publicly available due to sensitive information contained in patient medical records. Interested parties should contact the corresponding author to inquire about access. Source code for this study is available from the corresponding author upon reasonable request.

## Authors' Contributions

EMT and CS participated in interpreting data and drafting the manuscript. DDW, CM, and MAC participated in study conceptualization and design, analysis, interpreting data, and drafting or revising the manuscript. BL, DF, CAV, MSB, ACS, ARK, SRP, SM, RM, ML, and LD participated in editing and revising the manuscript. All authors approved this manuscript for submission.

## Conflicts of Interest

CM and LD are employees of Blue Circle Health. RM is a consultant for Sanofi. ML has received research grants from Eli Lilly and Novo Nordisk and has been a consultant or has received honoraria from Astra Zeneca, Boehringer Ingelheim, Eli Lilly, Nordicinfu Care, Novo Nordisk, and Rubin Medical, all outside the submitted work. MAC is a consultant for Glooko, Inc. and receives research support from Dexcom and Abbott Diabetes Care. All other authors are responsible for the reported research and stated that they have no affiliation, financial agreement, or involvement with any company or other organization with a financial interest in the subject matter of the submitted manuscript.

Multimedia Appendix 1
Electronic health records–based identification of a cohort of youth with type 1 diabetes.
[DOCX File, 27 KB - diabetes_v10i1e69142_app1.docx ]

Multimedia Appendix 2
Top 30 most important features for predicting 90-day percent change in glycated hemoglobin in youth with type 1 diabetes.
[DOCX File, 30 KB - diabetes_v10i1e69142_app2.docx ]

Multimedia Appendix 3
Sensitivity, specificity, positive predictive value, and negative predictive value of predicted versus true percent change in glycated hemoglobin for each cross-validation K-fold.
[DOCX File, 30 KB - diabetes_v10i1e69142_app3.docx ]

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## Abbreviations

**CCSR:** Clinical Classification Software Revised
**CGM:** continuous glucose monitoring
**CPT:** Current Procedural Terminology
**EHR:** electronic health record
**$HbA_{1c}$:** glycated hemoglobin
**ICD-10:** *International Statistical Classification of Diseases, Tenth Revision*
**ICD-9:** *International Classification of Diseases, Ninth Revision*
**MAE:** mean absolute error
**ML:** machine learning
**NPV:** negative predictive value
**PPV:** positive predictive value
**RF:** random forest
**RMSE:** root-mean-square error
**SNOMED CT:** Systematized Nomenclature of Medicine Clinical Terms
**T1D:** type 1 diabetes
**T2D:** type 2 diabetes
**TF-IDF:** term frequency-inverse document frequency



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# Privacy-Preserving Glycemic Management in Type 1 Diabetes: Development and Validation of a Multiobjective Federated Reinforcement Learning Framework

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## Abstract

**Background:** Effective diabetes management requires precise glycemic control to prevent both hypoglycemia and hyperglycemia, yet existing machine learning (ML) and reinforcement learning (RL) approaches often fail to balance competing objectives. Traditional RL-based glucose regulation systems primarily focus on single-objective optimization, overlooking factors such as minimizing insulin overuse, reducing glycemic variability, and ensuring patient safety. Furthermore, these approaches typically rely on centralized data processing, which raises privacy concerns due to the sensitive nature of health care data. There is a critical need for a decentralized, privacy-preserving framework that can personalize blood glucose regulation while addressing the multiobjective nature of diabetes management.

**Objective:** This study aimed to develop and validate PRIMO-FRL (Privacy-Preserving Reinforcement Learning for Individualized Multi-Objective Glycemic Management Using Federated Reinforcement Learning), a novel framework that optimizes clinical objectives—maximizing time in range (TIR), reducing hypoglycemia and hyperglycemia, and minimizing glycemic risk—while preserving patient privacy.

**Methods:** We developed PRIMO-FRL, integrating multiobjective reward shaping to dynamically balance glucose stability, insulin efficiency, and risk reduction. The model was trained and tested using simulated data from 30 simulated patients (10 children, 10 adolescents, and 10 adults) generated with the Food and Drug Administration (FDA)–approved UVA/Padova simulator. A comparative analysis was conducted against state-of-the-art RL and ML models, evaluating performance using metrics such as TIR, hypoglycemia (<70 mg/dL), hyperglycemia (>180 mg/dL), and glycemic risk scores.

**Results:** The PRIMO-FRL model achieved a robust overall TIR of 76.54%, with adults demonstrating the highest TIR at 81.48%, followed by children at 77.78% and adolescents at 70.37%. Importantly, the approach eliminated hypoglycemia, with 0.0% spent below 70 mg/dL across all cohorts, significantly outperforming existing methods. Mild hyperglycemia (180-250 mg/dL) was observed in adolescents (29.63%), children (22.22%), and adults (18.52%), with adults exhibiting the best control. Furthermore, the PRIMO-FRL approach consistently reduced glycemic risk scores, demonstrating improved safety and long-term stability in glucose regulation..

**Conclusions:** Our findings highlight the potential of PRIMO-FRL as a transformative, privacy-preserving approach to personalized glycemic management. By integrating federated RL, this framework eliminates hypoglycemia, improves TIR, and preserves data privacy by decentralizing model training. Unlike traditional centralized approaches that require sharing sensitive health data, PRIMO-FRL leverages federated learning to keep patient data local, significantly reducing privacy risks while enabling adaptive and personalized glucose control. This multiobjective optimization strategy offers a scalable, secure, and clinically viable solution for real-world diabetes care. The ability to train personalized models across diverse populations without exposing raw data makes PRIMO-FRL well-suited for deployment in privacy-sensitive health care environments. These results pave the way for future clinical adoption, demonstrating the potential of privacy-preserving artificial intelligence in optimizing glycemic regulation while maintaining security, adaptability, and personalization.

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**KEYWORDS**

reinforcement learning; federated learning; federated reinforcement learning; multiobjective optimization; diabetes management; blood glucose control; privacy-preserving artificial intelligence; reward shaping; AI



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# Introduction

## Background

Maintaining optimal blood glucose levels is a critical aspect of diabetes management, particularly for individuals with type 1 and advanced type 2 diabetes. Poor glycemic control can lead to severe short- and long-term complications, including hypoglycemia, hyperglycemia, cardiovascular disease, kidney failure, and neuropathy [1,2]. Hypoglycemia (<70 mg/dL) poses an immediate danger, causing confusion, seizures, and in extreme cases, coma or death. On the other hand, hyperglycemia (>180 mg/dL) increases the risk of long-term vascular and neurological complications. Given the life-threatening consequences of glucose fluctuations, maintaining time in range (TIR)—the percentage of time blood glucose remains between 70 and 180 mg/dL—has become a key metric in assessing diabetes management effectiveness.

In recent years, technological advancements have significantly improved glycemic management. Closed-loop insulin delivery systems, commonly known as artificial pancreas systems, use continuous glucose monitoring (CGM) sensors and insulin pumps to automate glucose regulation. These systems rely on control algorithms such as proportional-integral-derivative (PID) controllers and model predictive control (MPC) to adjust insulin dosing dynamically [3]. While these methods have enhanced automation, they remain limited in their ability to personalize treatment for individual patients due to variations in metabolism, diet, physical activity, and insulin sensitivity.

To address these limitations, machine learning (ML) and reinforcement learning (RL) approaches have emerged as promising alternatives, enabling data-driven and adaptive insulin dosing strategies [4-8]. However, these approaches still face significant challenges related to multiobjective optimization, privacy concerns, and generalizability across diverse patient populations.

## Research Gaps in Existing Methods

Traditional closed-loop control systems, such as PID- and MPC-based insulin delivery, rely on fixed mathematical models to regulate blood glucose levels [3]. These methods provide some level of automation but face limited adaptability to individual patient variations. Since they use predefined rules, they often fail to accommodate real-time metabolic fluctuations, making them less effective for personalized treatment. Moreover, these systems prioritize glucose stabilization but do not explicitly optimize other clinical factors, such as insulin efficiency and glycemic variability reduction [3].

ML techniques have improved glucose prediction and insulin recommendation by analyzing historical patient data. Supervised learning models, such as deep neural networks, have been used to forecast glucose trends based on CGM data [7,8]. While these models demonstrate strong predictive capabilities, they rely heavily on large datasets that may not always be available due to privacy regulations [9,10]. Furthermore, ML-based approaches lack decision-making capabilities, as they are designed for prediction rather than active control, making them insufficient for fully automated glucose regulation [8].

RL offers a more dynamic and adaptive solution, as it allows artificial intelligence (AI) models to learn optimal insulin dosing strategies through trial and error. Unlike traditional ML, RL does not require explicit supervision and can adjust insulin delivery based on real-time feedback from CGM data. Several RL-based frameworks have demonstrated improvements in personalized insulin dosing [4-7,11]. Recent work has also applied RL to personalize digital health interventions and optimize treatment recommendations in diabetes care [12,13]. However, existing RL methods face three major challenges:

1. Single-objective optimization: most RL models optimize only TIR but fail to balance other critical objectives such as reducing glycemic variability, preventing hypoglycemia, and minimizing insulin overuse [11,14].
2. Privacy and data security risks: standard RL models require centralized patient data for training, raising concerns about data privacy, security, and regulatory compliance [9,15,16].
3. Limited scalability and generalizability: traditional RL models often struggle to generalize across diverse patient populations, as they are typically trained on homogeneous datasets that may not reflect real-world variability in metabolic responses [17-19].

The limitations of existing glycemic management methods highlight the need for a privacy-preserving, scalable, and multiobjective learning framework. A truly effective system must:

1. Optimize multiple clinical goals: traditional models focus primarily on TIR, but optimal glycemic control requires simultaneously addressing insulin efficiency, hypoglycemia prevention, and glucose stability. A multiobjective RL approach is needed to balance these competing factors effectively.
2. Ensure data privacy without sacrificing learning efficiency: most AI-based systems rely on centralized training, which exposes sensitive patient data to security risks. Federated learning (FL) enables models to be trained locally on patient devices, ensuring privacy preservation while still allowing for robust learning. Recent studies have demonstrated the viability of FL to support privacy-preserving collaboration in health care, including frameworks tailored for clinical research [20,21].
3. Improve generalizability and scalability: existing methods often fail to adapt to diverse patient populations due to limited training data. A FL-based approach can leverage distributed patient data without centralizing information, thereby enhancing model robustness and adaptability.

## Proposed Solution: PRIMO-FRL

To address these challenges, we propose PRIMO-FRL (Privacy-Preserving Reinforcement Learning for Individualized Multi-Objective Glycemic Management Using Federated Reinforcement Learning). PRIMO-FRL integrates RL with FL to develop a secure, scalable, and adaptive system for personalized glycemic control.

PRIMO-FRL differs from existing approaches in several key ways. First, it incorporates multiobjective reward shaping, allowing the model to optimize not just TIR but also insulin



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efficiency, glycemic stability, and hypoglycemia prevention. Second, by leveraging FL, PRIMO-FRL enables decentralized training, ensuring that patient data remains local while still benefiting from collaborative learning across multiple devices. Finally, this approach improves scalability and generalizability by enabling models to learn from diverse patient populations without requiring direct data exchange.

### Key Contributions

This study introduces a novel PRIMO-FRL framework for glycemic management. The key contributions of this work are (1) development of a privacy-preserving RL framework that enables secure, decentralized model training without centralizing patient data, (2) integration of multiobjective optimization to balance TIR, insulin efficiency, glycemic stability, and hypoglycemia prevention, (3) scalable and adaptive learning mechanism that ensures generalizability across diverse patient populations using federated RL, and (4) secure and efficient model aggregation that prevents data breaches while allowing models to benefit from shared knowledge across distributed environments.

The aim of this study is to develop and validate PRIMO-FRL, a privacy-preserving federated RL framework for glycemic management that optimizes multiple clinical goals—maximizing TIR, reducing hypoglycemia and hyperglycemia, and minimizing glycemic risk—while ensuring patient data privacy through decentralized training.

## Methods

### Overview

Our proposed system, PRIMO-FRL, integrates FL and RL to develop a decentralized, privacy-preserving insulin optimization framework. Unlike traditional insulin delivery systems that rely on predefined algorithms or centralized AI models, PRIMO-FRL allows each patient device to locally train an RL agent, ensuring personalized adaptation while protecting sensitive medical data.

By leveraging federated RL, PRIMO-FRL enables a collaborative learning process where individual patient devices contribute to the improvement of a global insulin optimization model without sharing raw glucose and insulin data. This approach ensures that (1) personalized insulin dosing policies are developed based on patient-specific metabolic patterns, (2) multiobjective optimization is applied to balance glucose control, insulin efficiency, and safety, and (3) FL ensures privacy by keeping patient data local while still allowing collective model improvements.

This framework enables a privacy-compliant, scalable, and adaptive insulin therapy solution, addressing key challenges in modern glycemic management.

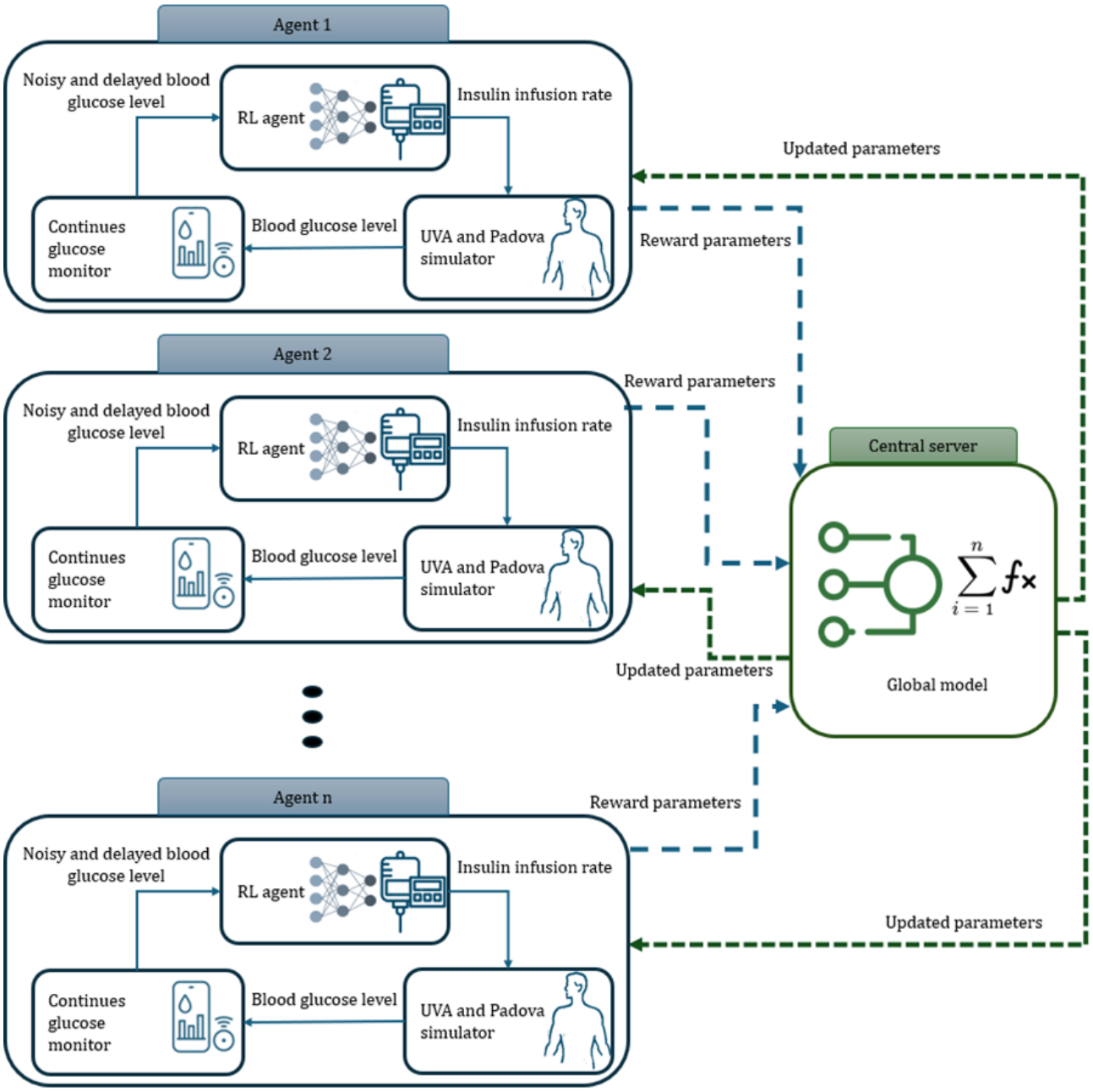
### Federated RL Workflow

Glycemic regulation in closed-loop insulin delivery systems can be framed as a decision-making process under uncertainty, modeled as a partially observable Markov decision process [8]. As shown in Figure 1, in this framework, an RL agent learns an insulin dosing policy through continuous interaction with the environment, receiving partial observations of the patient's metabolic state.



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**Figure 1.** System architecture. RL: reinforcement learning.




The key components of the partially observable Markov decision process formulation in this context are defined as follows: (1)

1. State (s): the patient's glucose level, insulin history, carbohydrate intake, and physiological parameters.
2. Action (a): the insulin dosage recommended by the RL agent.
3. Observation (o): real-time glucose readings from a continuous glucose monitoring (CGM) device, which are noisy and affected by sensor delays.
4. Reward (r): a multiobjective function balancing glucose control, insulin efficiency, and safety.

Since glucose metabolism is dynamic and influenced by past events, partially observable Markov decision process modeling allows the agent to make optimized insulin dosing decisions despite uncertainty in observations.

## System Components and FL Integration

PRIMO-FRL is structured around an FL framework in which multiple client devices (each representing an individual patient) collaboratively train a global model without centralizing patient data. The four main components of the system are as follows:

1. RL agents on client devices: each patient device runs a soft actor-critic (SAC) RL agent, which continuously learns an insulin dosing policy based on real-time glucose readings. SAC is particularly suitable for this application due to its ability to balance exploration and exploitation, ensuring that the agent learns optimal dosing strategies while adapting to patient-specific metabolic patterns [22].
2. UVA/Padova diabetes simulator [23,24]: a simulation tool for glucose-insulin dynamics in patients with type 1 diabetes, allowing agents to train in a controlled simulated environment.



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3. Continuous glucose monitoring (CGM)/glucose sensor: each client device is connected to a CGM sensor, which provides glucose data with noise and delays to simulate real-world monitoring conditions.
4. FL coordination server: a central server acts as a federated coordinator, aggregating model updates from multiple patient devices while ensuring that raw glucose and insulin data remain private. The FL loop follows these steps: (1) each client device trains its RL agent locally; (2) instead of sharing patient data, the client sends model updates (reward parameters, policy weights, and gradients) to the central server; (3) the server aggregates the updates using federated averaging, adjusting for factors such as risk levels and patient variability; and (4) the updated global model is sent back to all clients, allowing each RL agent to benefit from knowledge gained across the network while maintaining patient privacy.

### Reward Optimization and Multiobjective Learning

A critical innovation in PRIMO-FRL is its multiobjective reward function, designed to balance competing goals in insulin therapy. It integrates components to encourage exploration (via policy entropy), penalize glucose deviations and insulin overuse, and reward glucose stability. The reward function balances these objectives through tunable coefficients.

A full breakdown of the mathematical formulation and hyperparameter tuning strategy is provided in Multimedia Appendix 1.

Our multiobjective reward function ensures that RL agents focus on multiple goals, such as maintaining safe blood glucose levels, preventing hypoglycemia, and optimizing insulin use. This personalized reward system, combined with the FL process managed by the central server, enables the system to provide better individualized care while benefiting from shared knowledge across all clients. In multiobjective optimization, conflicting goals—such as maintaining high TIR while minimizing insulin use—are handled through a carefully designed reward function that combines multiple clinical objectives using weighted coefficients ($\alpha$, $\beta$, $\gamma$, and $\eta$). These weights were empirically tuned to reflect clinical priorities; for example, greater penalties are assigned to hypoglycemia and large glucose excursions than to moderate insulin use. This ensures that safety-critical outcomes are prioritized during training. In addition, the FL server plays a key role in balancing these trade-offs across the population. During the aggregation process, the server incorporates model updates from clients with diverse glycemic patterns and risk profiles. This distributed learning dynamic allows PRIMO-FRL to learn a globally balanced policy that generalizes well while still preserving local personalization. Future work may explore adaptive weighting strategies or Pareto front–based optimization to further refine trade-off resolution.

By integrating these advanced RL techniques with FL, our system not only enhances the personalization of glucose control but also ensures the privacy and security of patient data. This innovative approach addresses the critical challenges in diabetes management, paving the way for more effective and secure health care solutions.

### Ethical Considerations

This study did not involve human participants or identifiable personal data. All data were generated by the Food and Drug Administration (FDA)–approved UVA/Padova type 1 diabetes simulator.

## Results

### Overview

We conducted comprehensive experiments to evaluate the effectiveness of PRIMO-FRL with an entropy-based reward function for personalized blood glucose control. This section presents experimental results, highlighting the model's performance across multiple patient cohorts and its effectiveness in achieving safe, adaptive, and privacy-preserving insulin optimization.

### Experimental Setup

#### *Simulated Patient Data*

Due to ethical, privacy, and logistical constraints in collecting real-world patient data, we used a validated simulation model for evaluation. The FDA-approved UVA/Padova simulator, a widely recognized tool for modeling glucose-insulin dynamics in patients with type 1 diabetes, was used to generate realistic, diverse patient data [19,25].

We simulated 30 simulated patients categorized into three groups: children, adolescents, and adults, with 10 patients per group. To promote realistic variability and support generalizability, these patients were randomly assigned to federated agents, ensuring heterogeneity in physiological characteristics such as insulin sensitivity, glucose absorption, and glycemic response. Each patient exhibited unique physiological characteristics to reflect diverse metabolic profiles. Data were generated over 5-day periods, including CGM readings recorded every 5 minutes and insulin dosages delivered at equivalent intervals. These simulated datasets provided a controlled and privacy-preserving environment to evaluate PRIMO-FRL's performance.

#### *Model Training and FL Implementation*

The PRIMO-FRL framework was trained using federated reinforcement learning (FRL) principles. Each patient device independently trained a SAC RL agent, which optimized insulin dosing based on real-time glucose fluctuations.

The model parameters are as follows:

- Neural network architecture: 2 gated recurrent unit layers (128 hidden units each), followed by a fully connected output layer for insulin dosing decisions.
- Training details: 300 epochs, with a 5-day epoch length and a batch size of 256.
- FL aggregation: agents periodically transmitted model updates (policy gradients and reward parameters) to a central aggregation server, which performed federated averaging to update the global model.
- Reward function optimization: the entropy-based reward function incorporated glucose stability, insulin efficiency, and hypoglycemia prevention.



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The trained models were validated using hold-out test data to ensure robust performance. To reduce the risk of overfitting, training incorporated several safeguards: (1) dropout layers were applied to neural network models, (2) model performance was periodically validated on hold-out simulated patients not used during training, and (3) early stopping was used based on plateaued improvements in validation metrics. Importantly, the FL framework trained agents across 30 diverse simulated patients spanning children, adolescents, and adults, promoting generalization by preventing overspecialization to any single cohort.

## Performance Evaluation

### *Glycemic Control Outcomes*

PRIMO-FRL was evaluated based on key glycemic control metrics, particularly TIR, hypoglycemia prevention, and hyperglycemia reduction across all patient cohorts. The following summarizes the model's performance across these clinical indicators:

1. TIR (70 - 180 mg/dL): the TIR metric, a primary measure of glycemic management, showed that PRIMO-FRL effectively maintained blood glucose within the target range across all age groups: (1) adults achieved the highest TIR (81.48%), followed by children (77.78%), and adolescents (70.37%) and (2) overall TIR across all groups was 76.54% , surpassing clinical benchmarks for optimal glucose control.
2. Hypoglycemia (<70 mg/dL) prevention: a major highlight of PRIMO-FRL is its ability to completely eliminate hypoglycemia—0.0% time spent in hypoglycemia across all cohorts (0 out of 30 patients), demonstrating the framework's safety and effectiveness in preventing dangerously low blood glucose levels.
3. Hyperglycemia (>180 mg/dL) management: Mild hyperglycemia (180-250 mg/dL) was observed, particularly in younger patients. The adolescent group showed the highest incidence (29.63%), followed by children (22.22%), and adults (18.52%). These findings are consistent with known age-related glucose variability.
4. Severe hyperglycemia (>250 mg/dL): no severe hyperglycemia was observed in any cohort, demonstrating the system's robustness in managing extreme glucose excursions.

Table 1 provides a detailed breakdown of glycemic control performance.

**Table .** Aggregated glycemic control results across patient groups. Percentages represent the average proportion of simulation time spent in each glucose range per group (N=10 simulated patients per group).

| Patient group | <50 mg/dL, % | 50 - 70 mg/dL, % | 70 - 180 mg/dL, % | 180 - 250 mg/dL, % | >250 mg/dL, % |
|---|---|---|---|---|---|
| Child | 0.0 | 0.0 | 77.78 | 22.22 | 0.0 |
| Adolescent | 0.0 | 0.0 | 70.37 | 29.63 | 0.0 |
| Adult | 0.0 | 0.0 | 81.48 | 18.52 | 0.0 |
| Overall | 0.0 | 0.0 | 76.54 | 23.46 | 0.0 |

### *Comparative Analysis With Existing Studies*

To contextualize PRIMO-FRL's effectiveness, we compared its results with prior ML- and RL-based blood glucose regulation methods. A detailed comparison with prior ML and RL methods is available in Multimedia Appendix 2.

### *Key Observations and Improvements*

The following key findings highlight how PRIMO-FRL improves upon existing methods across safety, glycemic control, and clinical effectiveness:

1. Superior safety*:* PRIMO-FRL eliminated hypoglycemia entirely, outperforming prior approaches such as RL-Scratch in [8], which reported a 0.73% hypoglycemia incidence.
2. Strong TIR performance: the overall TIR of 76.54% aligns with or surpasses other RL-based methods (eg,~73% in [5]).
3. Effective hyperglycemia control: mild hyperglycemia (180 - 250 mg/dL) was effectively managed, and severe hyperglycemia (>250 mg/dL) was avoided in all groups.

## Risk Improvement and Stability Analysis

Figure 2 presents the 24-hour blood glucose trajectories for 3 representative patients. The blue line represents blood glucose levels, while the dashed orange and red lines indicate the hypoglycemia (70 mg/dL) and hyperglycemia (180 mg/dL) thresholds, respectively. The key insights from this figure include the following:

1. Effective glucose control: the PRIMO-FRL approach successfully maintains glucose levels within safe physiological ranges, preventing both severe hypoglycemia and hyperglycemia.
2. Stable glycemic response: patient child#001 starts with high glucose levels, which gradually decline and stabilize. Similarly, adult#006 and adolescent#006 exhibit relatively stable glucose trajectories, with fewer extreme fluctuations.
3. Reduced hyperglycemia episodes: the glucose trends suggest that the FRL model helps mitigate prolonged hyperglycemia, particularly for adolescent#006, who demonstrates a downward trend toward normal glucose levels.



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**Figure 2.** Twenty-four–hour glucose level trajectories for representative patients.

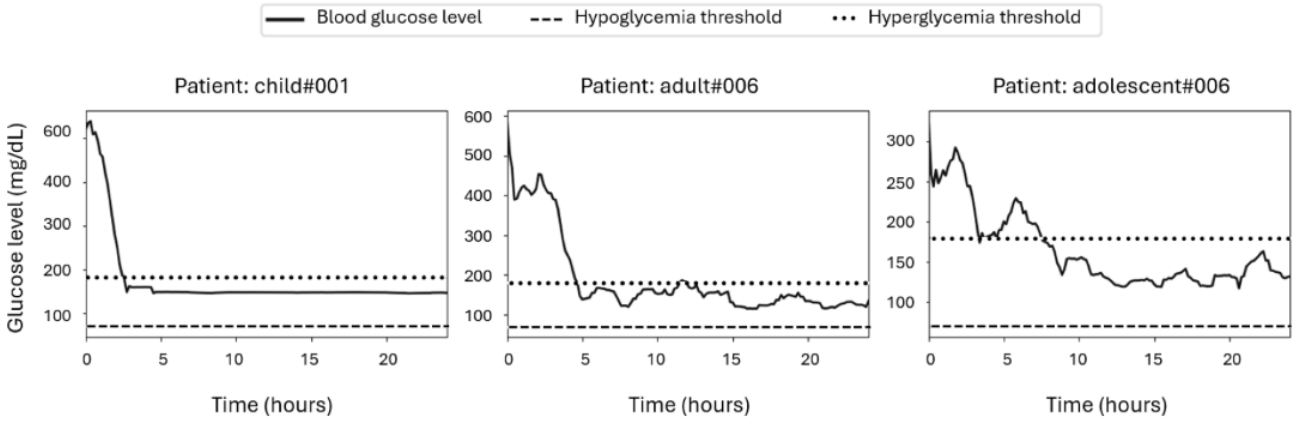
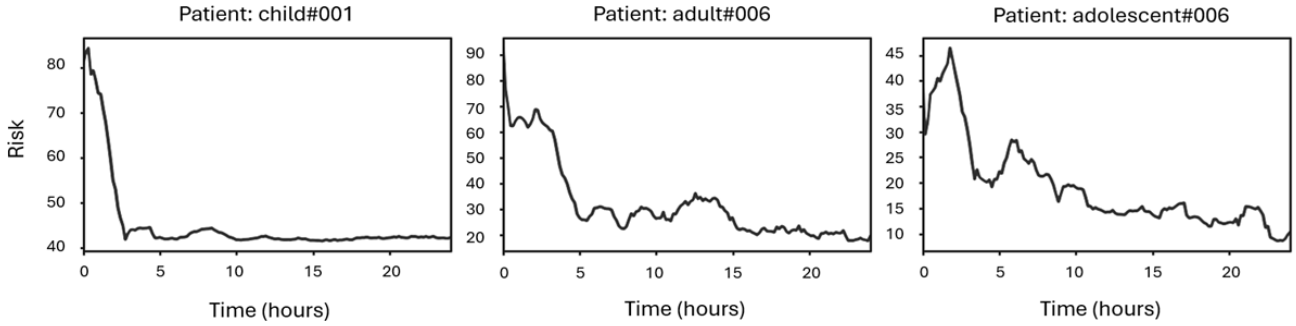



Figure 3 presents the risk trajectories for the same patients over 24 hours. The risk score (y-axis) quantifies the likelihood of adverse outcomes due to hypoglycemia or hyperglycemia, while the x-axis represents time. The key observations include:

1. Consistent risk reduction: across all 3 patients, the PRIMO-FRL approach significantly lowers risk scores over time, demonstrating its ability to penalize extreme glucose deviations while reinforcing stable glucose management.
2. Reduced glycemic variability: patients experience a noticeable decline in risk levels. For example, child#001 initially exhibits high risk, which then stabilizes at a lower level, indicating a reduced likelihood of hypoglycemic or hyperglycemic events. Similarly, adult#006 and adolescent#006 show smoother, sustained risk reductions, suggesting better glucose regulation.
3. Improved stability: over time, risk scores not only decrease but also stabilize, as evidenced by the flattening trends in later hours. This stability highlights the FRL approach's effectiveness in providing long-term consistency in glucose management.

**Figure 3.** Twenty-four–hour risk improvement for representative patients.




These findings confirm that the PRIMO-FRL approach effectively reduces patient risk while ensuring a more stable and safe glucose control mechanism.

## Discussion

### Principal Findings

In this work, we proposed a novel FRL framework, PRIMO-FRL, for personalized blood glucose control, incorporating an entropy-based reward function to enhance adaptability and privacy preservation. Our approach addresses key challenges in diabetes management, including variability in patient responses, data privacy concerns, and the need for robust, individualized treatment strategies. By leveraging FL, PRIMO-FRL ensures that sensitive patient data remains local, thus safeguarding privacy while benefiting from the diversity of data across patients.

Experimental evaluations using validated simulation models demonstrated the effectiveness of our approach, achieving significant improvements in risk scores, time in the euglycemic range, and glucose stability across diverse patient categories. The entropy-based reward function encouraged policy exploration, effectively balancing glucose regulation, insulin usage, and glucose variability. Notably, these improvements were achieved without increasing insulin use, underlining the system's efficiency and safety.

### Limitations

While PRIMO-FRL offers several advantages, certain limitations must be acknowledged, and future directions should aim to address these challenges.

#### *Simulation Model Dependence*

The experimental results were obtained using validated simulation models. While these models provide valuable insights, real-world validation is essential to confirm the efficacy and safety of the framework in clinical settings. Although the model was trained on simulated data, we took precautions to avoid overfitting through dropout, early stopping, and evaluation on held-out patient profiles. Moreover, the federated structure naturally supports generalization, as it forces the model to adapt across distributed, heterogeneous patient agents. Future work involving real-world clinical validation will further evaluate



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model robustness and generalizability to unseen metabolic patterns. Integration with real-world CGM systems would likely occur through edge devices (eg, smartphones or insulin pump controllers), which would enable real-time data processing and model updates using FL without compromising data privacy.

### *Communication Overheads*

FL relies on transferring model updates between a central server and local devices. Although we aimed to minimize data exchange, communication overheads could still be a bottleneck in low-bandwidth or high-latency environments. Another potential challenge in real-world deployment is the communication overhead introduced by FL. PRIMO-FRL relies on periodic transmission of model updates (eg, policy gradients and reward parameters) between client devices and the central aggregator. In environments with limited bandwidth or high latency—such as rural areas or underresourced clinics—this could hinder real-time synchronization and degrade performance. To mitigate this, future iterations of PRIMO-FRL may incorporate model compression techniques, sparse update schemes, or asynchronous FL approaches to reduce communication costs while maintaining training efficiency and model accuracy.

### *Patient Heterogeneity*

Individual patient variability is high in diabetes management. While FL accommodates diverse patient data, additional personalization strategies or more extensive data might be necessary for complex cases with outlier metabolic profiles.

### *Privacy and Security Considerations*

While FL enhances privacy by keeping raw patient data local, it is not immune to adversarial threats. Techniques such as gradient inversion attacks could potentially reconstruct sensitive information from shared model updates, and adversarial participants could perform model poisoning to degrade global performance. To mitigate these risks, future iterations of PRIMO-FRL could incorporate privacy-preserving techniques such as differential privacy, secure multiparty computation, or robust aggregation algorithms (eg, Krum or Trimmed Mean). In addition, anomaly detection methods can help identify and exclude malicious client updates, further strengthening system resilience.

## Comparison With Prior Work

Prior research in AI-driven glycemic management has explored CGM systems, artificial pancreas technologies, and RL-based insulin dosing [2,3]. However, most existing approaches rely on centralized data collection, raising serious concerns about patient privacy, security, and regulatory compliance [9].

PRIMO-FRL offers a fundamental shift from these centralized approaches by leveraging federated RL, which ensures that raw patient data never leaves local devices. This privacy-preserving architecture aligns with recent advancements in decentralized learning paradigms but extends prior work by integrating a multiobjective entropy-based reward function specifically tailored for personalized insulin optimization. Unlike traditional RL methods that require pooled, centrally stored data [4,5,11], PRIMO-FRL achieves comparable or superior glycemic control performance while preserving patient confidentiality.

In addition, PRIMO-FRL addresses key limitations in existing RL-based insulin dosing systems, which often prioritize single-objective optimization (eg, maximizing TIR) [8,11]. By contrast, PRIMO-FRL explicitly optimizes multiple clinical goals, including hypoglycemia prevention, glucose stability, and insulin efficiency, making it better suited for real-world applications where trade-offs between multiple factors are necessary.

Compared to traditional diabetes management strategies, such as manual insulin dosing guided by fixed algorithms or carbohydrate counting, PRIMO-FRL offers a more adaptive and personalized approach. Standard insulin delivery methods, such as manual basal-bolus regimens or PID- or MPC-based closed-loop systems, are limited by fixed-rule control and lack of adaptability to individual metabolic responses. In contrast, PRIMO-FRL dynamically adjusts insulin dosing through real-time learning and explicitly incorporates clinical goals—including hypoglycemia avoidance, glycemic stability, and insulin efficiency—into its optimization framework. This alignment with current clinical best practices, combined with its ability to personalize care while preserving privacy, positions PRIMO-FRL as a clinically relevant advancement in AI-driven diabetes management.

## Conclusions

Our findings underscore PRIMO-FRL as a transformative, privacy-preserving framework for glycemic management. By eliminating hypoglycemia, improving TIR, and leveraging federated RL, PRIMO-FRL offers a scalable, secure, and multiobjective optimization strategy for real-world diabetes care.

Beyond diabetes management, the principles demonstrated in PRIMO-FRL have broader implications for other chronic disease management applications, where personalized, privacy-preserving, AI-driven decision-making is critical. Future work will focus on clinical trials, real-world deployment, and further optimization of the FL process to enhance efficiency, scalability, and adaptability across diverse patient populations.

Through its integration of RL, FL, and multiobjective optimization, PRIMO-FRL represents a next-generation approach to AI-driven personalized medicine, paving the way for safer, more adaptive, and privacy-compliant digital health solutions. While PRIMO-FRL demonstrates strong performance in glucose regulation, interpretability remains an important consideration for clinical acceptance. In practice, health care providers often require insight into the rationale behind AI-generated decisions, especially in high-risk domains like insulin dosing. Future work will explore methods to improve the explainability of RL agents, such as incorporating attention-based visualization of decision factors, generating counterfactual scenarios to highlight what influenced a particular dosing choice, or applying inherently interpretable policy architectures. Enhancing transparency will support shared decision-making and promote clinician confidence in AI-assisted care.



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## Authors' Contributions

FSR and JL conceptualized the framework and developed the overall methodology. FSR conducted the initial modeling and system design. FSR and JL provided critical input on experimental design and contributed to model validation, ensuring the robustness of the evaluation metrics. FSR performed the formal analysis of simulation outcomes and interpreted the results. FSR prepared the first draft of the manuscript, and JL oversaw subsequent revisions and edits for clarity and coherence.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Detailed reward function.
[DOCX File, 19 KB - diabetes_v10i1e72874_app1.docx ]

Multimedia Appendix 2
Comparative performance analysis with baseline machine learning and reinforcement learning models.
[DOCX File, 19 KB - diabetes_v10i1e72874_app2.docx ]

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## Abbreviations

**AI:** artificial intelligence
**CGM:** continuous glucose monitoring
**FDA:** Food and Drug Administration
**FL:** federated learning
**FRL:** federated reinforcement learning
**ML:** machine learning
**MPC:** model predictive control
**PID:** proportional-integral-derivative
**PRIMO-FRL:** Privacy-Preserving Reinforcement Learning for Individualized Multi-Objective Glycemic Management Using Federated Reinforcement Learning
**RL:** reinforcement learning
**SAC:** soft actor-critic
**TIR:** time in range

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# The Use of AI-Powered Thermography to Detect Early Plantar Thermal Abnormalities in Patients With Diabetes: Cross-Sectional Observational Study

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## Abstract

**Background:** Diabetic foot problems are among the most debilitating complications of diabetes mellitus. Diabetes prevalence and complications, notably diabetic foot ulcers (DFUs), continue to rise, challenging health care despite advancements in medicine. Traditional DFU detection methods face scalability issues due to inefficiencies in time and practical application, leading to high recurrence and amputation rates alongside substantial health care costs. Human medical thermography could significantly enhance disease monitoring and detection, including DFUs.

**Objective:** This study evaluated the efficacy of artificial intelligence–powered thermography in detecting plantar thermal patterns that differentiate between adult patients with diabetes with no visible foot ulcers and healthy individuals without diabetes.

**Methods:** This cross-sectional observational study included 200 patients—100 healthy and 100 with diabetes without a visible foot ulcer. Initial data were gathered through a questionnaire. Participants were prepared for thermal imaging to capture plantar thermal patterns. All collected data, including thermal images and questionnaire responses, were stored on a password-protected computer to ensure confidentiality and data integrity.

**Results:** In this study, participants were categorized into 2 groups: a healthy control group (n=98) with no prior diabetes or peripheral artery disease diagnosis and normal circulatory findings, and a group with diabetes (n=98) comprising patients with diabetes, regardless of peripheral circulatory status. Temperature analysis indicated a wider range in the group with diabetes (18.1-35.6 °C) than in the healthy controls (21.1-35.7 °C), with the former showing significantly higher mean temperatures (mean 29.0 °C, SD 3.0 °C) than controls (mean 28.9 °C, SD 2.8 °C; $P$<.001). Analysis of both feet revealed significantly greater differences between feet in the group with diabetes and the controls (control: mean 0.47 °C, SD 0.43 °C; group with diabetes: mean 1.78 °C, SD 1.58 °C; $P$<.001; 95% CI 0.99-1.63). These results identified clinically relevant abnormalities in 10% of the cohort with diabetes, whereas no such findings were observed in the control group. We used a linear regression model to indicate that being diagnosed with diabetes is a significant predictor of abnormal temperature, while age and sex were not found to be significant predictors in this model.

**Conclusions:** DFUs pose a significant health risk for patients with diabetes, making early detection crucial. This study highlights the potential of an artificial intelligence–powered computer vision system in identifying early signs of diabetic foot complications by differentiating thermal patterns between patients with diabetes with no visible ulcers and healthy individuals. The findings suggest that the technology could improve early diagnosis and outcomes in diabetic foot care, although further research is needed to fully validate its effectiveness. The ability of the technology to detect compromised blood supply indicates its value in preventative clinical strategies.

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**KEYWORDS**

AI; computer-assisted; digital health; eHealth; diabetic foot; diabetes; monitoring; detect; detection; diagnosis; diagnostic; thermography; thermology; thermal; population health; artificial intelligence; foot ulcer; diabetic; image; imaging



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## Introduction

### Diabetic Foot Ulcers

Diabetes affects 1 in 10 adults worldwide (537 million) [1]. This number is predicted to rise to 643 million by 2030 and 783 million by 2045. In the Middle East and North Africa region, the prevalence is higher as it affects 1 in 6 adults (73 million) [1]. Despite advances in medical therapies, the prevalence of diabetes mellitus and diabetes-related complications continues to rise [2].

Diabetic foot problems are among the most debilitating complications of diabetes mellitus. It is commonly referred to as diabetic foot ulcer (DFU). The International Working Group on the Diabetic Foot defines a DFU as a break of the skin of the foot that includes minimally the epidermis and part of the dermis among patients with diabetes mellitus [3]. It is estimated that one-third of people with diabetes will develop a DFU during their lifetime [4]. Armstrong et al [5] emphasized the alarming statistic that every 20 seconds, a lower limb is amputated due to complications of diabetes, with 85% of these amputations preceded by a foot ulcer. The mortality risk at 5 years for individuals with DFUs is 2.5 times higher than for those with no ulcers [4]. Furthermore, Driver et al [6] revealed that DFUs and lower extremity amputations are not only markers of poor health but also independent risk factors associated with premature death. Unfortunately, even after a DFU has been resolved, recurrence is common and is estimated to be 40% within 1 year, 60% within 3 years, and 65% within 5 years [4].

### Economic Burden

Diabetes foot care costs are the single largest category of diabetes-related medical costs. Kurkela et al [7] found that the cost of care for patients with a foot ulcer is 5.4 times higher than that for patients with diabetes with no ulcers, accentuating the heightened financial burden linked to DFUs. The study by Driver et al [6] stated that about one-third of the direct costs of diabetes is attributable to care for diabetic foot disease. Leveraging thermography as a screening modality for DFUs has already demonstrated a noteworthy cost-saving potential, as evidenced by the findings of Everett and Mathioudakis [8]. Despite the requirement for human thermographers in their methodology, their study projected substantial savings through the integration of thermography as a standard procedure.

### Current Challenges in Early Detection of DFUs

Unfortunately, DFUs can be difficult to detect, especially in the early stages when it is not visible to the human eye. This is due to a number of factors, including inconsistent screening guidelines, limited awareness among patients and providers, and the frequent occurrence of silent or nonstandard symptoms [4,9,10]. To improve the early detection of DFUs, it is important to develop and implement universal screening guidelines, increase awareness among patients and providers, and develop and implement better screening tools and methods.

### Role of Thermography in DFU Detection

Medical thermography results from decades of research and development in the performance of infrared imaging equipment, standardization of technique, and clinical protocols for thermal imaging [11,12]. It could visualize diseases not readily detected or monitored by other methods. It is a fast, passive, noncontact, and noninvasive imaging method that has been used by numerous peer-reviewed studies [13]. There is an increase in publications and high-impact studies, emphasizing thermography's importance as a crucial tool for the early detection, prevention, and management of diabetic foot issues [14]. The American Academy of Thermology (AAT) established guidelines for the use of thermography in the evaluation of patients with diabetes. These guidelines provide recommendations for the use of thermal imaging in the detection and monitoring of diabetic neuropathy, including protocols for image acquisition and interpretation [15]. Figure 1 shows the thermal images of the lower extremities of patients with diabetes.

A major limitation of the current state of medical thermography is that even the most skilled human thermographer can only observe, analyze, and successfully interpret a limited number of thermograms. Computers, however, can process an image efficiently and extract useful information. Leveraging artificial intelligence (AI) algorithms, specifically, computer vision, can objectively observe the findings and minimize interobserver variability.

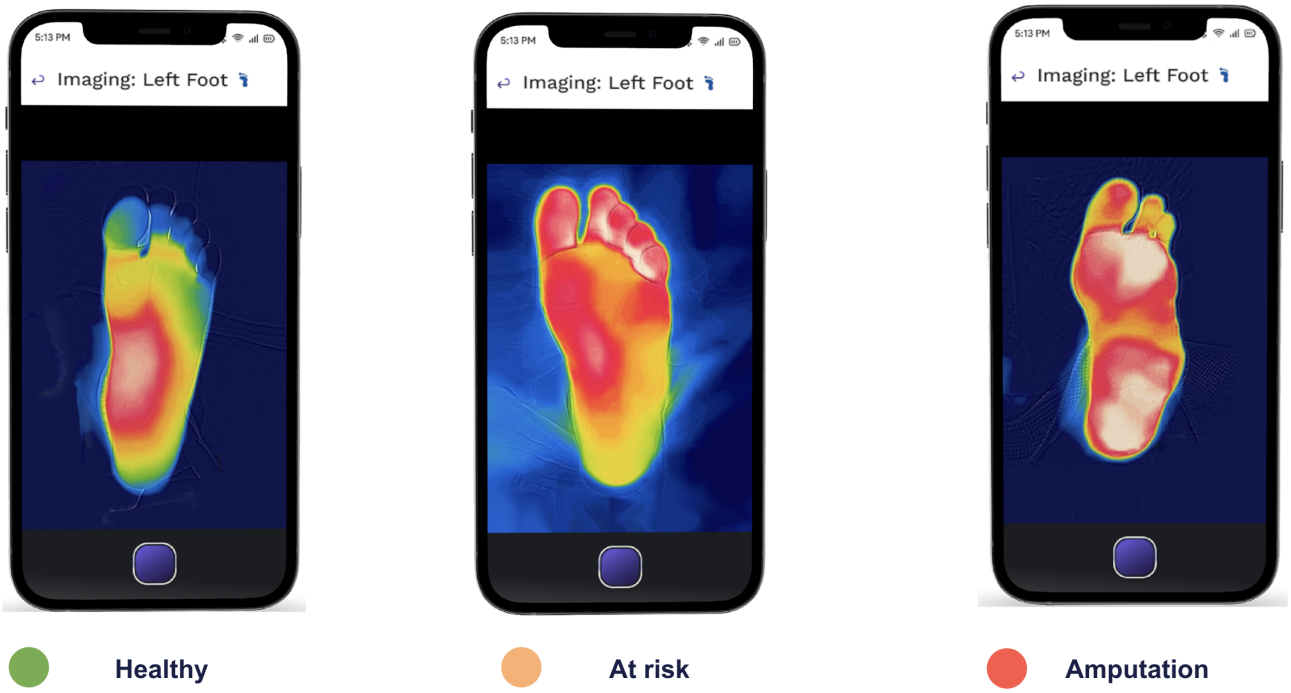
Thermography is helpful for the early detection of abnormalities of the foot by analyzing asymmetries and local temperature changes over time. Assessing temperature differences can enable the early detection of ulcers [16,17]. The application of thermal imaging for the detection of diabetic foot complications is based on the premise that variations in plantar temperature are associated with these types of complications [17-24]. Several papers highlighted that high temperature gradients between feet may predict the onset of foot ulcers [25-28]. Furthermore, the international working group of diabetic foot recommends a person with diabetes who is at moderate or high risk of foot ulceration to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a foot ulcer [29].

The rapid development of handheld smartphone-based thermal infrared imagers presents a creative solution for detecting and monitoring DFUs [30]. To address the lack of thermographers, practical AI algorithms are needed to automate the process of image acquisition and analysis. These rapidly expanding, low-cost, and widely available resources can help predict one's risk of developing foot ulcers, potentially saving limbs and lives. In this study, we will leverage AI technologies that are deployed on a smartphone-based thermal imager and application.



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**Figure 1.** Typical thermal images of plantar region for healthy patients, at-risk patients, and patients who underwent amputation.




### Rationale for the Study

The purpose of this study is to evaluate the efficacy of AI-powered thermography in detecting plantar thermal patterns that differentiate between adult patients with diabetes with no visible foot ulcers and healthy individuals with no diabetes.

## Methods

### Study Design

This is a cross-sectional observational study. The data collection phase spanned from June 2023 to February 2024. This time frame was sufficient to recruit people into the healthy group and individuals with no diabetes group.

### Study Location

Participants were recruited from King Khalid University Hospital, part of the King Saud University Medical City, a multidisciplinary facility offering general and subspecialty medical services, including primary, secondary, and tertiary care. Patients with diabetes were consecutively recruited from the diabetes clinics during the study period, reflecting real-world clinical practice. Healthy participants, on the other hand, were recruited from those visiting the hospital for routine check-ups or preventive care during the same period. All eligible individuals meeting the inclusion criteria were invited to participate, ensuring representativeness of the control group. A research assistant (RA) was present to facilitate recruitment and collect the necessary data. This consecutive sampling approach ensured that all eligible patients attending the clinic were considered for participation.

### Inclusion Criteria

The study included participants who were older than 18 years; healthy individuals, with no history of diabetes or cardiovascular disease (n=100); and have been diagnosed with diabetes (n=100). The inclusion of healthy participants as controls allowed for clear differentiation between diabetic and nondiabetic thermal patterns, emphasizing the distinct thermal asymmetry observed in patients with diabetes.

### Exclusion Criteria

Eligibility for participation was assessed through self-report during recruitment. The study excluded participants who have a visible foot pathology, such as visible ulcers, infections, or amputations, and are unable to stand without assistance due to the higher risk of falling or injuring themselves during the study. Participants who meet the inclusion criteria and are willing to participate were asked to provide their informed consent.

### Withdrawal of Participants From the Assessment

Participants were free to withdraw from the study at any time without giving a reason. Patients were advised that if they requested to withdraw from the study, at any time during the trial, then this would have no negative consequences.

### Description of the Technology

We have created a noninvasive system to identify diabetic foot complications at an early stage. We leverage off-the-shelf thermal cameras, compatible with smartphones or tablets, to capture detailed thermal images of participants' feet (Figure 2). We also used AI-based algorithms to perform semantic segmentation and reduce sensor noise in the captured thermograms. The AI models were trained to extract the plantar region as the region of interest and suppress any background or sensor noise. In addition, the AI was able to detect asymmetric thermal emission of 2.2 °C or greater, which can be indicative of pathology in a properly cooled participant [3,15,26,28,31,32].

The system used AI to process images efficiently and extract useful information. It made the findings more objective and minimized interobserver variability. This could result in faster throughput and through a centralized cloud-based processing

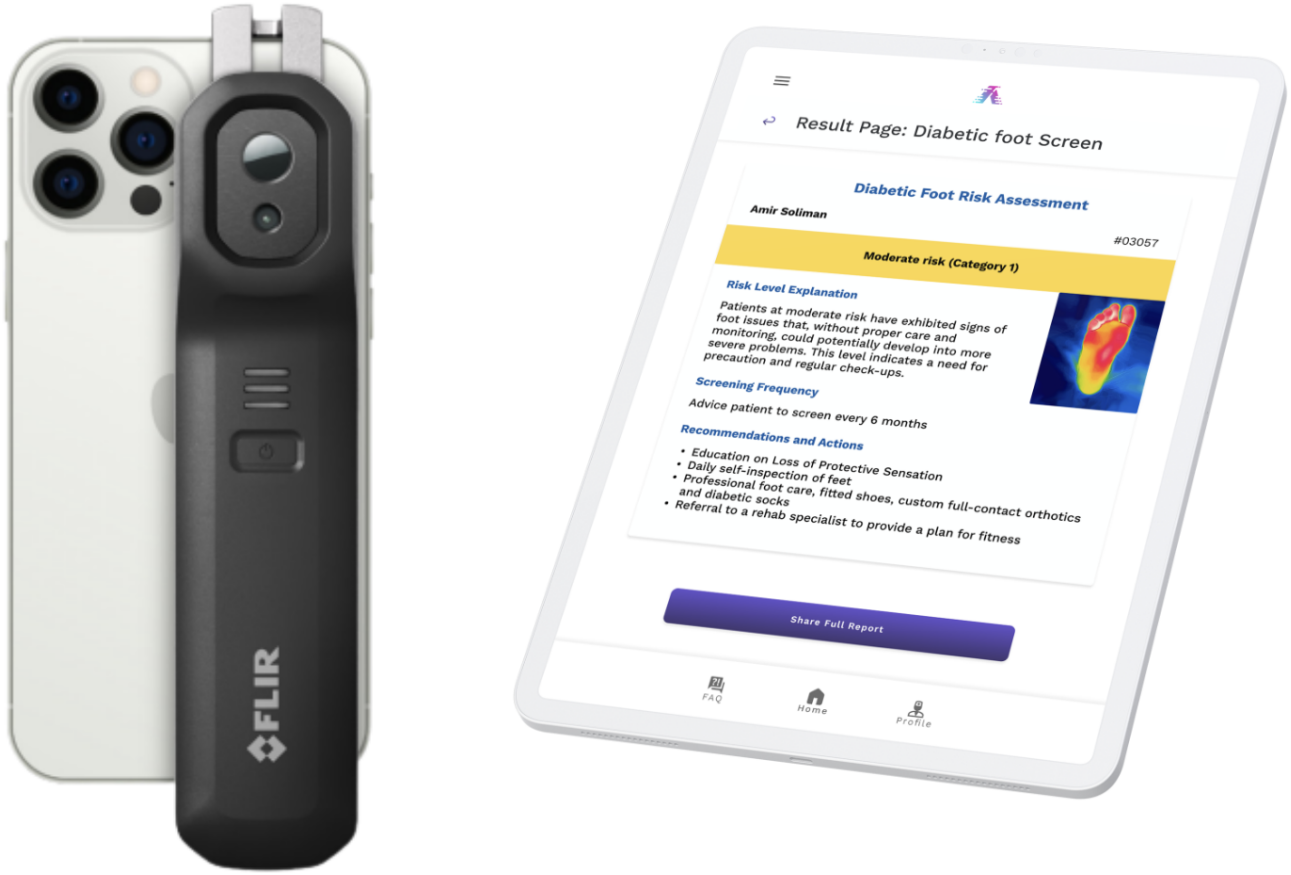


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where samples were anonymized by removing identifiable information from the data., increasing thermographic accuracy and reliability.

The technology analyzes thermal images captured from specific thermal camera models, the FLIR ONE Edge Pro. We selected the FLIR One Edge for its practicality and ease of use in clinical settings. While its resolution is lower than the AAT recommendation of 320×240 pixels, several studies have successfully used the FLIR One, which has an even lower resolution of 80×60 pixels, and concluded that it can effectively capture thermal signals indicative of DFUs [31,33,34]. The software identifies temperature variations consistent with inflammation and ulcerative patterns, signaling potential DFUs. The system records, stores, and transmits usage events from thermal cameras to a remote storage system.

**Figure 2.** Thermal imaging device.




## Data Collection

Before enrolling participants, the RA was trained to follow the study protocol, including participant recruitment, questionnaire administration, and thermal image capture. The RA completed a questionnaire via an app that included questions about the participant's age, sex, type of diabetes, duration of diabetes (years), hemoglobin $A_{1c}$ ($HbA_{1c}$), BMI, physical activity habits, smoking habits, and history of hypertension. In addition, they completed Inlow's 60-second Diabetic Foot Screen to assess the foot [35]. After completing the questionnaire, the RA prepared the participant and completed the thermal imaging.

## Experimental Equipment and Procedure

The results of infrared thermography can be influenced by various environmental, individual, and technical factors that affect human skin. To obtain accurate results, the thermal images of the participants in the study were carried out in compliance with the protocols and guidelines set by the AAT [15].

To maintain a stable blood flow to the feet, we asked participants to remove their shoes and socks and sit with their legs hanging freely for at least 10 minutes before the measurements were made. We maintained the humidity in the room to ensure that there is no moisture buildup on the skin, perspiration, or vapor levels that can interact with radiant infrared energy. Relative humidity below 70% is generally acceptable. The temperature was maintained between 19 ºC and 25 ºC. The camera was set about 1 m from the foot (the region of interest will fill ~75% of the image), and thermal masking was used to ensure a homogeneous background. Images of the plantar aspect of the feet were recorded for analysis.

## Ethical Considerations

Ethical approval for this study was obtained from King Saud University institutional review board (E-23 - 7866). Before agreeing to participate, all participants were informed about the nature of the research project, possible risks and benefits, and their rights as research participants. All participants completed a written consent form. They were also given a copy of the consent form. No compensation was provided to the participants. This decision was communicated to participants during the consent process, ensuring complete transparency.



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Participants were coded with a specific clinical investigation identification number. All participants were registered in a participant identification list (participant enrollment and identification list) that connects the participant's name and personal number with a clinical investigation identification number. All data were registered, managed, and stored in a manner that enables correct reporting, interpretation, and verification.

### Statistical Analysis

A database of the questionnaire results was created using unique nonidentifying numbers. The information is password-protected. Before conducting the analysis, data were cleaned and coded using Python Pandas NumPy and SciPy packages (pandas). Each item was discussed, and a decision concerning its eligibility and entry was made. The characteristics of participants are summarized with percentages for categorical variables and mean (SD) values for continuous variables. To compare the mean ages and BMI values between the healthy group and the group with diabetes, independent 2-sample 2-tailed *t* tests were conducted. For categorical variables, such as sex and health conditions, we used 2-proportion *z* tests to compare both groups.

For the correlation analysis, the foot skin temperature obtained is the average for the entire plantar region. We used the independent 2-tailed *t* test and the effect size (Cohen *d*) to compare foot skin temperature in healthy participants versus participants with diabetes. The level of significance is set at $P<.05$.

In addition, we conducted an ordinary least squares (OLS) regression to examine the relationship between temperature delta (difference in plantar temperatures between feet) and several predictor variables. The primary predictor of interest was diabetes status (healthy vs diabetic). To control for potential confounders, the model also included age, sex, BMI, physical activity level, diabetes duration, diabetes type, $HbA_{1c}$, and the presence of retinopathy. The OLS regression analysis was conducted to determine the significance and strength of the predictors in explaining the variance in the temperature delta. Statistical significance was set at $P<.05$.

While we did not perform a formal sample size calculation prior to the study, our sample size of 200 participants (100 individuals with diabetes and 100 healthy controls) was determined based on practical considerations, including the availability of eligible participants during the study period and the resources at our disposal. We aimed to ensure that the sample was sufficiently large to capture variability in thermal patterns between the 2 groups and to allow for meaningful statistical analyses. To support the adequacy of our sample size, we reviewed several related studies [17,19,21,24], many of which used smaller sample sizes while investigating similar research questions.

## Results

### Participant Characteristics

Participants were divided into 2 groups. Individuals with normal circulatory findings and with no earlier diagnosis of diabetes or peripheral artery disease (PAD) were assigned to the healthy control group (n=98). All patients with diabetes, with or with no peripheral circulatory disturbance, were assigned to the group with diabetes (n=98). It is important to note that the group with diabetes did not have a visible foot ulcer. Approximately 61% (119/196) of participants were female, with a mean age of 39.2 (SD 15.5) years. The average BMI was 26.4 (SD 5.6) kg/m². There was a significant difference between both groups and the group with diabetes was slightly older and had a higher BMI. Patients with diabetes exhibited various comorbidities: cardiovascular disease (16.9%, 33/98), retinopathy (15.4%, 30/98), neuropathy (11.8%, 23/98), and peripheral vascular disease (12.8%, 25/98). Furthermore, 15.9% of patients with diabetes reported poor glycemic control. The group with diabetes included 57.14% (56/98) with type 1 diabetes and 41.84% (41/98) with type 2 diabetes, with a mean diabetes duration of 15.38 (SD 8.99) years. The mean $HbA_{1c}$ level was 7.37%, with an SD of 1.56%. Table 1 illustrates the participant characteristics.



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**Table .** Participant characteristics (N=196).

| Variables | Total (N=196) | Healthy group (n=98) | Diabetic group (n=98) | *P* value | 95% CI |
|---|---|---|---|---|---|
| Age (years), mean (SD) | 39.3 (15.5) | 33.2 (11.2) | 45.7 (16.8) | <.05 | 8.4 to 16.5 |
| <25 | 21.7 (1.7) | 22.05 (1.3) | 21.1 (2.1) | >.05 | −2.1 to 0.3 |
| 40 | 31.2 (4.8) | 30.7 (4.7) | 32.6 (4.6) | >.05 | −0.3 to 4.3 |
| >40 | 55.4 (10.3) | 51.1 (7.6) | 57 (10.7) | <.05 | 0.8 to 11.1 |
| BMI (kg/m²), mean (SD) | 26.4 (5.6) | 24.31 (4.1) | 28.75 (6.2) | <.05 | 2.9 to 5.9 |
| Males, n (%) | 76 (38.7) | 38 (38.7) | 38 (38.7) | >.05 | −13.7 to 13.7 |
| Females, n (%) | 120 (61.2) | 60 (61.2) | 60 (61.2) | >.05 | −13.7 to 13.7 |
| Cardiovascular disease, n (%) | 33 (16.8) | 0 (0) | 33 (33.6) | <.05 | −44.2 to −23.1 |
| Retinopathy, n (%) | 30 (15.3) | 0 (0) | 30 (30.6) | <.05 | −40.7 to −20.4 |
| Neuropathy, n (%) | 23 (11.7) | 0 (0) | 23 (23.4) | <.05 | −32.5 to −14.4 |
| Peripheral vascular disease, n (%) | 25 (12.7) | 0 (0) | 25 (25.5) | <.05 | −34.9 to −16.1 |
| Diabetes type, n (%) | | | | | |
| Type 1 | 56 (57.14) | N/A[a] | N/A | N/A | N/A |
| Type 2 | 41 (41.84) | N/A | N/A | N/A | N/A |
| Other | 1 (1.02) | N/A | N/A | N/A | N/A |
| Duration of diabetes, mean (SD) | 15.38 (8.99) | N/A | N/A | N/A | N/A |
| $HbA_{1c}$[b], mean (SD) | 7.37 (1.56) | N/A | N/A | N/A | N/A |
| Physical activity, n (%) | | | | | |
| Never | 63 (32.14) | 39 (19.9) | 24 (12.24) | <.05 | 0.02 to 0.28 |
| Several times a week | 21 (10.71) | 7 (3.57) | 14 (7.14) | >.05 | −0.15 to 0.01 |
| Rarely | 58 (29.59) | 30 (15.31) | 28 (14.29) | >.05 | −0.10 to 0.14 |
| Once a week | 14 (7.14) | 9 (4.59) | 5 (2.55) | >.05 | −0.03 to 0.11 |
| Daily | 40 (20.41) | 13 (6.63) | 27 (13.78) | <.05 | −0.25 to −0.03 |

[a]N/A: not applicable.

[b]$HbA_{1c}$: hemoglobin $A_{1c}$.

## Thermographic Analysis

The temperatures spanned a wider range in the group with diabetes than in the healthy control group, with a range of 18.1-35.6 °C in the group with diabetes and of 21.1-35.7 °C in the control group. The mean temperatures were significantly higher in the group with diabetes than in the control group (*P*<.001). Considering both feet as 1 bloc, the mean temperatures were 28.9 °C (SD 2.8 °C) among controls, and 29.0 °C (SD 3.0 °C; *P*<.001) in the group with diabetes.

Side-to-side comparisons of temperatures revealed significant differences between feet (*P*<.05) at all measurement sites (Table 2). Analysis of both feet revealed significantly greater differences between feet in the group with diabetes compared with controls (control: mean 0.47 °C, SD 0.43 °C vs group with diabetes: mean 1.78 °C, SD 1.58 °C; *P*<.001; 95% CI 0.99-1.63). These results identified clinically relevant abnormalities in 10% of the cohort with diabetes, whereas no such findings were observed in the control group.



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**Table .** Absolute values of the between-foot temperature differences in healthy control participants and participants with diabetes.

| Region | Total (N=196) | Healthy group (n=98) | Diabetic group (n=98) | *P* value | 95% CI |
|---|---|---|---|---|---|
| Lateral calcaneal artery, mean (SD) | 1.182 (1.37) | 0.496 (0.44) | 1.87 (1.62) | <.05 | 1.04-1.71 |
| Medial calcaneal artery, mean (SD) | 1.197 (1.29) | 0.57 (0.47) | 1.81 (1.53) | <.05 | 0.92-1.56 |
| Lateral plantar artery, mean (SD) | 1.169 (1.30) | 0.54 (0.49) | 1.79 (1.54) | <.05 | 0.92-1.57 |
| Medial plantar artery, mean (SD) | 1.128 (1.29) | 0.49 (0.45) | 1.76 (1.52) | <.05 | 0.96-1.60 |
| Entire plantar region, mean (SD) | 1.13 (1.33) | 0.47 (0.43) | 1.78 (1.58) | <.005 | 0.99-1.63 |

## Regression Analysis of Thermographic Predictors

This analysis examines the relationship between the temperature delta (dependent variable) and the predictor variables (age, sex, BMI, diabetes duration, diabetes type, $HbA_{1c}$, and physical activity, and whether the participant was healthy or diagnosed with diabetes). The results of the OLS regression analysis are summarized in Table 3.

The overall model was not statistically significant (*F*-statistic=1.010; *P*=.46), indicating that the predictors collectively explained only a small proportion of the variance in the temperature delta. The $R^2$ (uncentered) value was 0.224, and the adjusted $R^2$ (uncentered) was 0.002, suggesting a weak fit of the model to the data.

However, diabetes status remained a statistically significant predictor of temperature delta (β=5.544; *P*=.02; 95% CI of 1.064-10.024). This confirms that participants with diabetes had significantly greater foot temperature asymmetry than healthy participants, even after adjusting for potential confounders. Retinopathy also emerged as a statistically significant predictor (β=1.3676; *P*=.04; 95% CI of 0.075-2.660), indicating that participants with retinopathy exhibited greater temperature asymmetry than those with no retinopathy. This finding highlights a potential link between microvascular complications and thermal abnormalities, consistent with the established connection between diabetic retinopathy and peripheral microvascular dysfunction.

In contrast, age (β=−.0165; *P*=.45), sex (β=−.5768; *P*=.29), BMI (β=.0366; *P*=.38), physical activity (β=−.1464; *P*=.37), diabetes duration (β=−.0440; *P*=.22), diabetes type (β=−.0264; *P*=.97), and $HbA_{1c}$ (β=−.1430; *P*=.38) were not statistically significant predictors of temperature delta in this model.

These results suggest that diabetes status itself is the strongest predictor of thermal asymmetry, while retinopathy provides an additional clinically meaningful signal. These findings suggest that plantar thermography may capture microvascular abnormalities relevant to broader diabetic complications.

**Table .** Regression analysis of predictors for between-foot temperature differences.

| Predictor | β coefficient | SE value | *t* test (*df*) | *P* value | 95% CI |
|---|---|---|---|---|---|
| Intercept | —[a] | — | — | — | — |
| Age (years) | −0.0165 | 0.022 | −0.756 (42) | .454 | −0.060 to 0.028 |
| Diagnosed with diabetes | 5.544 | 2.220 | 2.498 (42) | .017 | 1.064 to 10.024 |
| Gender | −0.5768 | 0.532 | −1.084 (42) | .285 | −1.651 to 0.497 |
| BMI | 0.0366 | 0.041 | 0.897 (42) | .375 | −0.119 to 0.046 |
| Physical activity | −0.1464 | 0.161 | −0.911 (42) | .367 | −0.471 to 0.178 |
| Diabetes duration | −0.0440 | 0.035 | −1.253 (42) | .217 | −0.115 to 0.027 |
| Diabetes type | −0.0264 | 0.611 | −0.043 (42) | .966 | −1.259 to 1.206 |
| $HbA_{1c}$ | −0.1430 | 0.162 | −0.884 (42) | .382 | −0.470 to 0.184 |
| Retinopathy | 1.3676 | 0.641 | 2.135 (42) | .039 | 0.075 to 2.660 |

[a]Not available.



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## Discussion

### Principal Findings

This study has indicated that the technology can objectively detect an abnormal thermal pattern in adult patients with diabetes with no visible foot ulcers when compared with healthy individuals with no diabetes. This abnormal heat signature could indicate the presence of a DFU. The skin temperature was significantly different between participants with diabetes and the healthy control group, and the blood skin surface temperature of patients with diabetes was higher than that of the healthy control group. In addition, the technology was able to reveal differences between angiosome areas, as outlined in Table 2. None of the healthy individuals exhibited a temperature delta of 2.2 °C or greater, whereas a subset of patients with diabetes did, highlighting the distinct thermal patterns associated with diabetes.

In addition to diabetes status, our analysis revealed that retinopathy was significantly associated with greater foot temperature asymmetry. This finding is clinically meaningful, as retinopathy reflects underlying microvascular dysfunction, which may also contribute to impaired circulation and thermal regulation in the feet. This reinforces the concept that diabetic complications are interconnected, and thermography could serve as a noninvasive window into broader microvascular health.

The technology offers a promising approach to identifying early signs of DFUs before these ulcers become visible without specialized tools. This capability implies that it could serve as an effective early warning system, potentially allowing for preventive measures to be taken before the condition worsens and becomes more challenging to treat.

### Comparison With Previous Work

Using technology to predict foot ulcers could play a vital role in the management of diabetes. Several studies have assessed the effectiveness of thermology in detecting abnormal temperature patterns among patients with mild diabetes [19,20,28]. It has been shown that the peripheral vessels and nerves are damaged producing an irregular thermoregulation of both feet [23,36]. However, there is a lack of prospective studies that used AI-powered thermography technology to detect these abnormal patterns.

Some of our findings confirm those previously reported in the context of using a human thermographer to detect DFUs. Our findings are in agreement with those of Hernandez-Contreras et al [20], Ilo et al [19], and Schaper et al [28], who concluded that thermography revealed local temperature differences in high-risk diabetic feet. However, these studies relied on a human thermographer to do the analysis while we leveraged an automated AI-powered software. It is the novel part of this study.

### Strengths and Limitations

The RA who was collecting the data was blinded to the results of the technology. An independent analyst compared the data between the group with diabetes and the healthy group. The use of AI and portable thermal cameras could enhance access to thermology and diabetic foot screening. It could also improve access throughout sparsely populated rural areas as they can access information remotely.

A limitation of this study is that the population with diabetes was not specifically stratified based on the duration of diabetes or the presence or absence of PAD. However, we did include self-reported data on PAD to mitigate its potential impact. While this approach might not be as robust as clinical verification, it helps ensure that any effect on the thermal imaging results is minimal. Although attempts were made to diversify recruitment, the findings should be interpreted with caution regarding their applicability to other racial or ethnic populations. Thus, studies with different ethnic populations should be performed. Another limitation of this study is that it was clinic-based and hence there could have been some referral bias in the selection of the participants. Finally, the sample size was relatively small and we lack a formal sample size calculation. In future research, we plan to perform formal sample size estimations based on preliminary data or expected effect sizes to enhance the statistical power and reliability of our studies. Nevertheless, despite these constraints, the outcomes imply that thermal imaging could serve as a beneficial supplementary resource within primary health care clinics.

### Implications for Practice and Future Research

The study aims to provide evidence of differences in plantar thermal patterns detected by computer vision between adult patients with diabetes with no visible foot ulcers and healthy individuals with no diabetes. The use of thermography is increasingly gaining importance in the early detection of DFUs [18-20]. Hernandez-Contreras et al [20] highlighted how thermography can adequately pinpoint local hotspots in patients with diabetes, aiding in uncovering subclinical infections and discovering areas of high plantar pressure, where early identification is key to effective management. Furthermore, Schaper et al [28] found that thermography could provide early clinical insights before visible signs of foot ulcers. We have included a temperature analysis image (Figure 3) to illustrate how the system identifies areas of concern, including the angiosome divisions. This detailed representation allows individuals with diabetes and their health care providers to focus on specific regions of the foot for targeted care and monitoring. Several researchers recommend regular thermogram assessments for patients with diabetes, even in those with controlled diabetes, since high glucose levels can damage blood vessels and nerves at any time [23,28,36].

Early active intervention can significantly lower the incidence of foot ulcers and amputations in people with diabetes [37]. Therefore, it is essential to diagnose and treat DFUs early. An annual foot examination for people with diabetes is recommended to find high-risk conditions. Depending upon findings, more frequent assessments may be required, as recommended by the International Working Group on the Diabetic Foot [29]. Patients should receive professional diabetic foot care if they have 1 or more high-risk foot conditions [3]. Many pharmacological and nonpharmacological interventions are available to promote blood circulation in diabetic feet.

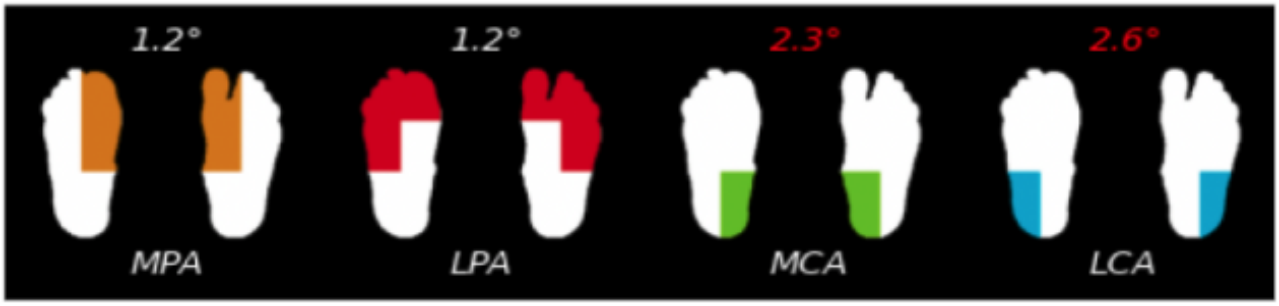


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This study provides insights into the effectiveness of the technology in identifying early signs of DFUs. The key advantage of the technology is that it leverages core thermography principles while eliminating the need for a specialized thermographer. This attribute significantly enhances its use, enabling a broader range of health care practitioners to use this technology. The system could automatically generate a report of the findings and share it with the health care providers or the patient. If thermography shows a compromised blood supply to a specific angiosome in patients with diabetes, we can focus more on preventing the development of diabetic ulcers in that area. Health care providers can view the data to determine whether additional testing or procedures are necessary to avoid foot complications or amputations. If an intervention is carried out at an early stage, it is expected that serious foot complications can be prevented and treated [17,19,20]. The integration of the technology into clinical practice has the potential to offer a more accessible, efficient, and effective approach to managing the risks associated with DFUs.

We are conducting additional studies to compare AI-based thermography with the assessment of a health care professional. In addition, future studies should examine skin temperature maps and how they correspond with patient symptoms, conditions, and disease stages. A larger and more heterogeneous sample with a longer follow-up period could confirm the study findings and expand the knowledge around the effectiveness of the technology in predicting DFUs. In addition, future studies should evaluate the feasibility of the technology as a complementary diagnostic tool or screening test for DFUs. It is important to conduct further studies to better understand the relationship between the unusual heat signatures that were detected and the actual development of DFUs. Understanding this connection could significantly enhance our ability to predict and prevent these ulcers, improving patient outcomes and reducing the need for more invasive treatments.

**Figure 3.** Asymmetry divided by angiosomes. LCA: lateral calcaneal artery; LPA: lateral plantar artery; MCA: medial calcaneal artery; MPA: medial plantar artery.




## Conclusions

DFU significantly impacts the morbidity and mortality of patients with diabetes, with early detection being crucial in limiting its progression and the potential for amputation. This study introduces the use of AI as an effective tool for early detection. It validated a system that detects plantar thermal patterns, distinguishing between healthy individuals and patients with diabetes with no visible ulcers, to demonstrate its potential in identifying early diabetic foot complications. Our findings indicate that the technology can distinguish between the thermal patterns of patients with diabetes and healthy individuals, highlighting its capability to enhance early diagnosis and outcomes in diabetic foot care. It can identify compromised blood supply in patients with diabetes, which suggests that it could play a crucial role in targeted prevention strategies in clinical practice.

## Acknowledgments

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## Data Availability

The datasets generated during this study are not publicly available due to the confidential nature of the information but are available from the corresponding author on reasonable request.

## Authors' Contributions

MFA, MA, ASA, IA, MT, and AJ participated in ideation, design, conceptualization, methodology, analysis, and interpretation. AA and AAA participated in recruitment of participants. All authors met the ICMJE (International Committee of Medical Journal



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Editors) criteria for authorship, contributed equally to the subsequent preparation of the manuscript, wrote the initial draft, critically reviewed the manuscript, and reviewed and accepted the final version of the manuscript.

## Conflicts of Interest

The Seha Virtual Hospital, which is part of the Saudi Ministry of Health, and Amplifai Health sponsored this study. MFA and MA are employees and shareholders of Amplifai Health. All authors have reviewed and approved the final version of this manuscript.

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## Abbreviations

**AAT:** American Academy of Thermology
**AI:** artificial intelligence
**DFU:** diabetic foot ulcer
**$HbA_{1c}$:** hemoglobin $A_{1c}$
**OLS:** ordinary least squares
**PAD:** peripheral artery disease
**RA:** research assistant



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# Estimating the Risk of Lower Extremity Complications in Adults Newly Diagnosed With Diabetic Polyneuropathy: Retrospective Cohort Study

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## Abstract

**Background:** Diabetes-related lower extremity complications, such as foot ulceration and amputation, are on the rise, currently affecting nearly 131 million people worldwide. Methods for early detection of individuals at high risk remain elusive. While data-driven diabetic polyneuropathy algorithms exist, high-performing, clinically useful tools to assess risk are needed to improve clinical care.

**Objective:** This study aimed to develop an electronic medical record–based machine learning algorithm that would predict lower extremity complications.

**Methods:** We conducted a retrospective longitudinal cohort study to predict the risk of lower extremity complications within 24 months of an initial diagnosis of diabetic polyneuropathy. From an initial cohort of 468,162 individuals with at least 1 diagnosis of diabetic polyneuropathy at one of 2 multispecialty health care systems (based in northern California and Colorado) between April 2012 and December 2016, we created an analytic cohort of 48,209 adults with continuous enrollment, who were newly diagnosed with no evidence of end-of-life care. The outcome was any lower extremity complication, including foot ulceration, osteomyelitis, gangrene, or lower extremity amputation. We randomly split the data into training (38,569/48209; 80%) and testing (9,640/48209; 20%) datasets. In the training dataset, we used super Learner (SL), an ensemble learning method that employs cross-validation and combines multiple candidate risk predictors, into a single risk predictor. We evaluated the performance of the SL risk predictor in the testing dataset using the receiver operating characteristic curve and a calibration plot.

**Results:** Of the 48,209 individuals in the cohort, 2327 developed a lower extremity complication during follow-up. The SL risk estimator exhibited good discrimination (AUC=0.845, 95% CI 0.826-0.863) and calibration. A modified version of our SL algorithm, simplified to facilitate real-world adoption, had only slightly reduced discrimination (AUC=0.817, 95%CI 0.797-0.837). The modified version slightly outperformed the naïve logistic regression model (AUC=0.804, 95% CI 0.783-0.825) in terms of precision gained relative to the frequency of alerts and number of patients that needed to be evaluated.

**Conclusions:** We have built a machine learning–based risk estimator with the potential to improve clinical detection of diabetic patients at high risk for lower extremity complications at the time of an initial diabetic polyneuropathy diagnosis. The algorithm exhibited good discriminant validity and calibration using only data from the electronic medical record. Additional research will be needed to identify optimal contexts and strategies for maximizing algorithmic fairness in both interpretation and deployment.



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**KEYWORDS**

diabetes; neuropathy; machine learning; risk prediction; lower extremity complication; diabetic; AI; artificial intelligence; diabetic polyneuropathy; California; Colorado; USA; foot ulcer; logistic regression model; regression model; lower extremity

## Introduction

Up to 50% of the more than 38 million Americans who have diabetes experience some peripheral nerve damage, known as diabetic polyneuropathy [1,2]. Distal symmetric polyneuropathy, the most common type of diabetic polyneuropathy, is frequently characterized as pain, tingling, and numbness that starts in the extremities. Motor and autonomic involvement, also seen in those with diabetic polyneuropathy, can lead to foot deformity. Lower extremity complications associated with diabetic polyneuropathy include foot ulceration, osteomyelitis, and gangrene, leading to amputation [1-4]. Diabetic polyneuropathy is the leading risk factor for the recent resurgence in nontraumatic lower extremity amputations in the United States [3,4], with health care costs falling between US $ 4.6 and US $ 13.7 billion dollars per year [1].

Although there is no cure for this condition, it may be possible to reduce the clinical impact of diabetic polyneuropathy through control of blood sugar levels, annual foot checks, patient education, and specialty referrals (eg, podiatry) [5]. Novel digital interventions may also hold promise for improving self-care and function among individuals at risk of lower extremity complications [6]. While likely not done often enough, identifying and referring high-risk patients for enhanced educational intervention may be cost-effective [7].

Both clinical and nonclinical factors may contribute to delayed diagnosis and undertreatment in subgroups of this patient population [8-10]. For example, differences in patient presentation or clinician interpretation of symptoms may be driven by clinical, interpersonal and societal factors. Additional tools are needed to reduce diagnostic uncertainty, as well as augment human factors to promote evidence-based care [8].

Several screening tools designed to facilitate early detection of diabetic polyneuropathy are currently used in clinical practice. These include monofilament tests, brief questionnaires (eg, the Michigan Neuropathy Screening Instrument) [11], and vibration testing, among others. Collectively, these instruments have been criticized for their lack of accuracy and vulnerability to human error and biases that lead to missed opportunities for follow-up [9,10].

Validated tools are needed to facilitate risk detection and reduce diagnostic uncertainty in the management of diabetic polyneuropathy [12-16]. However, the quality and transparency of existing risk stratification systems and algorithms is highly variable, limiting their use in everyday clinical practice [17]. The aim of this study was to evaluate the accuracy and clinical use of a machine learning (ML)–based algorithm designed to predict complications that develop within 2 years of an initial diabetic polyneuropathy diagnosis.

## Methods

### Creation of Analytic Cohort of Patients Newly Diagnosed With Diabetic Polyneuropathy

All data for this study were extracted from electronic medical records (EMRs) at 2 Kaiser Permanente regions, Northern California and Colorado, with facilities serving more than 5 million people. Patients with diabetes and related chronic conditions receiving care in these facilities are typically assigned to a single primary care provider with a robust panel management approach that leverages performance feedback, system-wide efficiencies, disease registries, and evidence-based practice [18].

We included clinicians engaged in diabetes quality improvement initiatives from 4 Kaiser Permanente regions and the University of Michigan Health System at each stage of the research endeavor to maximize the potential clinical use of the resulting algorithm [19].

The EMRs at both Kaiser Permanente health systems have automated patient files, which facilitate longitudinal observation of use and clinical assessments obtained across systems of care (eg, hospital, laboratory, pharmacy, and clinic). The Kaiser Permanente Northern California and Colorado embedded research units share a common data model for organizing EMR and administrative (claims) data for research use [20]. Data captured by the common data model include, but are not limited to, outpatient encounters, emergency department and inpatient claims, pharmacy orders and prescription fills, laboratory orders and results, and member enrollment and benefit coverage.

Using the EMRs, we identified 468,162 individuals who carried at least 1 diabetes-related diagnosis based on the *International Classification of Diseases, Ninth and Tenth Revisions* (*ICD-9* and *ICD-10*, respectively) between April 1, 2012, and December 31, 2016. From this group, we identified a subset of 121,619 individuals with confirmed diabetic polyneuropathy (ie, at least 1 inpatient or 2 outpatient *ICD-9* or *ICD-10* diagnoses within 12 months of each other) who were at least 18 years of age at the time of their first diagnosis. Measures of polyneuropathy severity were not available through the electronic health record. Therefore, clinicians on the study team reviewed the list of codes and discussed any disagreements on code inclusion before the list was finalized. Detailed codes used to identify diabetic polyneuropathy are included in Multimedia Appendix 1.

From the cohort of 121,619, we excluded 20,806 individuals who had 2 or more months of disenrollment from the health plan in the 24 months before the first diabetic polyneuropathy diagnosis (ie, start of follow-up) to reduce the likelihood of missing healthcare use data. Among the remaining 100,813, we excluded 51,728 individuals who had evidence of a possible previous diagnosis of diabetic polyneuropathy. Finally, we also



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excluded 876 individuals who received hospice or palliative care during the 24 months before diagnosis because these individuals may be less likely to receive usual standard care and would be unlikely to benefit from early identification of lower extremity complications. The resulting analytic cohort included 48,209 adults with newly diagnosed diabetic polyneuropathy.

### Identification of Lower Extremity Events and Predictors

We created a composite time-to-event outcome that included the 4 most common diabetic polyneuropathy-related lower extremity complications: foot ulceration (77.4%), osteomyelitis (6.53%), gangrene (5.46%), and nontraumatic lower extremity amputation (10.61%). We used evidence from earlier literature and clinician review to determine the diagnoses to be included [21-26]. A comprehensive list of codes used to identify lower extremity events is included in Multimedia Appendix 2 . We relied on the earlier peer-reviewed literature to define a standard phase-out period to account for the resolution of treatment for each type of event in order to distinguish between new and ongoing events [24].

### Identification of Candidate Predictors

A list of candidate covariates for predicting the outcome is presented in Multimedia Appendix 3. Drawing on the existing literature, we included several baseline characteristics (up to 24 months before the start of follow-up, ie, first diabetic polyneuropathy diagnosis) that were identified in previous studies as covariates associated with adverse diabetic polyneuropathy-associated events. These included self-reported demographics (age, sex, race, and ethnicity), clinical risk factors ($HbA_{1c}$ levels, lipid levels, body mass index, comorbidity, blood pressure, use of specific medications [eg, insulin], smoking status, and alcohol use), specific comorbidities, (cardiovascular disease, peripheral artery disease, atrial fibrillation, heart disease, chronic pain, rheumatoid arthritis, sleep apnea, nondiabetic neuropathies, and previous falls), and other indicators of diabetes severity (number of different diabetes diagnoses, chronic kidney disease, cellulitis, diabetic retinopathy, stroke, Charcot foot, and previous diabetic polyneuropathy events) [12,13,17,26-28]. Several of these predictors, including laboratory results (blood pressure and cholesterol), use of health services (eg, durable medical equipment and diabetes medications), a Comorbidity Point Score [29] (based on the Centers for Medicaid and Medicare Services Hierarchical Condition Categories [score range: 0 - 1014; scores >300 are rare]) and behavioral risk factors (eg, smoking and alcohol use) were not included in previous prediction algorithms used to estimate the risk of neuropathy-related outcomes [12].

For each covariate with missing values, we included a missing indicator variable and imputed missing values for continuous variables with the median value. Covariates with missing values are indicated as imputed in Multimedia Appendix 3. We note that baseline covariate values marked as unavailable are not included as "missing data" because we aim to predict outcomes using the type of data routinely available in health care databases, which are, by their nature, highly variable across patients and systems. Thus, we did not use advanced analytic methods to address bias concerns associated with missing data, as is typically warranted in causal inference problems (eg, multiple imputation).

### Algorithm Development and Validation

We developed an algorithm to predict lower extremity complications during the 24 months following an initial diagnosis of diabetic polyneuropathy. The first observed date of a diabetic polyneuropathy diagnosis served as the index date for the algorithm; this timepoint was defined as the start of patient follow-up and the clinical decision point when the constructed algorithm would be applied in practice. The first observed lower extremity complication was identified as the event date. We administratively censored follow-up after the eighth quarter (91-day interval) of follow-up (ie, at approximately 2 years).

To develop the algorithm, we combined data from the 2 health systems into a single dataset, then randomly split the data into distinct training (38,569/48209; 80%) and testing (9640/48209; 20%) datasets [30]. Selection of a risk predictor using the super learner (SL) ensemble learning methodology [31] was based solely on the results obtained using the training dataset; the independent validation set was used to evaluate the resulting discrimination and calibration performance. SL is a general loss-based ensemble learning method that uses cross-validation to combine [32] multiple candidate risk predictors defined by ML algorithms (eg, random forest) or parametric (eg, logistic) models into a single risk predictor referred to as "super learner". The approach is grounded in statistical theory and its practical performance was demonstrated in previous applications [33].

Following the general approach of Polley and van der Laan [34], we used SL to construct a single point estimator of the vector of the discrete-time conditional hazards. The detailed mathematical formulas relating to the approach can been found in Multimedia Appendix 4. Implementation was generated using the sl3 R package (R Foundation for Statistical Computing) [35] with 10-fold cross-validation and the L2 loss function.

Due to potential limited computing infrastructures available to generate real-time predictions based on ML algorithms (eg, random forest) in some clinical settings, we also implemented a simplified version of the prediction approach described above in which we restricted the library of candidate predictors to a main-term logistic regression using training data pooled across all 8 quarters. This is equivalent to a classical discrete-time survival model with a logit link function [36]. The resulting predictor is thus a simpler function of predicted values from a single logistic regression that can be easily initiated in real-world clinical settings. In addition to this hazard-based logistic regression estimator for the cumulative incidence at 24 months, we also implemented a naïve estimator of the same cumulative incidence using a simple complete-case logistic regression in which outcomes from patients that were right-censored due to death or disenrollment from the health plan occurring before 24 months were treated as missing. We compared the performance [37] of the 3 estimators of the previously-described cumulative risks at 24 months (hazard-based SL, hazard-based logistic regression, and naïve logistic regression) using the areas under the receiver operating characteristic curves (AUCs) to



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evaluate sensitivity and specificity, calibration plots (ie, plots of observed versus predicted risks), and standard measures of predictive accuracy for a diagnostic test including sensitivity, specificity, positive and negative predictive value, and number needed to evaluate outcomes over a range of risk thresholds [38].

Finally, to determine whether the SL predictions were consistent with previous predictive approaches, we also examined select patient characteristics identified as predictive of risk in earlier studies by quintiles of the SL risk estimates for the 9640 patients in the testing data set. Based on the results from previous studies, the following characteristics were examined: age, $HbA_{1c}$ levels, race and ethnicity, sex, evidence of select comorbid conditions known to be associated with lower extremity risk (ie, chronic kidney disease, heart failure, and peripheral artery disease), and a history of diabetic polyneuropathy events. We also examined differences in rates of symptoms by risk score quintile in the subset of patients in the test dataset who had been screened for diabetic polyneuropathy during the 12 months before their diagnosis using a single-item questionnaire (3644/9590; 38%). Data were extracted and formatted using SAS (version 9.4; SAS Institute) and analyses were performed in R (version 3.4.4).

### Ethical Considerations

This study was approved by the institutional review board at Kaiser Permanente Northern California. Kaiser Permanente Colorado ceded authority to the Kaiser Permanente Northern California Institutional Review Board. For this study, the requirement that informed consent and Health Insurance Portability and Accountability Act Privacy Rule authorization be obtained from study participants was waived. To protect the data and privacy of the patients included in our study, we limited the number of individuals who would have access to identifiable data. We removed personal identifiers from data that were transmitted outside each health system via a secure transfer site. Password-protected data were stored on the servers behind the firewalls maintained by each health system. Primary data were not distributed outside the 2 health care systems and only summary tables and figures were shared with external collaborators. In addition, we used randomly generated identifiers on all study documents, secured storage of digital data (computer files) on password-protected computers, and limited access to data with potentially identifying features to members of the research team working under the direction of the investigators for the duration of the project.

## Results

### Baseline Characteristics of Patients Meeting the Inclusion Criteria

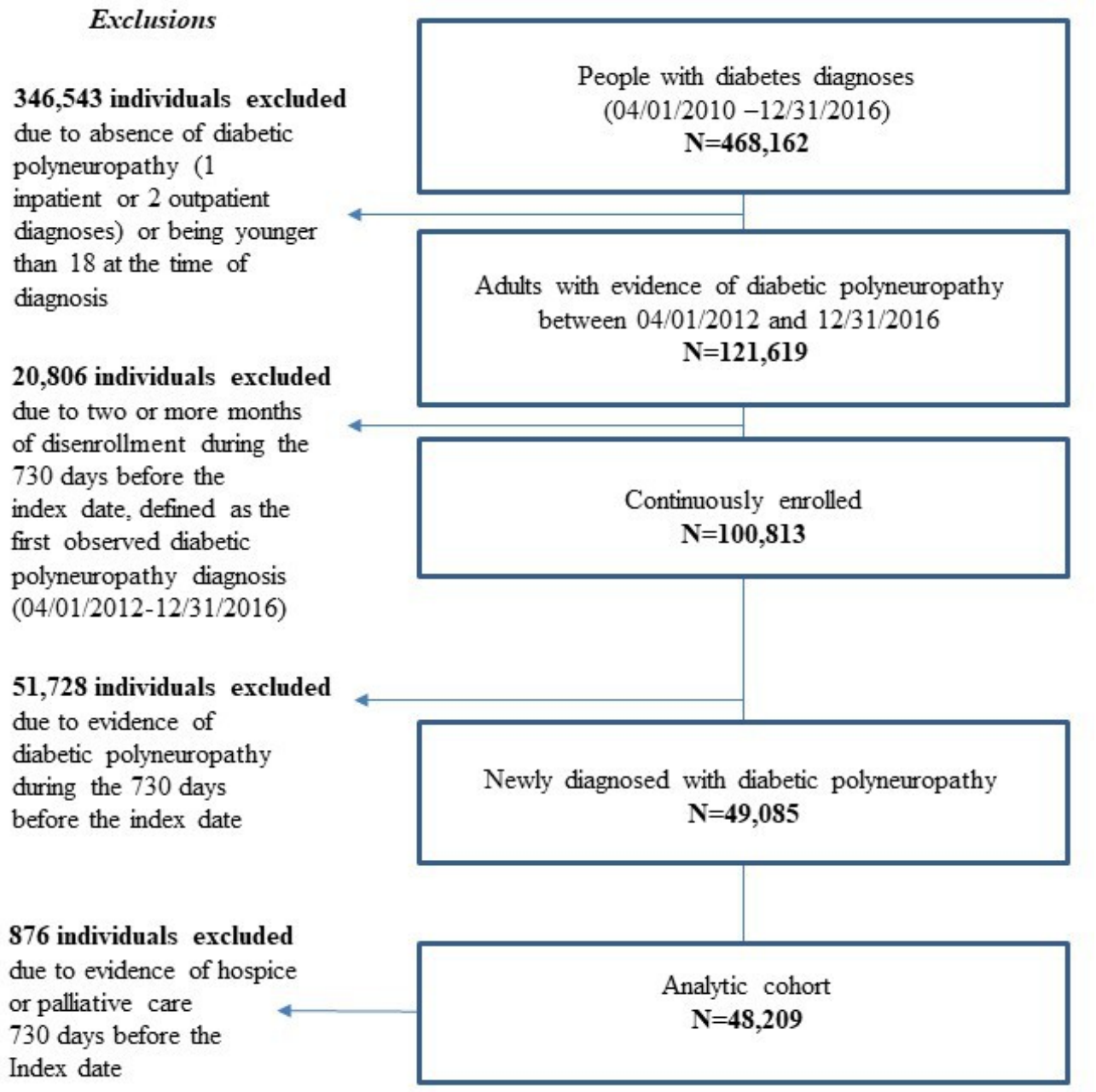
The cohort identification strategy is described in Figure 1; 48,209 adults newly diagnosed with diabetic polyneuropathy met the inclusion criteria for this study. At the time of their initial diabetic polyneuropathy diagnosis, characteristics of individuals in the training and testing datasets exhibited similar demographic and clinical characteristics. A comprehensive list of characteristics is presented in the Multimedia Appendix 3. Overall, the average age at the time of diabetic polyneuropathy diagnosis was 64 years (SD 12 years). In this cohort, 54% (25,828/48,209) were male and 52% (25,110/48,209) were of White race, 13% (6095/48,209) were of Asian race, 11% (5221/48,209) were of Black or African American race, 20% (9708/48,209) were of Hispanic or Latinx ethnicity, fewer than 2%(797/48,209) were of Native Hawaiian, Pacific Islander or Native American race and fewer than 3% (1278/48,209) had unknown race or ethnicity. The comorbidity point score [29,39], which was calculated using diagnosis records within 12 months previous the diabetic polyneuropathy diagnosis, was 36.91 (SD 31.05).

Among the 48,209 patients newly diagnosed with diabetic polyneuropathy in this study sample, 2327 (4.83%) developed a lower extremity complication during the 24-month follow-up period. A comparison of characteristics of those who did and those who did not develop a lower extremity complication during follow-up is presented in Multimedia Appendix 5.



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**Figure 1.** Cohort identification and selection criteria.




## Discrimination and Calibration

As shown in Figure 2, the AUC statistic for the more complex SL was 0.845 (95% CI 0.826-0.863), indicating very good discrimination between high- and low-risk patients. Figure 2A compares the ability of the model to distinguish between those at high and low risk compared with a perfect test and chance. The solid blue lines at the left and top borders represent a hypothetical test that perfectly distinguishes between high and low risk patients. The solid black curve displays the results of the predictive model, which correctly classifies patients with an event more often than it incorrectly misclassifies patients. The dashed line bisecting the graph represents a test that correctly classifies patients 50% of the time (i.e., by chance). Figure 2B displays the observed and predicted probability of an event over the 24 months following an initial DPN diagnosis. The dotted line represents a hypothetical model that perfectly predicts the event. The dashed line is the model-predicted risk at 24 months. The filled circles represent the number of actual events occurring over time.

The SL predictor correctly classified patients who experienced an event as being at higher risk more often than it misclassified patients who did not experience an event as being at higher risk. Also shown in Figure 3 is a comparison of the observed with the predicted probability of a lower extremity complication over the 24 months following an initial diabetic polyneuropathy diagnosis. The blue line with circles represents the percent of people with an event or the positive predictive value. The green line with diamonds represents the number needed to treat. The algorithm demonstrated a high level of accuracy in predicting risk relative to perfect prediction.

The receiver operation characteristics curve for a simplified SL approach that included only one learner (logistic regression)



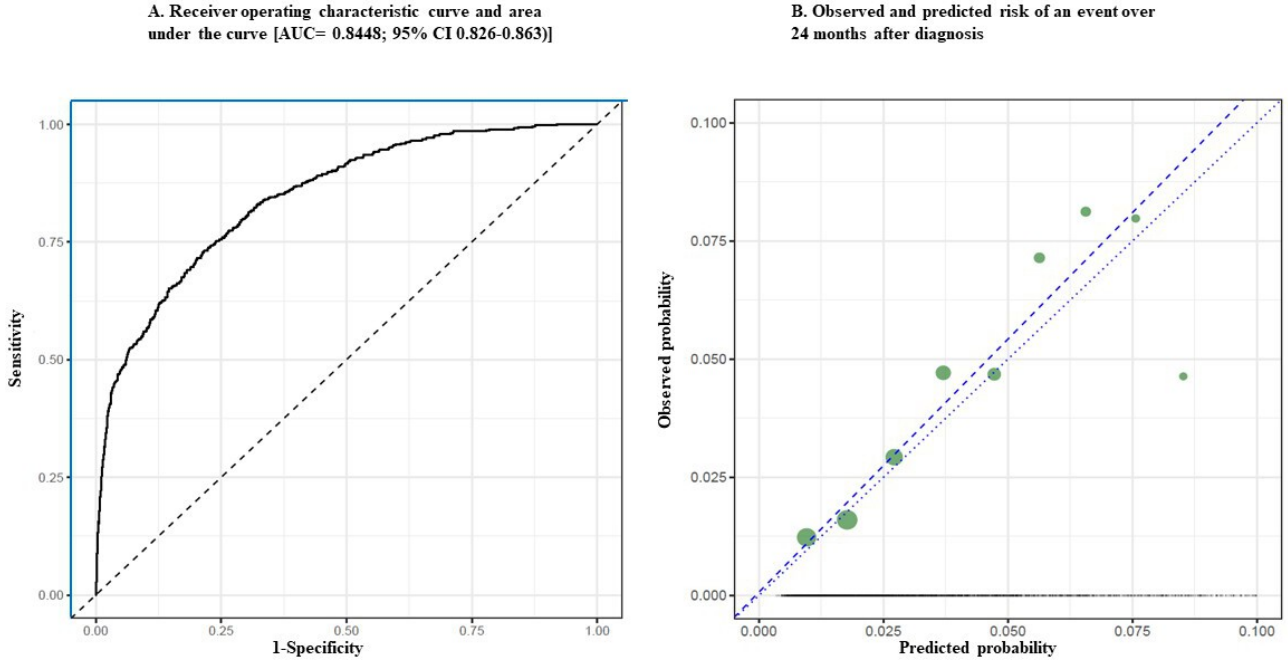
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was performed similarly to the more complex SL approach; the AUC for the simplified SL approach was 0.817 (95% CI 0.797-0.837). The similar performance indicated that a simplified logistic regression approach may be a viable alternative approach for use in clinical practice. By contrast, a naïve logistic regression model underperformed relative to both the complex and simplified SL approaches, with an AUC of 0.804 (95% CI 0.783-0.825).

To evaluate the use of these estimators for clinical decision-making, we compared the sensitivity, specificity, and the number needed to evaluate for varying risk thresholds at which an alert would be issued for the simplified SL compared with the naïve regression approach, as shown in Multimedia Appendix 6. Relative to a naïve logistic regression approach, the simplified SL approach yielded greater precision, triggered fewer alerts, and required fewer patients to be evaluated.

Figure 3 shows the positive predictive value relative to the number of patients needed to be evaluated as a function of the decision threshold. Setting an alert to trigger when an individual's estimated risk reaches 30% - 50% using the simplified SL approach would yield a positive predictive value between 70% - 80%. Furthermore, we estimate that fewer than 2 patients would need to be evaluated to identify one likely to develop a lower extremity complication.

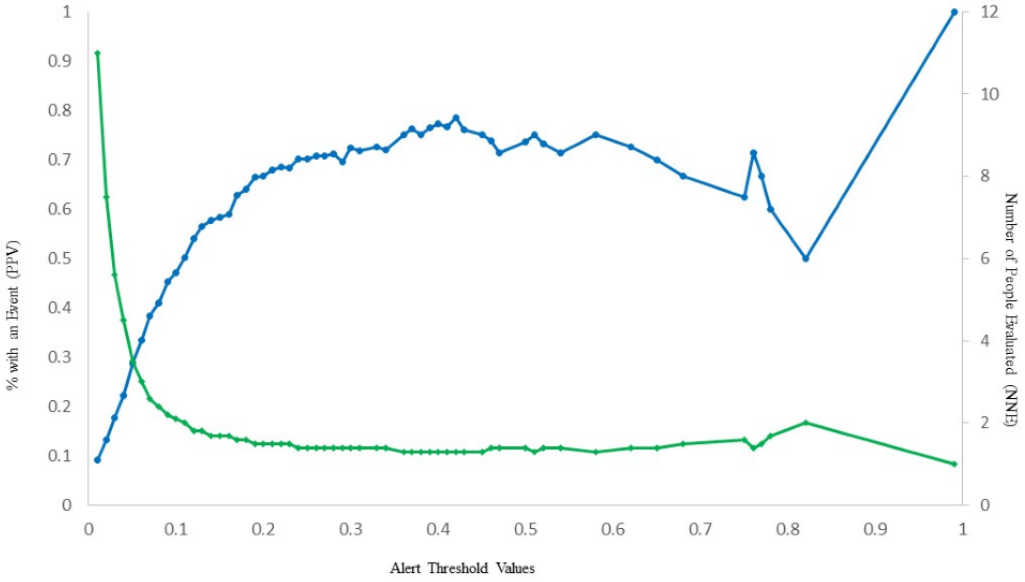
**Figure 2.** Discrimination and calibration plots for the model predicting hazard of lower extremity events among adults newly diagnosed with diabetic peripheral neuropathy (n=48,209). (A) Comparison of the model's ability to distinguish between those at high and low risk compared with a perfect test and chance. The solid blue lines at the left and top borders represent a hypothetical test that perfectly distinguishes between high- and low-risk patients. The solid black curve displays the results of the predictive model, which correctly classifies patients with an event more often than it incorrectly misclassifies patients. The dashed line bisecting the graph represents a test that correctly classifies patients 50% of the time (ie, by chance). (B) Display of the observed and predicted probability of an event over the 24 months following an initial diagnosis of diabetic polyneuropathy. The dotted line represents a hypothetical model that perfectly predicts the event. The dashed line is the model-predicted risk at 24 months. The filled circles represent the number of actual events occurring over time.






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**Figure 3.** Positive predictive value and number needed to evaluate as a function of the decision threshold. The blue line with enclosed circles represents the percent with an event or the positive predictive value. The green line with enclosed diamonds represents the number needed to evaluate.




## Discussion

### Principal Findings

In this study, we leveraged rich clinical data from a longitudinal electronic health record to estimate the risk of developing lower extremity complications (ie, foot ulceration, osteomyelitis, gangrene, or amputation) among adults newly diagnosed with diabetic polyneuropathy. The resulting ML-enabled algorithm predicted risk of lower extremity complications with a high level of discriminant validity (AUC=0.845, 95%CI 0.826-0.863) and calibration. We concluded that a clinician would have to evaluate fewer than 2 patients newly diagnosed with diabetic polyneuropathy to identify one who would have a lower extremity event within the next 2 years.

### Comparison With Previous Work

Our algorithm performed better than a similar algorithm developed by Goyal et al [40] to identify infections in diabetic foot ulcers (AUC of 0.658). This difference may be due to our use of data from systems with a common data model, which reduces coding variability. Two other approaches reported accuracies for predicting diabetic foot and the severity of neuropathy that exceeded 0.9 [41,42] However, these studies used additional data, including clinical assessments and patient questionnaires that are not routinely documented in clinical practice.

Consistent with the earlier literature [12,13,40-43], our predictor identified several clinical subgroups that may be at higher risk for lower extremity complications, including individuals with poorer glycemic control, cardiovascular comorbidity, and previous lower extremity events. However, additional work will be needed to estimate both intended and unintended effects [44] of implementing the prediction algorithm in diverse care settings.

### Strengths and Weaknesses

Compared with previously published studies, strengths of our prediction approach include the use of a shorter time horizon (ie, 2-year time horizon), internal validation using an independent testing dataset, the inclusion of risk factors that are commonly available in EMRs, the use of a common data model [45], and the focus on overall risk of all lower extremity events rather than a single outcome (eg, foot ulceration).

Nonetheless, our prediction approach featured several important weaknesses. First, the predictor may be vulnerable to bias due to variability in the frequency of clinical monitoring during follow-up (ie, informative interval censoring). Second, our earlier studies identified differences in rates of diagnosis based on demographic factors (eg, age, race, and socioeconomic factors) [10]. This finding suggests that the predictor may underestimate risk in underserved populations. Additional research will be needed to evaluate the potential harm associated with the use of risk scores as well as other potential biases resulting from interval censoring [44].

### Future Directions

The diabetic polyneuropathy predictor developed using ML methods and electronic health data from a common data model demonstrated good calibration and a high level of predictive accuracy. Such a tool could be useful for identifying patients who might benefit from promising interventions. However, the use of this and similar prediction tools is limited by the availability of evidence-based practices and protocols to guide clinical decision making in response to risk information. Given the potential benefit of risk stratification of newly diagnosed patients, our results support the value of further research into



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how this might be implemented in clinical practice, including the potential unintended consequences of applying risk predictors in clinical practice and ensuring that these tools are applied equitably to the benefit of all patients.

## Conclusions

Diabetic polyneuropathy is a complex condition. There is not always a clear way to perform risk stratification for lower extremity complications associated with this disorder based on easily identifiable characteristics [2,5]. We hypothesize that diabetic polyneuropathy predictive analytics may be especially useful for identifying patients with diabetic polyneuropathy who are at highest risk for lower extremity complications soon after an initial diagnosis [8,17]. Nonetheless, technology-based prediction tools are not a panacea for complex clinical management. Consistent, strong evidence from diverse datasets and health care systems will be needed to determine the use of these and other strategies for patients, providers, and health systems in the context of real-world clinical practice [46].

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## Data Availability

The data used in this analysis were obtained directly from the electronic health records of the study participants. Because of privacy issues, our institutional review board does not permit us to make these data publicly available. However, metadata are available from author RN upon reasonable request.

## Authors' Contributions

ASA and RN performed the research and generated data, contributed to the discussion, and wrote the first draft of the manuscript. GE, EAB, BC, RWG, MH, JAS, CMT, LKG, and EK contributed to the discussion and reviewed and edited the manuscript. ASA, CL, GE, NSH, LM, and RN performed the research and reviewed and edited the manuscript. All authors approved the final version of the manuscript. RN is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

## Conflicts of Interest

BC receives editorial and research support from the American Academy of Neurology (AAN), consults for Dynamed, and performs medical legal consultations.

Multimedia Appendix 1
List of *International Classification of Diseases, Ninth and Tenth Revisions* codes used to identify individuals with diabetic polyneuropathy.
[DOCX File, 15 KB - diabetes_v10i1e60141_app1.docx ]

Multimedia Appendix 2
Procedures used to identify the onset of lower extremity complications among adults newly diagnosed with diabetic polyneuropathy.
[DOCX File, 14 KB - diabetes_v10i1e60141_app2.docx ]

Multimedia Appendix 3
Characteristics of the study cohort.
[DOCX File, 34 KB - diabetes_v10i1e60141_app3.docx ]

Multimedia Appendix 4



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Detailed description of algorithm development.
[DOCX File, 13 KB - diabetes_v10i1e60141_app4.docx ]

Multimedia Appendix 5
Comparison of predictor characteristics by event type.
[DOCX File, 31 KB - diabetes_v10i1e60141_app5.docx ]

Multimedia Appendix 6
Statistical performance of different risk prediction approaches.
[DOCX File, 15 KB - diabetes_v10i1e60141_app6.docx ]

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## Abbreviations

**AUC:** area under the receiver operating characteristic curve
**EMR:** electronic medical record
***ICD-10*:** *International Classification of Diseases, Tenth Revision*
***ICD-9*:** *International Classification of Diseases, Ninth Revision*
**ML:** machine learning
**SL:** super learner

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# Natural Language AI Models and Pediatric Type 1 Diabetes: Can Chatbots Help With Diabetes Self-Management and Patient Education?

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## Abstract

Diabetes self-management plays a major role in controlling blood sugar levels and avoiding chronic complications. In this report, we investigate the strengths and limitations of artificial intelligence chatbots in supporting patients with type 1 diabetes and their families. With the growing accessibility of these constantly evolving tools, front-line providers must advocate for their responsible use.

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**KEYWORDS**

type 1 diabetes; chatbots; artificial intelligence; patient education; diabetes self-management

## Introduction

Type 1 diabetes (T1D) is one of the most common chronic diseases of childhood with significant morbidity and mortality. High-level evidence supports the optimization of blood sugar control to prevent chronic complications [1]. Even with remarkable advances in diabetes technology, such as continuous glucose monitoring systems and automated insulin delivery pumps, a majority of patients fail to meet glycemic targets [2].

Diabetes self-management and education play a major role in glycemic control. However, several challenges limit the potential of traditional educational models: shortages of diabetes educators, reduced access to care for some patient groups (exacerbated by the recent pandemic), and inherent limitations to addressing patients' and caregivers' individual needs.

Chatbots are tools powered by artificial intelligence (AI) that have shown promise in many aspects [3]. They are computer programs designed to respond to questions in natural language as if they were a real person. It is anticipated that such tools will be increasingly used by patients and their families because of their ease of access. Clinicians nonetheless remain a key source for trusted health information, and pediatricians and other front-line health care providers must understand the strengths and limitations of such tools.

A recent paper in *Diabetes Care* [4] noted strengths and inaccuracies of the recent GPT-4 model developed by OpenAI when asked questions on diet/exercise, glycemic management, and insulin storage and administration in adult patients. Children with T1D have unique needs regarding self-management when compared to adults. In this brief report, we sought to evaluate the strengths and weaknesses of an AI tool for pediatric diabetes management.

## Methods

We asked a multidisciplinary team at the Pediatric Diabetes Clinic of the Montreal Children's Hospital at McGill University Health Centre, a tertiary care center caring for 900 pediatric patients with T1D, to help craft a comprehensive list of questions regarding education and self-management of children with T1D spanning 4 key categories (Textbox 1). The multidisciplinary team included a pediatric endocrinologist, a pediatric emergency room physician, a medical student with previous experience in pediatric diabetes research, 3 certified diabetes educators, and 1 parent partner, all affiliated with the Montreal Children's Hospital.



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The questions were asked in both French and English to the chatbot, and its answers were evaluated qualitatively based on whether they reflected what is routinely taught to families and whether the answers were complete, accurate, and correct.

**Textbox 1.** Questions asked to ChatGPT with GPT-4.

**New diagnosis**

1. My child was just diagnosed with T1D. What is this? I have only heard of diabetes in older obese adults.
2. Will my child have any restrictions in his life?
3. When will my child be ready to go back to school? What should I say to the school teacher?
4. Can you recommend reliable websites where I can read more about T1D?

**Recognizing and managing hypo- and hyperglycemia**

1. What is the blood sugar level that the doctors kept mentioning?
2. What is a normal blood sugar?
3. What symptoms will my child have if his/her blood sugar is high or low?
4. What do I do if my child's blood sugar is high or low?
5. My child is vomiting and his blood sugar is high. Should I bring him to the ER?

**Glucometers and insulin**

1. My child's doctor and nurse showed to me how to use a glucometer but I can not remember the exact steps. Can you give me step by step instructions?
2. My child's doctor and nurse gave me 2 different insulins; a long acting and a short acting. What is the difference?
3. My child's doctor and nurse showed me how to use an insulin pen but I cannot remember the exact steps. Can you give me step by step instructions?
4. Which body parts should I use to do the insulin injections?

**Newer diabetes technologies**

1. My child's doctor and nurse mentioned continuous glucose monitors and insulin pumps. What are these? Are they recommended for children with T1D?
2. How often do I need to change the CGM and the pump?
3. How do I interpret the different metrics on a CGM? What is the goal target in range?
4. What type of insulin is given in an insulin pump?

## Results

Textbox 2 compiles the feedback given by the multidisciplinary diabetes team, highlighting strengths and limitations of ChatGPT for diabetes self-management and patient education. We found that the answers provided by ChatGPT had the same limitations in both French and English.



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**Textbox 2.** Feedback provided by the multidisciplinary diabetes team on ChatGPT's answers.

**Strengths**

- Conversation tone imitated a real human-to-human interaction
- Clear instructions in point form
- Easily understood and mostly accurate responses from multiple trustworthy online sources
- No medical jargon
- Most answers safely highlighted the importance of remaining in contact with the child's health care provider
- Generally useful information, available 24-7
- Potential for immediate translation to support families who face language barriers

**Limitations**

- New diagnosis
  - No reference to the International Society for Pediatric and Adolescent Diabetes, which provides specific guidelines for children, such as a target blood glucose range of 70-180 mg/dl (4-10 mmol/L)
- Recognizing and managing hypo- or hyperglycemia
  - No mention of home ketone testing in the management of hyperglycemia, a critical step in assessing the risk of diabetic ketoacidosis while the child is still at home
  - No mention that the amount of carbohydrates used to treat hypoglycemia depends on the child's weight; for example giving 15 g of carbohydrates to a 20 kg child would cause rebound hyperglycemia, while 5 g of carbohydrates to an adolescent would not be enough; also, the type of insulin therapy influences how a low blood glucose is treated; for example, if the child is on standard pump therapy and has a glucose level <3 mmol/L, we recommend suspending insulin delivery until glucose >4 mmol/L
- Glucometers and insulin analogs
  - It would be useful if images accompanied the step-by-step instructions on how to use a glucometer, the insulin pen, and the body parts where insulin injections can be self-administered.
  - No mention of admelog (insulin lispro) or trurapi (insulin aspart), insulin products approved by Health Canada. No mention of Tresiba, a newer long-acting insulin often used to provide more flexibility.
- Newer diabetes technologies
  - Blood glucose is provided only in mg/dl. ChatGPT did not provide the international consensus guidelines on time above range (<25%) and time below range (<4%).
  - Incorrect information that insulin pumps only give short- or rapid-acting insulin. Long-acting insulin is not necessary as the pump delivers tiny amounts of insulin every few minutes.

## Discussion

When asked common questions on T1D, ChatGPT provided useful answers, though they were at times lengthy and lacked pediatric-specific details. It used clear terminology that had the potential for immediate translation to different languages. One important deficiency was noted regarding counseling for hyperglycemia, as it omitted the need for ketone measurement at home. The chatbot also provided inaccurate information on the type of insulin delivered by pumps (Textbox 2).

AI chatbots for diabetes education of patients and families can free precious health care provider time, allowing clinicians to support patients with the greatest need for more frequent human touchpoints. A human-AI interaction that integrates safeguards such as easily interpretable care algorithms can thus enable more frequent technology-enabled contact.

To understand the limitations of AI tools in diabetes education, we need to consider the way that they are developed and trained. They use an extraordinarily large text database from the internet and generate answers based on the likelihood of phrases following each other. They are not trained on databases specific to medical information and are not capable of evaluating the reliability of the answers they provide. Thus, they are prone to the phenomenon of "hallucination": answers that sound reasonable but are factually incorrect [5].

As with any new technology in health care, it is important to consider ChatGPT's strengths, limitations, and ethical implications prior to implementing its use in routine clinical practice. It is essential to ensure that AI-based resources are easily accessible to our patients to prevent worsening existing health care disparities. Moreover, transparency in how information is generated and communicated is critical, so that patients can interpret responses with appropriate caution. With the growing ease of access to these constantly evolving tools, front-line providers must advocate for use that is responsible and promotes value-based care [6].



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## Acknowledgments

The pediatric diabetes educators at the Montreal Children's Hospital, Sara Seguin-Plourde, RN; Sandra Kambites, RN; and Charleen Magee, RN provided valuable feedback on the answers provided by ChatGPT. AM and EO are funded by the Fonds de recherche du Québec-Santé.

## Authors' Contributions

FV and AM conceptualized the project, developed the methodology, analyzed the results, and wrote the manuscript. EO, PD, and PK analyzed the findings and reviewed and edited the manuscript.

## Conflicts of Interest

None declared.

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## Abbreviations

**AI:** artificial intelligence
**T1D:** type 1 diabetes

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# An Innovative Insulin Dose Self-Titration Toolkit for Adults Living With Type 2 Diabetes Mellitus

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## Abstract

We developed an innovative bilingual toolkit comprising a personalized action plan and educational videos to encourage insulin dose self-titration by adults living with type 2 diabetes.

***(JMIR Diabetes 2025;10:e75903)*** doi:10.2196/75903

**KEYWORDS**

type 2 diabetes mellitus; outpatient diabetes care; insulin dose self-titration; toolkit; patient education

## Introduction

"Insulin self-titration" is a strategy where people living with diabetes adjust their insulin doses within parameters recommended by their diabetes care team. While commonly used by people living with type 1 diabetes mellitus, this strategy is remarkably less frequent for people living with insulin-treated type 2 diabetes mellitus (T2D). People living with T2D are less confident with insulin self-titration [1-3]. Studies on insulin self-titration in T2D have been mostly limited to basal insulin [4-9]. Furthermore, although these studies showed that insulin self-titration could be equally or more effective than physician-directed titration [4-10], their interventions required close medical surveillance which could be challenging for long-term and widespread implementation in diabetes clinics [9]. The objective of this feasibility study was to develop an educational toolkit on insulin dose self-titration for people living with T2D.

## Methods

### Ethical Considerations

The Ottawa Health Science Network Research Ethics Board exempted this study (on 18 November 2024) as quality improvement. Furthermore, the contents of the toolkit abide by current clinical care guidelines. Participants provided informed voluntary consent. Participants' survey responses were collected anonymously, and no compensation was provided.

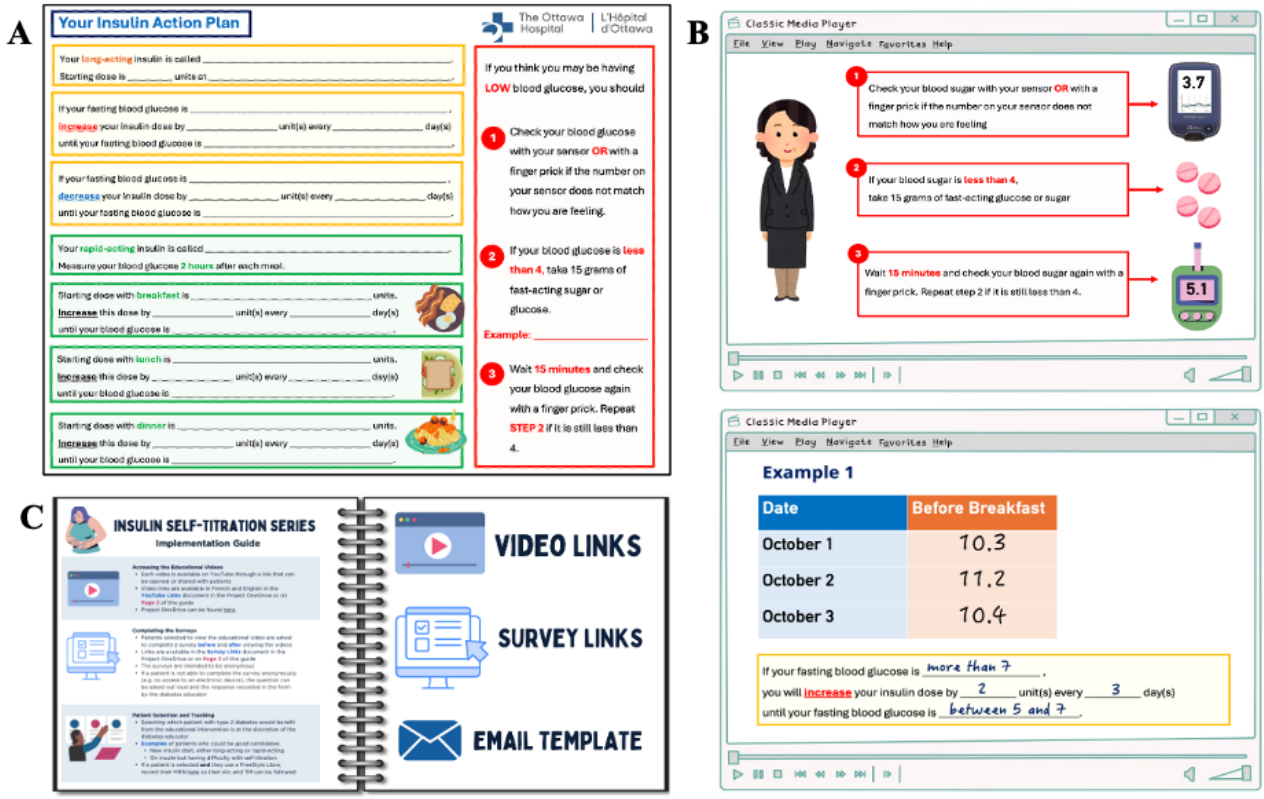
### Study Design

This was a quality improvement initiative at the diabetes clinics of a Canadian academic tertiary care center. We developed a toolkit in English and French (Figure 1). The toolkit included a customizable insulin dose self-titration guide, "Insulin Action Plan" (Multimedia Appendix 1), which included information on hypoglycemia recognition and management. Certified diabetes educators (CDEs), who are part of the circle of care, tailored this guide using their medical directives for insulin dose adjustment recommendations within 20% of the current dose for each person living with T2D. The CDEs also provided web site links (Multimedia Appendix 1) to educational videos containing examples on how to apply the Insulin Action Plan. Toolkit development was informed by diabetes care guidelines with feedback incorporated from CDEs and people living with T2D. Exclusion criteria were known cognitive impairment or known history of hypoglycemia unawareness. Online pre- and post-toolkit anonymous surveys were sent (via Google Forms) to participants 1 week apart to rate their self-assessed understanding of insulin self-titration on a scale of 1 to 10.



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**Figure 1.** The customizable Insulin Action Plan showing (A) titration of long-acting insulin and rapid-acting insulin and hypoglycemia management. Samples from videos: hypoglycemia management (B, top), long-acting insulin titration (B, bottom). Implementation guide for healthcare providers (C).




## Results

Table 1 summarizes data obtained from participants who completed the pre- (n=15) and post-toolkit (n=10) self-assessments of their comprehension of insulin dose self-titration. The median score increased from 3 (IQR 1 - 7) in the pre-toolkit responses to 8 (IQR 6 - 9) in the post-toolkit responses. A Mann-Whitney *U* test indicated a statistically significant increase in the subjective understanding of insulin dose self-titration (U=27, Z=-2.63, *P*=.004), with a large effect size (*r*=0.53).

**Table .** Participants' self-assessment survey results.

| Survey question | Response to survey question | |
|---|---|---|
| On a scale of 1 to 10 (where 1 is no understanding and 10 is complete understanding), how would you rate your understanding of how to titrate your insulin dose? | Before insulin dose self-titration toolkit (n=15) | After insulin dose self-titration toolkit (n=10) |
| No understanding (1) | 5 | - |
| Little understanding (2-3) | 4 | 1 |
| Some understanding (4-6) | 2 | 3 |
| Good understanding (7-9) | 3 | 6 |
| Complete understanding (10) | 1 | - |

## Discussion

In this feasibility study, people living with insulin-treated T2D were generally accepting of this toolkit, which was easy to integrate into routine clinical care. The online delivery of this toolkit is accessible to participants all day, every day. Therefore, it is worthwhile to proceed to a full study that will aim to address this feasibility study's many limitations.

The main strength of this innovative toolkit is that, once optimized, minimal ongoing resources will be required. The "Insulin Action Plan" is easy to personalize and update for each participant. This toolkit was co-created with CDEs and people living with T2D to be easily integrated into routine care. The toolkit's freely accessible online educational videos with concrete examples of insulin dose self-titrations can be viewed as often as needed to refresh and solidify understanding of this concept.

The major limitations of this feasibility study include the lack of sociodemographic data collection, objective assessment regarding whether these people living with T2D correctly



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self-titrated their insulin doses or the eventual impact on glycated hemoglobin, time-in-range, and hypoglycemia occurrence. The generalizability of this feasibility study's results is limited by the small sample size and short follow-up.

The next phase of this innovative toolkit will include the collection of sociodemographic data and longitudinal follow-up to determine outcomes including the accuracy of participants' insulin dose self-titrations, as well as their impact on their glycated hemoglobin, time-in-range, and hypoglycemia occurrences. We would anticipate an improvement in these determinants of glucose management with successful insulin dose self-titration [4-7]. Future directions for this initiative would be a full study recruiting participants reflecting the diversity of people living with T2D, ongoing gathering of feedback from people living with T2D, and evaluating objective glycemic measures with longitudinal follow-up.

## Acknowledgments

We thank Chantal Bornais (registered nurse and certified diabetes educator) for her involvement in this study. CJS is supported by The Ottawa Hospital Department of Medicine Early Career Investigator Chair.

## Data Availability

Data are available from the corresponding author upon reasonable written request.

## Authors' Contributions

NA and CJS designed the study and the content for the insulin dose self-titration toolkit. HL and CJS (endocrinologists), and SG and AGM (certified diabetes educators) provided feedback on the toolkit from their respective professional perspectives. All co-authors participated in the preparation of this manuscript.

## Conflicts of Interest

None declared.

Multimedia Appendix 1
Web site links for the toolkit components.
[PDF File, 159 KB - diabetes_v10i1e75903_app1.pdf ]

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## Abbreviations

**CDE:** certified diabetes educator
**T2D:** type 2 diabetes mellitus

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# Agreement Between AI and Nephrologists in Addressing Common Patient Questions About Diabetic Nephropathy: Cross-Sectional Study

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## Abstract

**Abstract:** This research letter presents a cross-sectional analysis comparing the agreement between artificial intelligence models and nephrologists in responding to common patient questions about diabetic nephropathy.

***(JMIR Diabetes 2025;10:e65846)*** doi:10.2196/65846

**KEYWORDS**

artificial intelligence; diabetic nephropathy; nephrologist; ChatGPT; Google Gemini

## Introduction

Diabetic nephropathy (DN) is one of the most frequent and severe complications of diabetes, requiring early detection and management [1]. Patients with diabetes should receive accurate information from health care professionals on preventing kidney disease. However, many turn to artificial intelligence (AI) models, like ChatGPT and Google Gemini, for web-based medical information [2-4]. To evaluate the capabilities of ChatGPT-4 and Google Gemini versus nephrologists in providing accurate DN information, their performance in answering the DN-related questions most commonly raised by patients was assessed.

## Methods

### Collection of Questions

To generate patient-focused questions, the following query was prompted to AI models: “What are the most frequently asked questions by individuals regarding diabetic nephropathy?”

The AI-generated responses were systematically reviewed. The final question set was refined and adjusted based on the principal investigator’s experience in clinical practice, ensuring alignment with common patient concerns encountered in real-world practice.

Ultimately, 10 questions covering various DN aspects were developed. Questions 1, 3, and 7 were used to evaluate DN’s diagnosis, risk factors, and prevention, respectively.

Questions 2, 6, and 9 were used to evaluate DN management. Questions 8 and 10 were included to assess DN complications. To evaluate DN progression and severity, questions 4 and 5 were selected.

### Collecting Chatbot and Nephrologist Responses

To ensure consistency, a single investigator entered all questions into ChatGPT-4 and Google Gemini between May 23 and July 7, 2024. Each question was entered into ChatGPT-4 twice—initially and after 45 days—to assess changes in accuracy over time. Google Gemini was used once—concurrently with the second ChatGPT-4 round—and was limited to short-response tasks. Two experienced faculty nephrologists from Loma Linda University with clinical and academic experience also completed the questionnaire via a Google Forms survey.

### Evaluation of Chatbot and Nephrologist Responses

An independent reviewer—a professor of medicine from the same academic center—evaluated AI and nephrologists’ responses. Each answer was graded as “completely inaccurate,” “relatively inaccurate,” “irrelevant,” “relatively accurate,” or “completely accurate.” To prevent grading bias, the reviewer was not informed about the nephrologists’ identities.

### Statistical Analysis

Analyses were conducted by using RStudio (version 4.3.0; RStudio Inc), with $P$ values of $<.05$ considered significant.

### Ethical Considerations

As no patient data were involved, ethical approval was not required. This study adhered to ethical principles for research integrity and transparency.



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## Results

Table 1 presents the accuracy distribution of responses for each question assessed by reviewers. No responses were categorized as irrelevant or inaccurate; all were rated as relatively or completely accurate.

Table 2 summarizes the interrater reliability indices among different respondents. The two nephrologists showed statistically significant agreement (κ=0.61; *P*=.04). ChatGPT-4 and Google Gemini had moderate but nonsignificant agreement (κ=0.52; *P*=.10). No significant agreement was found between either AI and the nephrologists (all *P* values were >.05). ChatGPT-4 responses lacked consistency over time (κ=−0.08; *P*=.78). Further analysis showed negligible, nonsignificant agreement among all respondents (κ=0.083; *P*=.41). Excluding ChatGPT-4's second-round responses did not alter the results (κ=0.09; *P*=.45), confirming the lack of significant agreement.

**Table .** Distribution of answers according to each respondent.

| Questions | Accuracy of answers | | | | |
|---|---|---|---|---|---|
| | ChatGPT-4, first round | ChatGPT-4, second round | Google Gemini | Nephrologist 1 | Nephrologist 2 |
| 1. What is the gold standard for diagnosis of diabetic nephropathy? | Completely accurate | Completely accurate | Completely accurate | Completely accurate | Completely accurate |
| 2. What is the current standard medication therapy for diabetic nephropathy? | Completely accurate | Completely accurate | Completely accurate | Completely accurate | Completely accurate |
| 3. Can diabetic nephropathy be prevented? | Completely accurate | Relatively accurate | Completely accurate | Relatively accurate | Relatively accurate |
| 4. Can tobacco use accelerate the progression of diabetic nephropathy? | Completely accurate | Relatively accurate | Completely accurate | Completely accurate | Completely accurate |
| 5. How is the severity of diabetic nephropathy determined? | Completely accurate | Completely accurate | Relatively accurate | Relatively accurate | Completely accurate |
| 6. How frequently should a patient be screened for diabetic nephropathy? | Relatively accurate | Completely accurate | Completely accurate | Relatively accurate | Relatively accurate |
| 7. What are the risk factors for the development of diabetic nephropathy? | Completely accurate | Completely accurate | Completely accurate | Relatively accurate | Relatively accurate |
| 8. What is the incidence of kidney failure in diabetic nephropathy? | Completely accurate | Relatively accurate | Completely accurate | Relatively accurate | Relatively accurate |
| 9. When should dialysis begin in diabetic nephropathy? | Relatively accurate | Relatively accurate | Relatively accurate | Relatively accurate | Completely accurate |
| 10. What is the most common cause of death in diabetic nephropathy? | Relatively accurate | Completely accurate | Relatively accurate | Completely accurate | Completely accurate |



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**Table .** Interrater reliability indices[a] across different respondents.

| Respondents | ChatGPT-4, first round | ChatGPT-4, second round | Google Gemini | Nephrologist 1 | Nephrologist 2 |
|---|---|---|---|---|---|
| ChatGPT-4, first round | | | | | |
| κ | —[b] | −0.08 | 0.52 | 0.07 | −0.08 |
| *P* value | — | .78 | .10 | .78 | .78 |
| ChatGPT-4, second round | | | | | |
| κ | −0.08 | — | −0.08 | 0.23 | 0.16 |
| *P* value | .78 | — | .78 | .43 | .60 |
| Google Gemini | | | | | |
| κ | 0.52 | −0.08 | — | 0.07 | −0.52 |
| *P* value | .10 | .78 | — | .78 | .09 |
| Nephrologist 1 | | | | | |
| κ | 0.07 | 0.23 | 0.07 | — | 0.61 |
| *P* value | .78 | .43 | .78 | — | .04 |
| Nephrologist 2 | | | | | |
| κ | −0.08 | 0.16 | −0.52 | 0.61 | — |
| *P* value | .78 | .60 | .09 | .04 | — |

[a]Interrater reliability was measured by using the Cohen and Fleiss κ, with agreement classified as follows: 0.0 - 0.20 (none), 0.21 - 0.39 (minimal), 0.40 - 0.59 (weak), 0.60 - 0.79 (moderate), 0.80 - 0.90 (strong), and >0.90 (almost perfect) [5].

[b]Not applicable.

## Discussion

We found that AI models generally provided accurate responses to DN-related questions, with moderate agreement on their accuracy among nephrologists. However, agreement between AI outputs and nephrologists' assessments was minimal, indicating a lack of standardized evaluation or clinical alignment. Further, the moderate concordance between ChatGPT-4 and Google Gemini suggests similar underlying approaches, and the improved agreement in ChatGPT-4's second round indicates potential learning and adaptability; however, their limited alignment with nephrologists raises concerns regarding their clinical applicability. Despite that, interactive AI potentially enhances clinical processes by supporting patient education and facilitating communication between patients and clinicians regarding typical disease prevention–related queries [6]; the more questions lean toward subspecialties, the less accurate AI responses tend to be [7].

Although AI models can offer helpful responses about DN, they are not substitutes for thorough clinical discussions, due to observed inconsistencies. Given this study's preliminary nature, findings should be interpreted cautiously. Further research with larger datasets is warranted to evaluate AI's reliability in clinical use.

This study has several limitations. The AI models used were not specifically designed for medical applications, and the free versions, which we intentionally selected to reflect typical patient use, may underperform when compared to premium versions. Moreover, including only 2 nephrologists limits the diversity of clinical perspectives, and evaluations by a single senior nephrologist may introduce bias; future studies should include multiple reviewers to strengthen evaluation reliability and validity. Lastly, we did not assess AI responses' clarity or helpfulness from the patient perspective, highlighting the need for user-centered evaluations in future research.

### Data Availability

All data supporting the findings of this study are included within the manuscript, and no supplementary materials are provided.

### Authors' Contributions

NE, who is certified with the American Board of Artificial Intelligence in Medicine (ABAIM) [8], designed the study and drafted the manuscript. MV analyzed and interpreted the study data and edited the manuscript. ST reviewed the answers. AA, who is also certified with the ABAIM [8], reviewed and edited the manuscript and supervised the study. All authors read and approved the final manuscript.



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## Conflicts of Interest

None declared.

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## Abbreviations

**AI:** artificial intelligence
**DN:** diabetic nephropathy

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