JMIR Diabetes

Contents

Original Papers

Viewpoint

Reviews

Original Paper

The Associations of COVID-19 Lockdown Restrictions With Longer-Term Activity Levels of Working Adults With Type 2 Diabetes: Cohort Study

Christian John Brakenridge[1,2], BClinExPhys; Agus Salim[1,3], PhD; Genevieve Nissa Healy[4], PhD; Ruth Grigg[1], BAppSci; Alison Carver[2], PhD; Kym Rickards[1], MPH; Neville Owen[1,5], PhD; David Wayne Dunstan[1,6], PhD

[1]Baker Heart and Diabetes Institute, Melbourne, Australia

[2]Mary Mackillop Institute for Health Research, Australian Catholic University, Melbourne, Australia

[3]School of Population and Global Health, The University of Melbourne, Melbourne, Australia

[4]School of Human Movement and Nutrition Sciences, The University of Queensland, Queensland, Australia

[5]Centre for Urban Transitions, Swinburne University of Technology, Melbourne, Australia

[6]School of Exercise and Nutrition Sciences, Institute for Physical Activity and Nutrition, Deakin University, Melbourne, Australia

Corresponding Author:
Christian John Brakenridge, BClinExPhys
Baker Heart and Diabetes Institute
99 Commercial Rd
Melbourne, 3004
Australia
Phone: 61 385321853
Email: christian.brakenridge@baker.edu.au

Abstract

Background: Lockdown restrictions reduce COVID-19 community transmission; however, they may pose challenges for noncommunicable disease management. A 112-day hard lockdown in Victoria, Australia (commencing March 23, 2020) coincided with an intervention trial of reducing and breaking up sitting time in desk workers with type 2 diabetes who were using a provided consumer-grade activity tracker (Fitbit).

Objective: This study aims to compare continuously recorded activity levels preceding and during COVID-19 lockdown restrictions among working adults with type 2 diabetes participating in a sitting less and moving more intervention.

Methods: A total of 11 participants (n=8 male; mean age 52.8, SD 5 years) in Melbourne, Australia had Fitbit activity tracked before (mean 122.7, SD 47.9 days) and during (mean 99.7, SD 62.5 days) citywide COVID-19 lockdown restrictions. Regression models compared device (Fitbit Inspire HR)–derived activity (steps; metabolic equivalent tasks [METs]; mean time in sedentary, lightly, fairly, and very active minutes; and usual bout durations) during restrictions to prerestrictions. Changes in activity were statistically significant when estimates (Δ%) did not intercept zero.

Results: Overall, there was a decrease in mean steps (–1584 steps/day; Δ% –9%, 95% CI –11% to –7%); METs (–83 METs/day; Δ% –5%, 95% CI –6% to –5%); and lightly active (Δ% –4%, 95% CI –8% to –1%), fairly active (Δ% –8%, 95% CI –21% to –15%), and very active (Δ% –8%, 95% CI –11% to –5%) intensity minutes per day, and increases in mean sedentary minutes per day (51 mins/day; Δ% 3%, 95% CI 1%-6%). Only very active (+5.1 mins) and sedentary (+4.3 mins) bout durations changed significantly.

Conclusions: In a convenience sample of adults with type 2 diabetes, COVID-19 lockdown restrictions were associated with decreases in overall activity levels and increases in very active and sedentary bout durations. A Fitbit monitor provided meaningful continuous long-term data in this context.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12618001159246; https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12618001159246

XSL•FO
RenderX

Introduction

The COVID-19 pandemic continues to have a lasting impact on the health care system [1,2]; as of December 2021, there have been 270 million confirmed cases since the pandemic began [3]. Type 2 diabetes mellitus is prevalent in patients admitted to hospitals with COVID-19 [4,5], with rates as high as 33.8% [6]. Poorer glycemic control can also be a predictor of COVID-19 mortality [7,8]. Regular physical activity is recognized as a cornerstone of diabetes management and glycemic control [9]. However, there is now evidence that some of the public health measures used to contain the spread of the virus, including restriction of movement via community-level lockdowns, may have impacted physical activity levels [10].

Specifically, there is evidence of pandemic-associated decreases in overall physical activity [11,12] and decreases in activity of different intensities (ie, light, moderate, and vigorous) [13,14], along with an increase in sedentary time [15]. For example, a study using hip-worn accelerometers found that sedentary behavior time and prolonged sedentary bouts increased and total daily steps decreased during lockdowns [16]. Collectively, these findings suggest that COVID-19 lockdown restrictions are likely to adversely impact a set of lifestyle behaviors important to the management of type 2 diabetes; however, the relevant evidence has some limitations. Most of these studies have used self-report measures of activity [17-19] with many involving cross-sectional designs [15,20] or using retrospective data collection [12,21]—design types that are prone to recall and reporting biases. In those studies where devices were used (eg, body-worn accelerometers), short time frames (7-8 days) were observed [16,22], which limits the opportunity to understand long-term trends. Aside from a few studies [23-26], most investigations have featured short or singular time frames of observation and, importantly, have not measured activity behaviors both immediately before and at the point of a COVID-19 outbreak. Furthermore, despite being recognized as a population at greater risk of the health impacts of COVID-19, no studies have assessed physical activity with continuously worn devices prior to and during COVID-19 in people with type 2 diabetes.

Prolonged and restrictive lockdown conditions imposed on residents living in Melbourne, Australia coincided with the conduct of a clinical trial in working adults with type 2 diabetes (ANZCTRN12618001159246), targeting both reductions in sedentary time and increases in physical activity. With one of the intervention components requiring participants to use a wrist-worn activity tracker throughout, this presented an opportunity to ascertain the impact of lockdown on these trial participants.

This exploratory study uses data from a wrist-worn consumer device (Fitbit) to describe and compare activity levels of working adults with type 2 diabetes participating in a behavior change intervention trial prior to and during a prolonged citywide lockdown due to COVID-19.

Methods

Participants and Setting

Participants were from the intervention arm of the OPTIMISE Your Health trial [27]. This trial, which began in 2019, aims to both reduce sedentary behavior (sit less) and increase movement (move more) in desk workers with type 2 diabetes aged 35 to 65 years [28]. Eligibility is based on having been diagnosed with type 2 diabetes (confirmed with recent hemoglobin A_{1c} [HbA_{1c}] test), not being on insulin therapy, working in a desk-based occupation (0.8-1 full-time equivalent), high sedentary time (>50% of waking hours), not meeting physical activity guidelines (ie, doing <150 min of moderate-vigorous physical activity/week and <2 strength sessions/week), and living within a 40 kilometer radius of the Baker Heart and Diabetes Institute (Melbourne, Australia). Participants were randomized following baseline assessments into control or intervention arms. Those in the intervention arm received a height-adjustable desk, a Fitbit Inspire HR wrist-worn fitness tracker, and behavior change health coaching support, as described in detail elsewhere [27]. In brief, the health coaching involved participants setting incremental goals to reduce sitting and increase physical activity, which was facilitated by behavioral strategies that encouraged self-management (eg, standing up after a work task or taking a light walk after finishing a meal). A convenience sample of 11 intervention-arm participants who wore the Fitbit both prior to and during the lockdown restriction periods were included in this study. Participants were recruited sequentially into the broader trial, hence Fitbit observation windows differed for each participant.

Ethical Considerations

Protocols and ethics were approved by the Alfred Health Ethics Committee (#359/18), and all participants provided written informed consent.

Data Collection

The baseline assessment included demographic questions, anthropometric measures (height, weight), and a fasting blood glucose examination. Two weeks following baseline assessment, participants were provided with their Fitbit Inspire HR device, which they were encouraged to wear as often as possible to promote and maintain physical activity behaviors. Participants were not required to wear the Fitbit while sleeping; therefore, sleep was not investigated. Participants consented to give access to their Fitbit activity (recorded on the study account) via Fitabase (Small Steps Labs LLC), a third party web-based data management platform. Each participant was set up with a unique Fitabase study account linked to their Fitbit device and associated smartphone app. All data synchronized from the wearable device to the Fitbit app was uploaded to Fitabase automatically where it could then be exported into date- and time-stamped minute intervals for the time period from August

XSL•FO

RenderX

10, 2019 (start of data collection for the first participant) until October 18, 2020 (the end of the first major lockdown period).

COVID-19 Lockdown in Melbourne, Australia

The first COVID-19 lockdown restrictions in Melbourne, Australia commenced on March 23, 2020, and were eased intermittently, then reinstated, and not lifted until October 18, 2020. During this time, Australia was ranked as having one of the strictest pandemic mitigation strategies in the world, reaching a high of 80 in a 1 to 100 stringency scale in March 2020 [29]. Of all Australian cities, Melbourne had the strictest lockdown during this time due to high rates of transmission and the state government's intention for complete elimination of community transmission of the virus. Varying restrictions were imposed in Melbourne throughout the period of observation; these are described in greater detail in Multimedia Appendix 1.

The lockdown restrictions led to the OPTIMISE Your Health trial being placed on temporary hold. This entailed the suspension of recruitment and clinical assessment visits. Following this, participants were sent a survey via email with a series of questionnaires enquiring about any changes incurred due to the pandemic. The questions pertained to changes in work hours; work location; sitting, standing, and activity behaviors at work; workload; care load; physical activity and exercise; sedentary behavior; motivation; work environment; and musculoskeletal health. Enrolled participants who were involved in the trial during the lockdown period were encouraged to complete their participation to the end of the original trial date (6 months).

Fitbit-Derived Activity Metrics

The Fitbit Inspire HR is a wrist-worn, triaxial accelerometer. The device also uses photoplethysmography, which measures heart rate with infrared light through the skin. The device is powered by a lithium polymer battery with an average battery life of 5 days depending on use. A proprietary algorithm converts the raw acceleration signal from the tracker into step counts and activity intensity. Each minute interval is categorized as sedentary (<1.5 metabolic equivalent tasks [METs] according to Fitbit), lightly active (1.5-3 METs), fairly active (3-6 METs), or very active (>6 METs or ≥145 steps/min in at least 10 min bouts) according to Fitbit's determination of METs [30]. Data were collected continuously by the wrist-worn tracker for 30 days, at which point the device must be synchronized via Bluetooth with a smartphone and the Fitbit app. For the OPTIMISE Your Health trial, the provision of the Fitbit allowed participants to monitor their activity behaviors on the device and the smartphone app. Participants were encouraged to self-select daily stepping goals and activity break reminders (up to 14 per day) that prompted them to achieve 250 steps in each hour of the day.

A recent validation study determined that the Fitbit Charge 2, an older model, demonstrated high correlation (intraclass correlation coefficient >0.89) with an established research-grade accelerometer (Actigraph GT1X) in free-living observations [31]. In that study, correlations between the Fitbit Flex and GT3X+ data were high for sedentary time (r=0.9) but weaker and overestimated for moderate-vigorous intensity physical activity (r=0.65-0.76) [32]. A systematic review in 2016 featuring analysis of 13 studies examining the accuracy of Fitbit in free-living conditions determined that the Fitbit had a tendency to overestimate steps (700-1800 steps/day) compared to research-grade devices [33]. There is currently no validation study published for the Fitbit Inspire HR used in this trial.

Statistical Analyses

For each study participant, the following data was downloaded via Fitabase for the entire wear period: daily steps, METs, heart rates, and estimated daily sleeping time (if available). Steps, METs, and heart rate data are available in 1-minute resolutions, and the associated time stamps are available for all variables. Prior to analyses, all data where the time stamps matched at least one of these criteria were removed: corresponded to time intervals detected as sleeping time by Fitbit, was between midnight and 5 AM daily, and time stamped with a heart rate reported as 0. The first two criteria were used to remove segments that correspond to sleeping time, and the third was used to remove segments when the Fitbit was not worn. This defined the daily waking period. The remaining data were analyzed with models fitted for each participant, separately for METs per minute, the intensity minute categories (sedentary, lightly active, fairly active, very active intensity mins), and step counts. For METs-based analysis, data were analyzed at 1-minute resolution with the logarithm of each day determined as a METs per day–dependent variable. For the intensity-based analyses, the log average number of minutes spent in each intensity category was used as the dependent variable. For steps-based analysis, the logarithm of the daily number of steps was used as the dependent variable. These dependent variables were log transformed to improve the normality of residuals in the model and to ensure nonnegative predicted values following back transformation. The usual bout duration, also known as the weighted median statistic (w50 or x50), was calculated for all activity intensities according to a previously devised method [34]. This entailed all bouts being ordered according to bout duration (mins) and normalized as a proportion of total time spent in each activity intensity type. Participants accumulated half of all their activity time in bouts longer than their usual bout duration.

We used fixed-effect meta-analysis to combine the regression coefficient with lockdown effects into a pooled result for all participants. The METs per minute and intensity minutes models were fitted using generalized least squares regression with autoregressive error structure to handle within-individual autocorrelation. Step counts were fitted with negative binomial regression methods. For all models, the main independent variable was the lockdown time indicator. This indicator included two states: before lockdown (before March 23) or during lockdown (on or after March 23). Independent variables were also added to adjust for differences in Fitbit wear habits that may have occurred following lockdown restrictions: these were calculated as $\sin(2\pi t/24)$ and $\cos(2\pi t/24)$, where t was the time stamp in a 24-hour continuous time format, and the interaction between lockdown time indicator and sin and cosine terms was modeled. To determine the average absolute change following restrictions, steps and METs were transformed from hour and minute intervals to per day for ease of interpretation.

For all analyses, the main parameter of interest was the antilog of the regression coefficient associated with the lockdown variable; this was interpreted as relative rates, with the prelockdown period considered the reference. Relative rates were then transformed into percentages (Δ%). A statistically significant difference between the lockdown period and the prelockdown period was determined when Δ% did not intercept zero.

A postpower calculation was performed using the R Package "PASSED" version 1.2.1 [35] for daily step count. For this analysis, it was assumed that steps per day followed a negative binomial distribution with the distribution statistic (theta) set at 5. Given a mean daily step count of 10,000 steps prelockdown restrictions and a minimum of 100 days prelockdown and 100 days following lockdown restrictions, there was at least 80% power to detect a 10% or more reduction in step count for 11 participants.

Results

Sample Characteristics and Period of Observation With Fitbit in the COVID-19 Pandemic

The mean age of the 11 participants was 52.8 (SD 5) years, and the majority were male (n=8, 73%). In line with the trial inclusion criteria, participants were overweight/obese (mean BMI 35.2, SD 5.1 kg/m^2), with a mean HbA$_{1c}$ of 7.6% (SD 0.8%) at the commencement of their trial participation. A timeline of stage 2, 3, and 4 COVID-19 lockdown restrictions that entailed stay-at-home orders are summarized with novel case data for the state of Victoria (capital city: Melbourne) in Figure 1. According to questionnaire findings (Multimedia Appendix 2), following the imposed restrictions, participants (n=9) reported a shift toward working from home more, a less desirable workplace environment, and reductions in physical activity and exercise participation. None of the participants reported having a COVID-19 infection or having to self-isolate as a close contact during the period of observation. Timelines of Fitbit data collection were reported for each participant. A total of 2447 wear days were recorded across the 11 participants with a median of 197 (range 167-418) days per participant. All participants had substantial periods of observation prior to (mean 122.7, SD 47.9 days) and during the lockdowns (mean 99.7, SD 62.5 days).

Figure 1. New COVID-19 cases in the months preceding and during the 2020 pandemic in Melbourne, Victoria, Australia. Fitbit observation period for each participant is depicted by red lines. Stage 2 restrictions (initiated March 23) entailed shutdown of all nonessential businesses and activities. Stage 3 restrictions (initiated March 30) enforced that people only leave their homes for four reasons: food and supplies, medical care, exercise, and work or education. Gatherings of no more than two people were allowed outside unless they were members of an immediate household or if it was for work or education purposes. Stage 4 restrictions (initiated August 2) included Stage 3 restrictions and the addition of a nightly curfew 7 PM to 5 AM, mandatory face coverings in public, the closing of schools and businesses, and a 5 km radius (around the home) for exercising and essential shopping. On October 18, 2020, the radius of restriction increased to 25 km, 10 people from 2 households allowed to gather in outdoor spaces, and businesses allowed to reopen with conditions. Novel case data and timeline extracted from Victorian Department of Health and Human Services data dashboard [36].
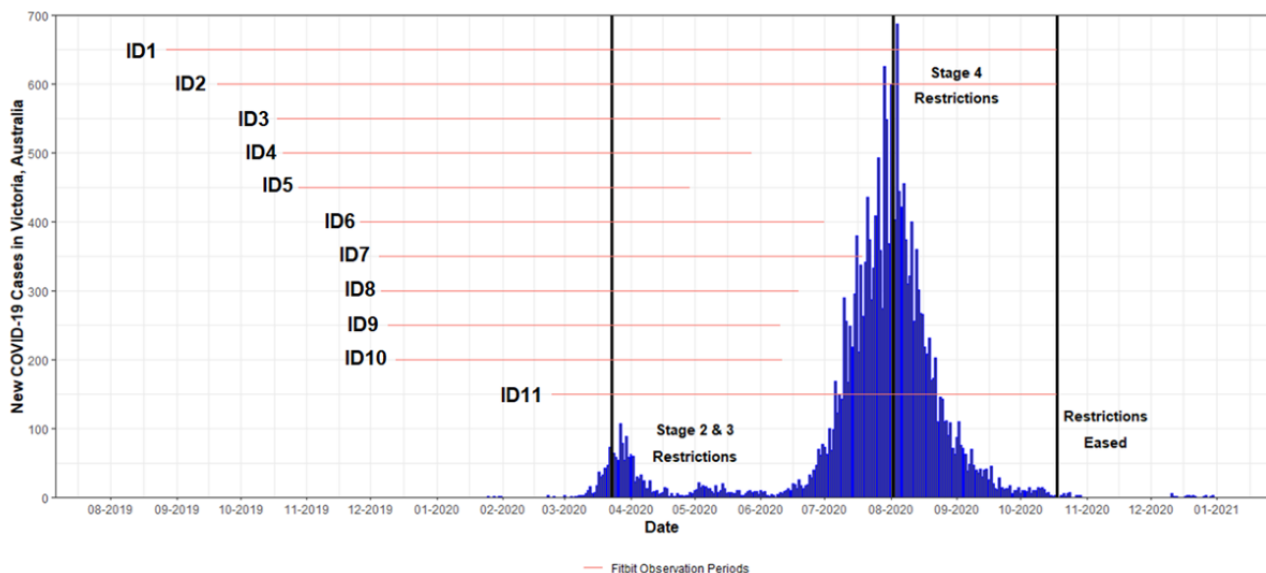
Comparison of Activity Minutes Identified by the Fitbit During and Prior to Lockdown

In the overall pooled-analysis of the participants' activity levels (Table 1), it was determined that both steps (absolute change −1584; Δ% −9%, 95% CI −11% to −7%) and METs per day (absolute change −83; Δ% −6%, 95% CI −6% to −6%) decreased under lockdown restrictions compared with prerestriction levels. Lightly active minutes (absolute change −11 mins; Δ% −4%, 95% CI −8% to −1%) and fairly active minutes (absolute change −3 mins; Δ% −18%, 95% CI −21% to −15%) decreased following the restrictions, and there was a gain to sedentary minutes (absolute change 51 mins; Δ% 3%, 95% CI 1%-6%). Minutes of very active intensity decreased (absolute change −5

mins; Δ% –8%, 95% CI –11% to –5%); however, the usual bout duration of the very active bouts increased (absolute change 5.1 mins; Δ% 25%, 95% CI 4%-49%). Usual sedentary bout duration also increased (absolute change 4.3 mins; Δ% 20%, 95% CI 16%-25%). There were minimal changes to lightly active and fairly active intensity usual bout durations following restrictions, with estimates not reaching statistical significance.

In the individual participant analysis (Multimedia Appendix 3), there was evident heterogeneity in the participants' responses to lockdown restrictions. Considering the 11 participants individually, 4 increased their mean daily step counts with 2 of these participants also increasing their METs. The increases made to activity levels by these participants were outweighed by the remaining sample that saw a decrease in activity for steps (mean increase 575 steps; mean decrease 2760 steps) and for

METs (mean increase 43 METs; mean decrease 144 METs). Discrepancies between changes in step counts and energy expenditure occurred due to differing engagement in activity intensities following the restrictions. Of all participants, 3 increased lightly active intensity minutes, 4 increased fairly active intensity minutes, 5 increased very active intensity minutes, and 5 decreased sedentary minutes per day. The most consistent changes at the individual level were increases to usual sedentary bout durations with 10 participants (9 statistically significant) increasing their volume of time spent in sedentary bouts. Similarly, 7 participants increased usual very active intensity bout durations, although only 2 had statistically significant within-individual changes. The individual responses to the lockdown restrictions are depicted in the Figure 2 heat map visualizations for each participant.

Table 1. Activity conducted during lockdown restrictions compared to activity conducted prior to lockdown restrictions.

| | Overall pooled estimates | | | |
	Prior to lockdown restrictions, mean (SD)	During lockdown restrictions, mean (SD)	Difference	Δ%[a] (95% CI)
Total activity per day				
Steps (n/day)	10,623 (4439)	9039 (3351)	–1584	–9 (–11 to –7)
METs[b] (n/day)	1940 (264)	1857 (173)	–83	–5 (–6 to –5)
Lightly active intensity (mins/day)	251 (6)	240 (6)	–11	–4 (–8 to –1)
Fairly active intensity (mins/day)	16 (0)	13 (1)	–3	–18 (–21 to –15)
Very active intensity (mins/day)	32 (1)	27 (2)	–5	–8 (–11 to –5)
Sedentary (mins/day)	1064 (25)	1115 (36)	51	3 (1 to 6)
Usual bout duration[c]				
Lightly active intensity (mins)	4.4 (0.5)	4.5 (0.9)	0.1	1 (–4 to 7)
Fairly active intensity (mins)	2.7 (0.6)	2.5 (0.7)	–0.2	–7 (–19 to 6)
Very active intensity (mins)	15.7 (20.2)	20.8 (25.7)	5.1	25 (4 to 49)
Sedentary (mins)	20.2 (6)	24.5 (7.6)	4.3	20 (16 to 25)

[a]Δ%: change in activity following pandemic lockdown restrictions.

[b]MET: metabolic equivalent task.

[c]Usual bout duration describes the median weighted bout length; participants accumulate half of all their activity time in bouts longer than the estimate.

Figure 2. Minute-by-minute physical activity intensities during the period of Fitbit observation. Heat maps are numbered according to the participant. Red=sedentary minute, green=lightly active minute, blue=fairly active minute, cyan=very active minute, black=Fitbit not worn/sleep period. The yellow vertical line indicates the start of the lockdown period and stage 2 and 3 restrictions on March 23, 2020; the fuchsia vertical line indicates stage 4 restrictions that started on August 2, 2020.
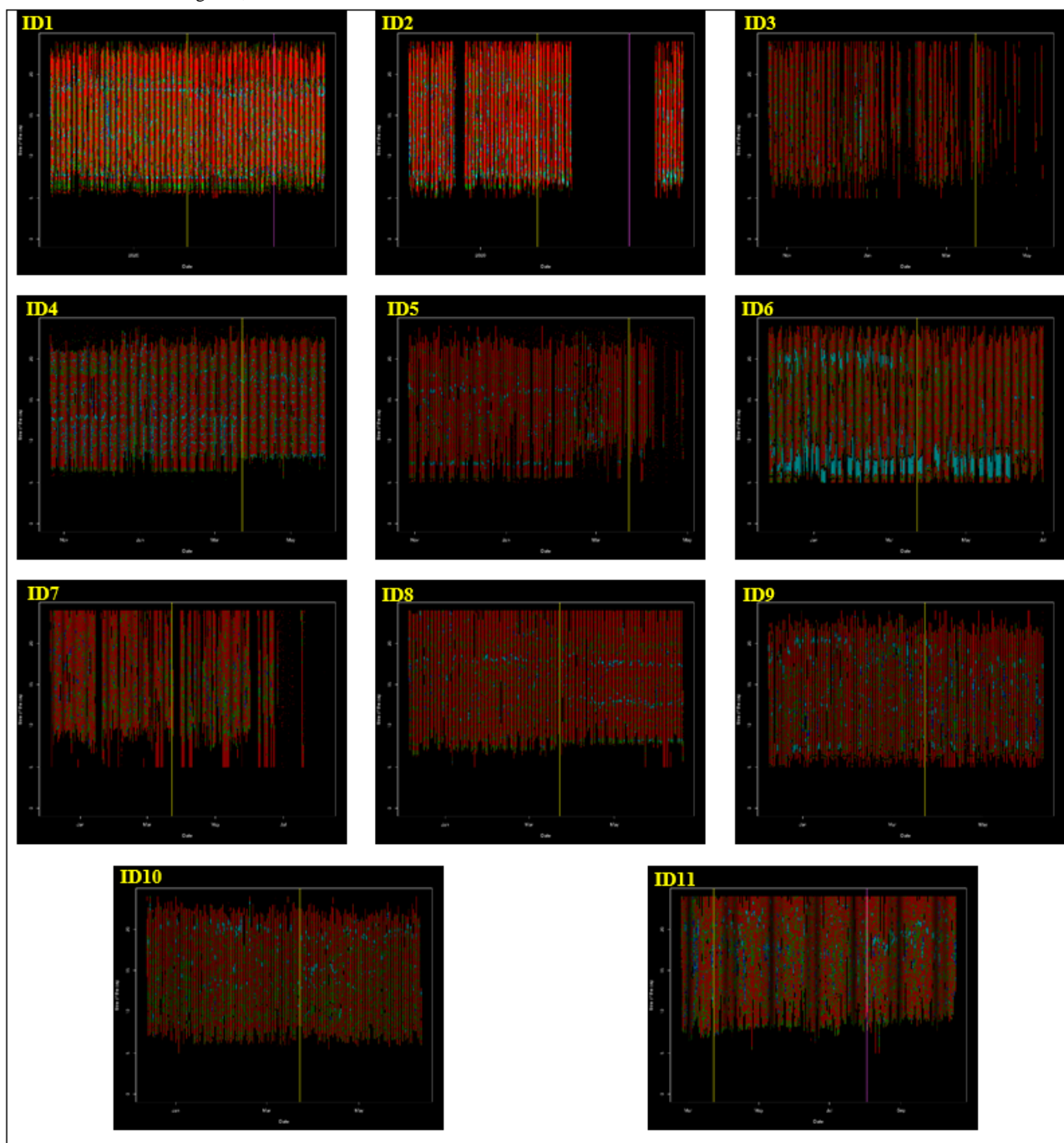
Discussion

Principal Findings

Participants with type 2 diabetes involved in an intervention targeting sitting less and moving more wore a consumer-grade activity-monitoring device (Fitbit Inspire HR) that identified overall decreases in active time and increases in sedentary time following COVID-19 lockdown restrictions. These changes were characterized by a decrease in time spent in lightly active, fairly active, and very active physical activity intensities, and an increase to time spent sedentary. Combined, these behavioral

changes would be expected to have adverse implications for glycemic control and diabetes management.

Findings from this study corroborate current evidence on changes to physical activity associated with the COVID-19 pandemic [10] and confirm findings published online by Fitbit in early 2020 [37]. They also align with observations that those who are overweight or obese were also likely to have their physical activity levels adversely affected by the pandemic [23]. In Spain, a study of 72 patients with diabetes self-reported a significant decline in their weekly walking time during lockdown restrictions [38]. Examining data from a cohort similar

to those in our study, a recent study [39] featuring people with type 2 diabetes living in Melbourne, Australia found that self-reported total physical activity did not change, but incidental walking decreased. For this study, less incidental activity could have contributed to the observed prolonging of sedentary bouts. This could be due to a number of reasons such as minimizing movement to reduce chance of transmission in the community [40], anxiety leaving the house [41], a reduction in physically active commuting [42], and widespread changes to permitted activities in the neighborhood environment [43]. It has previously been reported that fitness-oriented walking was surmised to have increased due to it being designated as one of the permissible reasons to leave home during restrictions [39]. More purposeful fitness-based walking may have explained the slight increase in very active intensity bout duration found in our Fitbit analysis. However, the modest increases to average time spent in very active intensity bouts were not sufficient to counter the overall decline in total activity in the pooled analyses.

Comparison With Prior Work and Implications for Future Research

In the context of a continuing pandemic that may involve future restrictions, we have identified the need to proactively address sedentary behavior reduction and the promotion of increased physical activity (even light-intensity physical activity) in people with type 2 diabetes [44]. The overall decline in step counts observed in this study have potential implications for health outcomes. Based on previous observational research findings, a reduction of 500 steps per day in inactive people is associated with an approximate 2% to 9% increased risk of cardiovascular morbidity and all-cause mortality, and is associated with a 5% increase in all-cause mortality risk when measured by wrist-worn devices [45]. These extrapolations are important for people with type 2 diabetes who are already at heightened risk of cardiovascular disease and morbidity [46]. Conversely, maintaining physical activity levels is associated with a lower susceptibility to viral infections such as COVID-19 [47], improved vaccine efficacy [48], and reduced odds of hospitalization with severe COVID-19 outcomes [49]. Therefore, during public health crises like a pandemic, physical activity levels should be monitored to inform policy that strikes a balance between disease mitigation and the maintenance of physical activity participation in the community [50].

Here, we used a Fitbit device to evaluate the effects of COVID-19 restrictions, with the overall findings indicating a decline in activity levels largely corroborated by other recent evidence. It should, however, be acknowledged that some people within this analysis succeeded in either increasing their activity or decreasing sedentary time despite the lockdown restrictions. For example, the heat map visualizations in Figure 2 illustrate that both ID6 and ID11 increased their very active intensity bout lengths when they engaged in them, while ID10 spent less time in unbroken sedentary bouts that contributed to the preservation of their activity levels. For ID7, there was a significant increase in time spent in lightly active intensities and an increase in lightly active bout durations following the restrictions. While the findings overall indicate a negative impact of the lockdown restrictions, understanding how some

participants maintained or improved their activity levels may inform intervention approaches and recommendations for subsequent lockdown restrictions and preventative measures.

Beyond the pandemic, there is potential for consumer-grade devices to be used for measurement in research studies [51], especially considering their ubiquity in society and constant technological advancement. Importantly, these devices can capture physical activity data over longer periods of time than those achieved by traditional research-grade activity monitors that typically measure 7 to 14 days of data. However, consumer-grade devices need to be validated against measures derived from traditional research-grade monitors, and comparisons made between short-term and longer-term periods of physical activity measurement. There is the potential for consumer-grade devices to be used in determining physical activity adherence and the effects of interventions (eg, following physical activity or dietary intervention) or to investigate longer periods of activity and the relevance to long-term factors of diabetes management such as glycated hemoglobin, adiposity, or diabetes complications. Consumer-grade continuous measurement devices have already been used to prompt behavior change and improve glycemic control [52], and there may be added benefit through combining their use with continuous glucose monitors.

Strengths and Limitations

This is one of only a few studies [23,53] that has used a continuous objective measure of physical activity to determine activity levels prior to and during the COVID-19 pandemic lockdown restrictions and the first to use this methodology in a sample of patients with type 2 diabetes. Using a Fitbit wrist-worn activity tracker, over 2000 wear days were recorded measuring physical activity continuously via accelerometry and heart rate, collected at 1-minute intervals. A wrist-worn device permitted enhanced capturing of physical activity levels when compared to a smartphone app, especially when confined to the home setting. With regression modeling, we were able to investigate the prospective associations of lockdown restrictions on activity levels.

Although we used an advanced method of analysis with high-resolution data with hundreds of wear days per person, we were limited by a small sample size, thus the findings are exploratory. Further participant recruitment was not feasible with pandemic restrictions, and it was necessary to restrict the selection of participants to a period in which they were exposed to comparable lockdown measures. Therefore an a priori power analysis to estimate necessary sample size was not pragmatic. The findings may have limited generalizability to the broader population of adults with type 2 diabetes. For instance, our participants were involved in an intervention trial in which they received coaching and tools to increase activity and reduce sedentary behavior, which became suspended because of restrictions. As the control group was not provided a Fitbit, the influence of the intervention could not be differentiated. One possibility is that the intervention could have provided protection from even further declines in activity level. Nevertheless, the observation that most of these intervention participants did not manage to keep their current activity levels may illustrate the

substantial impact of the lockdown restrictions. All participants had type 2 diabetes, and while having relatively good management, evidenced by their levels of glycemic control, they had low baseline levels of physical activity that may have predisposed them to have greater changes induced by the restrictions. Another consideration is that, compared to other cities and countries, Melbourne and Australia had stringent lockdown restrictions. This means that these findings may not apply to other jurisdictions with less severe restrictions. Finally, the Fitbit is uniquely able to characterize longer-term physical activity; however, the model (Inspire HR) that we used does not have a validation study supporting it. Future studies are now required to corroborate these findings with research-grade

measures and to better understand the potential for Fitbit to characterize physical activity over long observation periods.

Conclusions

For participants with type 2 diabetes enrolled in an intervention trial to reduce sitting time and increase daily physical activity, the COVID-19 pandemic and subsequent lockdown restrictions led to a decrease in steps; METs; and lightly active, fairly active, and very active physical activity intensities, and an increase in time spent in very active and sedentary bout durations overall; however, there was wide individual variation. Data from the wrist-worn Fitbit consumer device provided interpretable long-term activity data to be able to examine these activity patterns. Further corroboration using concurrent data from research-grade measures is required.

Authors' Contributions

CJB conducted the analysis, wrote the manuscript, recruited participants, and devised the original study design. AS devised the statistical modeling and advised on the writing of the statistical analyses section. RG and KR recruited participants and advised on the writing and editing of the manuscript. AC, GNH, NO, and DWD were involved in the conception of the study design, advised on the analyses, and edited the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
COVID-19 pandemic restrictions timeline in Melbourne, Australia, 2020.
[DOCX File , 19 KB - diabetes_v7i2e36181_app1.docx]

Multimedia Appendix 2
Self-reported changes in work, physical activity, sedentary behaviour, motivation, and musculoskeletal discomfort following COVID-19 pandemic lockdown restrictions.
[DOCX File , 136 KB - diabetes_v7i2e36181_app2.docx]

Multimedia Appendix 3
Linear regression activity comparisons prior to lockdown restrictions and during for each participant.
[DOCX File , 35 KB - diabetes_v7i2e36181_app3.docx]

References

1. Kaye A, Okeagu C, Pham A, Silva R, Hurley J, Arron B, et al. Economic impact of COVID-19 pandemic on healthcare facilities and systems: international perspectives. Best Pract Res Clin Anaesthesiol 2021 Oct;35(3):293-306 [FREE Full text] [doi: 10.1016/j.bpa.2020.11.009] [Medline: 34511220]
2. Blumenthal D, Fowler EJ, Abrams M, Collins SR. Covid-19 - implications for the health care system. N Engl J Med 2020 Oct 08;383(15):1483-1488. [doi: 10.1056/NEJMsb2021088] [Medline: 32706956]
3. WHO Coronavirus (COVID-19) dashboard. World Health Organization. 2021. URL: https://covid19.who.int/ [accessed 2021-07-07]

XSL•FO
RenderX

4.   Petrilli CM, Jones SA, Yang J, Rajagopalan H, O'Donnell L, Chernyak Y, et al. Factors associated with hospital admission and critical illness among 5279 people with coronavirus disease 2019 in New York City: prospective cohort study. BMJ 2020 May 22;369:m1966 [FREE Full text] [doi: 10.1136/bmj.m1966] [Medline: 32444366]

5.   Liang W, Liang H, Ou L, Chen B, Chen A, Li C, China Medical Treatment Expert Group for COVID-19. Development and validation of a clinical risk score to predict the occurrence of critical illness in hospitalized patients with COVID-19. JAMA Intern Med 2020 Aug 01;180(8):1081-1089 [FREE Full text] [doi: 10.1001/jamainternmed.2020.2033] [Medline: 32396163]

6.   Richardson S, Hirsch JS, Narasimhan M, Crawford JM, McGinn T, Davidson KW, the Northwell COVID-19 Research Consortium, et al. Presenting characteristics, comorbidities, and outcomes among 5700 patients hospitalized with COVID-19 in the New York City Area. JAMA 2020 May 26;323(20):2052-2059 [FREE Full text] [doi: 10.1001/jama.2020.6775] [Medline: 32320003]

7.   The OpenSAFELY Collaborative, Williamson E, Walker AJ, Bhaskaran K, Bacon S, Bates C, et al. OpenSAFELY: factors associated with COVID-19-related hospital death in the linked electronic health records of 17 million adult NHS patients. medRxiv Preprint posted online on May 7, 2020. [doi: 10.1101/2020.05.06.20092999]

8.   Barron E, Bakhai C, Kar P, Weaver A, Bradley D, Ismail H, et al. Associations of type 1 and type 2 diabetes with COVID-19-related mortality in England: a whole-population study. Lancet Diabetes Endocrinol 2020 Oct;8(10):813-822 [FREE Full text] [doi: 10.1016/S2213-8587(20)30272-2] [Medline: 32798472]

9.   Colberg SR, Sigal RJ, Yardley JE, Riddell MC, Dunstan DW, Dempsey PC, et al. Physical activity/exercise and diabetes: a position statement of the American Diabetes Association. Diabetes Care 2016 Nov;39(11):2065-2079 [FREE Full text] [doi: 10.2337/dc16-1728] [Medline: 27926890]

10. Stockwell S, Trott M, Tully M, Shin J, Barnett Y, Butler L, et al. Changes in physical activity and sedentary behaviours from before to during the COVID-19 pandemic lockdown: a systematic review. BMJ Open Sport Exerc Med 2021;7(1):e000960. [doi: 10.1136/bmjsem-2020-000960] [Medline: 34192010]

11. McCarthy H, Potts HWW, Fisher A. Physical activity behavior before, during, and after COVID-19 restrictions: longitudinal smartphone-tracking study of adults in the United Kingdom. J Med Internet Res 2021 Feb 03;23(2):e23701 [FREE Full text] [doi: 10.2196/23701] [Medline: 33347421]

12. Meyer J, McDowell C, Lansing J, Brower C, Smith L, Tully M, et al. Changes in physical activity and sedentary behavior in response to COVID-19 and their associations with mental health in 3052 US adults. Int J Environ Res Public Health 2020 Sep 05;17(18):6469 [FREE Full text] [doi: 10.3390/ijerph17186469] [Medline: 32899495]

13. McDowell CP, Herring MP, Lansing J, Brower CS, Meyer JD. Associations between employment changes and mental health: US data from during the COVID-19 pandemic. Front Psychol 2021;12:631510. [doi: 10.3389/fpsyg.2021.631510] [Medline: 33643165]

14. Hargreaves EA, Lee C, Jenkins M, Calverley JR, Hodge K, Houge Mackenzie S. Changes in physical activity pre-, during and post-lockdown COVID-19 restrictions in New Zealand and the explanatory role of daily hassles. Front Psychol 2021;12:642954. [doi: 10.3389/fpsyg.2021.642954] [Medline: 33716912]

15. Ammar A, Brach M, Trabelsi K, Chtourou H, Boukhris O, Masmoudi L, et al. Effects of COVID-19 Home confinement on eating behaviour and physical activity: results of the ECLB-COVID19 international online survey. Nutrients 2020 May 28;12(6):1583 [FREE Full text] [doi: 10.3390/nu12061583] [Medline: 32481594]

16. Browne RA, Macêdo GAD, Cabral LL, Oliveira GT, Vivas A, Fontes EB, et al. Initial impact of the COVID-19 pandemic on physical activity and sedentary behavior in hypertensive older adults: an accelerometer-based analysis. Exp Gerontol 2020 Dec;142:111121 [FREE Full text] [doi: 10.1016/j.exger.2020.111121] [Medline: 33132145]

17. Bourdas DI, Zacharakis ED. Impact of COVID-19 lockdown on physical activity in a sample of Greek adults. Sports (Basel) 2020 Oct 21;8(10):139 [FREE Full text] [doi: 10.3390/sports8100139] [Medline: 33096721]

18. Gallo LA, Gallo TF, Young SL, Moritz KM, Akison LK. The impact of isolation measures due to COVID-19 on energy intake and physical activity levels in Australian University students. Nutrients 2020 Jun 23;12(6):1865 [FREE Full text] [doi: 10.3390/nu12061865] [Medline: 32585830]

19. Yang Y, Koenigstorfer J. Determinants of physical activity maintenance during the Covid-19 pandemic: a focus on fitness apps. Transl Behav Med 2020 Oct 08;10(4):835-842 [FREE Full text] [doi: 10.1093/tbm/ibaa086] [Medline: 32926160]

20. Castañeda-Babarro A, Arbillaga-Etxarri A, Gutiérrez-Santamaría B, Coca A. Physical activity change during COVID-19 confinement. Int J Environ Res Public Health 2020 Sep 21;17(18):6878 [FREE Full text] [doi: 10.3390/ijerph17186878] [Medline: 32967091]

21. Mitra R, Moore SA, Gillespie M, Faulkner G, Vanderloo LM, Chulak-Bozzer T, et al. Healthy movement behaviours in children and youth during the COVID-19 pandemic: exploring the role of the neighbourhood environment. Health Place 2020 Sep;65:102418 [FREE Full text] [doi: 10.1016/j.healthplace.2020.102418] [Medline: 32871499]

22. Rowlands AV, Henson JJ, Coull NA, Edwardson CL, Brady E, Hall A, et al. The impact of COVID-19 restrictions on accelerometer-assessed physical activity and sleep in individuals with type 2 diabetes. Diabet Med 2021 Oct;38(10):e14549 [FREE Full text] [doi: 10.1111/dme.14549] [Medline: 33650112]

XSL•FO

RenderX

23. Ding D, Cheng M, Del Pozo Cruz B, Lin T, Sun S, Zhang L, et al. How COVID-19 lockdown and reopening affected daily steps: evidence based on 164,630 person-days of prospectively collected data from Shanghai, China. Int J Behav Nutr Phys Act 2021 Mar 17;18(1):40 [FREE Full text] [doi: 10.1186/s12966-021-01106-x] [Medline: 33731132]

24. Kingsnorth A, Patience M, Moltchanova E, Esliger D, Paine N, Hobbs M. Changes in device-measured physical activity patterns in U.K. adults related to the first COVID-19 lockdown. Hum Kinet J 2021;4(3):247-256. [doi: 10.1123/jmpb.2021-0005]

25. Spruijt-Metz D, Nguyen-Michel ST, Goran MI, Chou C, Huang TT. Reducing sedentary behavior in minority girls via a theory-based, tailored classroom media intervention. Int J Pediatr Obes 2008;3(4):240-248 [FREE Full text] [doi: 10.1080/17477160802113415] [Medline: 19023773]

26. Henriksen A, Johannessen E, Hartvigsen G, Grimsgaard S, Hopstock LA. Consumer-based activity trackers as a tool for physical activity monitoring in epidemiological studies during the COVID-19 pandemic: development and usability study. JMIR Public Health Surveill 2021 Apr 23;7(4):e23806 [FREE Full text] [doi: 10.2196/23806] [Medline: 33843598]

27. Brakenridge CJ, Gardiner PA, Grigg RV, Winkler EAH, Fjeldsoe BS, Schaumberg MA, et al. Sitting less and moving more for improved metabolic and brain health in type 2 diabetes: 'OPTIMISE your health' trial protocol. BMC Public Health 2022 May 10;22(1):929. [doi: 10.1186/s12889-022-13123-x] [Medline: 35538430]

28. Office-based program to improve metabolic control in sedentary employees with type 2 diabetes: the 'OPTIMISE Your Health' study. Australian New Zealand Clinical Trials Registry. 2019. URL: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375487&isReview=true [accessed 2021-11-23]

29. Hale T, Angrist N, Goldszmidt R, Kira B, Petherick A, Phillips T, et al. A global panel database of pandemic policies (Oxford COVID-19 Government Response Tracker). Nat Hum Behav 2021 Apr;5(4):529-538. [doi: 10.1038/s41562-021-01079-8] [Medline: 33686204]

30. Semanik P, Lee J, Pellegrini C, Song J, Dunlop D, Chang R. Comparison of physical activity measures derived from the Fitbit Flex and the ActiGraph GT3X+ in an employee population with chronic knee symptoms. ACR Open Rheumatol 2020 Jan;2(1):48-52. [doi: 10.1002/acr2.11099] [Medline: 31943970]

31. Tedesco S, Sica M, Ancillao A, Timmons S, Barton J, O'Flynn B. Validity evaluation of the Fitbit Charge2 and the Garmin vivosmart HR+ in free-living environments in an older adult cohort. JMIR Mhealth Uhealth 2019 Jun 19;7(6):e13084 [FREE Full text] [doi: 10.2196/13084] [Medline: 31219048]

32. Redenius N, Kim Y, Byun W. Concurrent validity of the Fitbit for assessing sedentary behavior and moderate-to-vigorous physical activity. BMC Med Res Methodol 2019 Feb 07;19(1):29 [FREE Full text] [doi: 10.1186/s12874-019-0668-1] [Medline: 30732582]

33. Feehan LM, Geldman J, Sayre EC, Park C, Ezzat AM, Yoo JY, et al. Accuracy of Fitbit devices: systematic review and narrative syntheses of quantitative data. JMIR Mhealth Uhealth 2018 Aug 09;6(8):e10527 [FREE Full text] [doi: 10.2196/10527] [Medline: 30093371]

34. Chastin SFM, Winkler EAH, Eakin EG, Gardiner PA, Dunstan DW, Owen N, et al. Sensitivity to change of objectively-derived measures of sedentary behavior. Meas Phys Education Exerc Sci 2015 Aug 19;19(3):138-147. [doi: 10.1080/1091367x.2015.1050592]

35. Li J, Knigge R, Chen K, Leary E. PASSED: calculate power and sample size for two sample tests. R J 2021;13(2):450. [doi: 10.32614/rj-2021-094]

36. Victorian COVID-19 data. Coronavirus (COVID-19) Victoria. URL: https://www.dhhs.vic.gov.au/victorian-coronavirus-covid-19-data [accessed 2021-07-09]

37. The impact of coronavirus on global activity. Fitbit Blog. 2020. URL: https://blog.fitbit.com/covid-19-global-activity/ [accessed 2021-08-10]

38. Ruiz-Roso MB, Knott-Torcal C, Matilla-Escalante DC, Garcimartín A, Sampedro-Nuñez MA, Dávalos A, et al. COVID-19 lockdown and changes of the dietary pattern and physical activity habits in a cohort of patients with type 2 diabetes mellitus. Nutrients 2020 Aug 04;12(8):2327 [FREE Full text] [doi: 10.3390/nu12082327] [Medline: 32759636]

39. Sacre J, Holmes-Truscott E, Salim A, Anstey K, Drummond G, Huxley R, et al. Impact of the COVID-19 pandemic and lockdown restrictions on psychosocial and behavioural outcomes among Australian adults with type 2 diabetes: findings from the PREDICT cohort study. Diabet Med 2021 Sep;38(9):e14611 [FREE Full text] [doi: 10.1111/dme.14611] [Medline: 34053106]

40. Cheval B, Sivaramakrishnan H, Maltagliati S, Fessler L, Forestier C, Sarrazin P, et al. Relationships between changes in self-reported physical activity, sedentary behaviour and health during the coronavirus (COVID-19) pandemic in France and Switzerland. J Sports Sci 2021 Mar;39(6):699-704. [doi: 10.1080/02640414.2020.1841396] [Medline: 33118469]

41. Puccinelli PJ, da Costa TS, Seffrin A, de Lira CAB, Vancini RL, Nikolaidis PT, et al. Reduced level of physical activity during COVID-19 pandemic is associated with depression and anxiety levels: an internet-based survey. BMC Public Health 2021 Mar 01;21(1):425 [FREE Full text] [doi: 10.1186/s12889-021-10470-z] [Medline: 33648487]

42. Cusack M. Individual, social, and environmental factors associated with active transportation commuting during the COVID-19 pandemic. J Transp Health 2021 Sep;22:101089 [FREE Full text] [doi: 10.1016/j.jth.2021.101089] [Medline: 34513591]

XSL•FO

RenderX

43. Adlakha D, Sallis JF. Activity-friendly neighbourhoods can benefit non-communicable and infectious diseases. Cities Health 2020 Jul 24:1-5. [doi: 10.1080/23748834.2020.1783479]

44. Methnani J, Amor D, Yousfi N, Bouslama A, Omezzine A, Bouhlel E. Sedentary behavior, exercise and COVID-19: immune and metabolic implications in obesity and its comorbidities. J Sports Med Phys Fitness 2021 Nov;61(11):1538-1547 [FREE Full text] [doi: 10.23736/S0022-4707.20.11898-X] [Medline: 33305550]

45. Rowlands A, Davies M, Dempsey P, Edwardson C, Razieh C, Yates T. Wrist-worn accelerometers: recommending ~1.0 m as the minimum clinically important difference (MCID) in daily average acceleration for inactive adults. Br J Sports Med 2021 Jul;55(14):814-815. [doi: 10.1136/bjsports-2020-102293] [Medline: 32928741]

46. Einarson TR, Acs A, Ludwig C, Panton UH. Prevalence of cardiovascular disease in type 2 diabetes: a systematic literature review of scientific evidence from across the world in 2007-2017. Cardiovasc Diabetol 2018 Jun 08;17(1):83 [FREE Full text] [doi: 10.1186/s12933-018-0728-6] [Medline: 29884191]

47. Lee SW, Lee J, Moon SY, Jin HY, Yang JM, Ogino S, et al. Physical activity and the risk of SARS-CoV-2 infection, severe COVID-19 illness and COVID-19 related mortality in South Korea: a nationwide cohort study. Br J Sports Med 2021 Jul 22:bjsports-2021-104203 [FREE Full text] [doi: 10.1136/bjsports-2021-104203] [Medline: 34301715]

48. Chastin SFM, Abaraogu U, Bourgois JG, Dall PM, Darnborough J, Duncan E, et al. Effects of regular physical activity on the immune system, vaccination and risk of community-acquired infectious disease in the general population: systematic review and meta-analysis. Sports Med 2021 Aug;51(8):1673-1686 [FREE Full text] [doi: 10.1007/s40279-021-01466-1] [Medline: 33877614]

49. Sallis R, Young DR, Tartof SY, Sallis JF, Sall J, Li Q, et al. Physical inactivity is associated with a higher risk for severe COVID-19 outcomes: a study in 48 440 adult patients. Br J Sports Med 2021 Oct;55(19):1099-1105 [FREE Full text] [doi: 10.1136/bjsports-2021-104080] [Medline: 33849909]

50. Sallis JF, Adlakha D, Oyeyemi A, Salvo D. An international physical activity and public health research agenda to inform coronavirus disease-2019 policies and practices. J Sport Health Sci 2020 Jul;9(4):328-334 [FREE Full text] [doi: 10.1016/j.jshs.2020.05.005] [Medline: 32450160]

51. Natarajan A, Pantelopoulos A, Emir-Farinas H, Natarajan P. Heart rate variability with photoplethysmography in 8 million individuals: a cross-sectional study. Lancet Digit Health 2020 Dec;2(12):e650-e657 [FREE Full text] [doi: 10.1016/S2589-7500(20)30246-6] [Medline: 33328029]

52. Jiwani R, Dennis B, Bess C, Monk S, Meyer K, Wang J, et al. Assessing acceptability and patient experience of a behavioral lifestyle intervention using Fitbit technology in older adults to manage type 2 diabetes amid COVID-19 pandemic: a focus group study. Geriatr Nurs 2021;42(1):57-64 [FREE Full text] [doi: 10.1016/j.gerinurse.2020.11.007] [Medline: 33248357]

53. To QG, Duncan MJ, Van Itallie A, Vandelanotte C. Impact of COVID-19 on physical activity among 10,000 steps members and engagement with the program in Australia: prospective study. J Med Internet Res 2021 Jan 25;23(1):e23946 [FREE Full text] [doi: 10.2196/23946] [Medline: 33449907]

Abbreviations

HbA$_{1c}$: hemoglobin A$_{1c}$
MET: metabolic equivalent task

XSL·FO
RenderX

<u>Original Paper</u>

Text Messages and Financial Incentives to Increase Physical Activity in Adolescents With Prediabetes and Type 2 Diabetes: Web-Based Group Interviews to Inform Intervention Design

Mary Ellen Vajravelu[1,2], MSHP, MD; Talia Alyssa Hitt[3], MPH, MSHP, MD; NaDea Mak[4], MPH, CCRP, CIP; Aliya Edwards[5], BS; Jonathan Mitchell[6,7], PhD; Lisa Schwartz[7,8], PhD; Andrea Kelly[4,7], MSCE, MD; Sandra Amaral[5,7], MHS, MD

[1]Division of Pediatric Endocrinology, Diabetes, and Metabolism, Department of Pediatrics, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States

[2]Center for Pediatric Research in Obesity and Metabolism, University of Pittsburgh School of Medicine, Pittsburgh, PA, United States

[3]Division of Pediatric Endocrinology, Johns Hopkins University School of Medicine, Baltimore, MD, United States

[4]Division of Endocrinology & Diabetes, The Children's Hospital of Philadelphia, Philadelphia, PA, United States

[5]Division of Nephrology, The Children's Hospital of Philadelphia, Philadelphia, PA, United States

[6]Division of Gastroenterology, Hepatology and Nutrition, The Children's Hospital of Philadelphia, Philadelphia, PA, United States

[7]Department of Pediatrics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, United States

[8]Center for Childhood Cancer Research, Division of Oncology, The Children's Hospital of Philadelphia, Philadelphia, PA, United States

Corresponding Author:
Mary Ellen Vajravelu, MSHP, MD
Division of Pediatric Endocrinology, Diabetes, and Metabolism
Department of Pediatrics
University of Pittsburgh School of Medicine
4401 Penn Ave
Faculty Pavilion 6th Floor
Pittsburgh, PA, 15224
United States
Phone: 1 412 692 6533
Email: MaryEllen.Vajravelu@pitt.edu

Abstract

Background: Physical activity is a major component of treatment for adolescents with obesity and prediabetes or type 2 diabetes; however, sedentary behavior remains pervasive. An SMS text message–based intervention paired with financial incentives may be an effective way to promote physical activity in this population.

Objective: This study aims to obtain end-user feedback on SMS text message content and assess the acceptability of a planned SMS text messaging intervention with financial incentives to motivate youth with prediabetes or type 2 diabetes to increase physical activity.

Methods: Adolescents with overweight or obesity and prediabetes or type 2 diabetes who attended a large academic pediatric endocrinology clinic were recruited to participate in group interviews (2-4/group) via videoconferencing. Participants were asked to share their thoughts on the use of SMS text messages and financial incentives to remind and motivate them to be more physically active. They rated and provided feedback on specific messages to be used in clinical trials. Participants were also asked about their personal experience with rewards to motivate behavior change and their anticipated reactions to rewards provided for goal attainment (gain-framing) versus those provided and then taken away if a goal was not met (loss-framing). The interviews were conducted by 2 trained interviewers and a note-taker. Content analysis was used to explore themes.

Results: Group interviews were completed with 20 participants (11/20, 55% women; 15/20, 75% with type 2 diabetes; 5/20, 25% with prediabetes) with a mean age of 15 (SD 1; range 12-18) years and a mean BMI of 41 (SD 5) kg/m^2 (all >95th percentile for age and sex). Most participants were non-Hispanic Black (14/20, 70%) and 10% (2/20) were Hispanics. Participants frequently cited near-continuous smartphone use and agreed that SMS text messages would serve as good reminders to be physically active, but the consensus about the need for short messages was strong. Favorable content included references to what they were likely

XSL•FO
RenderX

to be doing when messages were sent (eg, homework or watching television) and messages that were upbeat or informative. Specific physical activity suggestions were rated favorably. Attitudes toward financial incentives varied, with differing opinions about whether loss-framed incentives would be motivating or discouraging. Many participants highlighted the role of intrinsic, rather than extrinsic, motivation in achieving and sustaining behavior change.

Conclusions: The engagement of adolescents with obesity and diabetes or prediabetes allowed for the refinement of SMS text messages for our planned intervention, with an emphasis on short, upbeat, relatable, and informative messages. Although an SMS text messaging intervention using financial incentives to motivate youth with prediabetes or type 2 diabetes to be more physically active is theoretically acceptable, the impact on actual activity levels in this population requires prospective evaluation in a clinical trial.

Introduction

Background

Once a disease of adulthood, type 2 diabetes is now becoming increasingly common among youth [1]. Among individuals with youth-onset type 2 diabetes, severe diabetes-related complications such as retinopathy, neuropathy, and nephropathy begin to emerge within 10 to 20 years of diagnosis and contribute to a 15-year reduction in life expectancy [2,3]. The increasing incidence is driven largely by obesity, which is present in 21% of persons aged 12 to 19 years in the United States [4] and quadruples the risk of youth-onset type 2 diabetes [5]. Globally, nearly one-fifth of children and adolescents aged 5 to 19 years old were overweight or obese in 2016, representing a more than 4-fold increase over 4 decades [6]. Prediabetes, which increases the risk of developing type 2 diabetes [7,8], is already present in approximately 20% to 30% of adolescents with obesity [9,10]. A healthy lifestyle, including adequate physical activity, plays a central role in the prevention and treatment of diabetes. Unfortunately, adolescents with type 2 diabetes typically do not reach the recommended duration of 60 minutes per day of moderate to vigorous physical activity [11], averaging only 8 (girls aged 15-18 years) to 26 (boys aged 10-14 years) minutes daily [12]. To reduce the risk of poor outcomes, effective methods to increase physical activity in youth with prediabetes and type 2 diabetes are needed.

Approximately 95% of teenagers in the United States now report ownership or access to a smartphone [13]. Smartphone ownership is also common throughout the world, although it is more prevalent in advanced economies (median 76% ownership of a smartphone; 17% of mobile phones that are not smartphones) than in emerging economies (median 45% ownership of a smartphone; 33% of mobile phones that are not smartphones). Notably, smartphone ownership is more common among younger individuals [14]. With such a high penetrance of smartphone and mobile phone ownership, one strategy to engage and motivate adolescents to be more physically active is via a text message–based intervention. Text message–based physical activity interventions have been studied in adolescents with overweight and obesity [15]; however, explicit focus on youth with prediabetes and type 2 diabetes has been limited [16]. To promote engagement and retention in a text message–based lifestyle intervention, however, it is critical to elicit adolescent viewpoints as part of intervention development [17,18]. This engagement is particularly needed for youth with obesity-related complications such as type 2 diabetes or prediabetes, in whom the perceived risk of poor health may impact responses to message tone and content.

Another potentially effective strategy to motivate youth to be more physically active is the provision of financial incentives. In adults, incentives framed as losses (upfront endowment with losses applied for failure to meet a goal) rather than gains (money earned upon completion of a goal) are more effective at inducing physical activity-related behavior change [19]. Financial incentives may also help counteract the rapid habituation of text message–based interventions that have been demonstrated in adolescents and young adults [20]. However, to our knowledge, the effectiveness of, or perspectives on, different financial incentive strategies to motivate adolescents to engage in physical activity have not been explored. In the Behavioral Economics for Activity Motivation (BEAM) trial (NCT04874415), a mobile health (mHealth)-based optimization trial, we are studying text messaging, loss-framed financial incentives, and gain-framed financial incentives as candidate components in a factorial experiment with youth with overweight or obesity and prediabetes or type 2 diabetes, with the aim of increasing time spent in moderate to vigorous physical activity.

Objectives

To prepare for the trial, we conducted group interviews with adolescents from the target population. We sought insights into message content and financial incentive strategies, including financial incentive preferences and the anticipated impact on one's motivation to be physically active.

Methods

Participants

A convenience sample of individuals from the target population of the BEAM trial, adolescents aged 13 to 18 years with overweight or obesity (BMI ≥85th percentile for age and sex) and prediabetes (hemoglobin A_{1c} 5.7%-6.4%, fasting glucose 100-125 mg/dL, and 2-hour oral glucose tolerance test glucose 140-199 mg/dL) or type 2 diabetes (hemoglobin A_{1c}≥6.5%, fasting glucose ≥125 mg/dL, and 2-hour oral glucose tolerance

test glucose ≥200 mg/dL and negative diabetes autoantibodies) were recruited from the pediatric endocrinology clinic at the Children's Hospital of Philadelphia, a large academic children's hospital in Philadelphia, Pennsylvania, United States, from December 2020 to April 2021. Potentially eligible participants were approached about the study at clinic visits or by phone within 2 weeks after a clinic visit by the study research coordinator or principal investigator. Individuals with limited English proficiency were excluded from this study. Eligible individuals were invited to participate in a 1-hour group interview. Electronic consent and assent (for participants aged <18 years) were obtained via REDCap (Research Electronic Data Capture; Vanderbilt University). Group interviews were roughly segmented by age when possible (13 to 15 or 16 to 18 years) to promote more open dialogue among similarly aged peers but not by other demographic or clinical characteristics. Participants were compensated with US $30 for their time. Limited medical record reviews to include demographic information and pertinent medical history were performed by the study team with the permission of the participants.

Ethics Approval

Ethics approval was obtained from the Children's Hospital of Philadelphia Institutional Review Board (IRB 20-017554).

Message Development

The text messages were developed by the investigators with the assistance of one high-school student (female, aged 17 years) and one college student (female, aged 20 years). Both students became involved after approaching the primary investigator regarding temporary research opportunities in pediatrics, independent of any school-required research experience. Messages were designed with the target population in mind; limited financial resources and transportation barriers are common, so physical activity suggestions included only those that were free or low-cost, as well as many that could be performed at home. Initial message development was guided by common barriers to being more physically active, including feeling too tired, lack of interest, lack of peer or family support, lack of equipment, lack of space indoors or outdoors, lack of motivation, preference to avoid sweating, embarrassment, lack of confidence in skills, and lack of knowledge about how to do so [21]. Messages were crafted to have different tones, including informative, encouraging, or funny, to enhance variety and improve interest and engagement. Messages often included emojis, and some included graphic interchange formats (GIFs). The initial messages were reviewed and edited by the study team for clarity and their potential to engage end users. A total of 84 messages (1 per day for the 12-week intervention) were created.

Web-Based Group Interviews

Group interviews were chosen rather than individual interviews to promote an atmosphere of engagement and the sharing of ideas among peers. Smaller group interviews (goal of 2 to 6 participants) were chosen over larger group interviews or focus groups (the original goal of 7 to 10 participants) because of the virtual nature of the interviews, which was necessitated by the COVID-19 pandemic. Although the original study design

included the use of focus groups, the richness of the data gathered from focus groups is heavily dependent on the ability to promote and maintain dynamic group discussions. It is possible to conduct focus groups in a virtual setting, but potential challenges include technological difficulties and the inability to control each individual's environment, which may lead to distractions and interruptions [22]. Therefore, we chose group interviews, in which the primary objective of the interviewer questions was to obtain individual responses rather than to stimulate group discussion as a method of information gathering [23]. Interviews were conducted by 2 primary interviewers (NM and AE), clinical research coordinators who identify as Black women in their 20s to 30s. NM had previous training and experience as a focus group facilitator and served as the primary interviewer. AE also participated in the recruitment of participants. MEV, the principal investigator, is a female pediatric endocrinologist who provides clinical care and conducts research with youth with prediabetes and type 2 diabetes; she assisted with interviews and identified the participants as White and Hispanic.

A semistructured interview guide was designed to elicit open-ended feedback on text messages for physical activity motivation (including acceptability, practical considerations, and preferred or nonpreferred content), experience with and motivation for behavior change, and experience with and attitudes toward the use of financial incentives for behavior change. The interview guides were piloted with nonmedically trained adults and revised as needed for clarity. The interviews were rehearsed by the interviewers with oversight by the study principal investigator (MEV), who had formal training in qualitative research methods. Interviewers practiced neutral, nondirective responses to participant answers and the use of open-ended probing questions to elicit more detailed responses. Before the start of the interview, interviewers informed participants that there were no correct answers and that all feedback, including critical feedback, was welcomed.

In addition to specific questions, 8 messages were reviewed during each interview. The number of messages was restricted to 8 to optimize the amount of time available for discussion, with the goal of understanding what aspects of the message were engaging or not rather than simply rating the specific message. Messages were selected to include a variety of barriers addressed and tones used (informative, encouraging, or funny) such that all combinations were tested at least once throughout the study. The messages were not repeated across groups; in total, 64 representative messages were reviewed. The remaining 20 messages were not substantially different in tone or content and thus were not reviewed by the study participants. During the interviews, message content was shared with participants via the videoconferencing platform's *screenshare* function and read aloud. Participants were asked to rate the messages as *great*, *OK*, or *bad*; these specific rating words were chosen to maximize the ability to identify message *outliers*—those that truly resonated (*great*) and those that were strongly disliked (*bad*)—so that themes relating to message success or failure could more easily be identified. Participants were invited to type their initial ratings in the platform's chat or respond aloud. After all initial ratings were shared, the participants were asked

to explain their ratings, including why they liked or disliked the message and how it could be improved.

All interviews were conducted via the videoconferencing platform BlueJeans (Verizon), accessed by participants using their preferred personal internet-connected device (smartphone or computer). Participants were asked to keep their camera on if comfortable doing so and to remain unmuted in a quiet setting if possible. If participants wrote in the chat rather than speaking, the interviewers reread the typed content, stating which participants responded.

Analysis

Participant characteristics were presented using summary statistics, including means and SDs for continuous variables and proportions for categorical variables. All interviews were recorded securely on a videoconferencing platform, and audio was transcribed using a professional transcription service. Transcripts were reviewed by the study staff, corrected as needed, and supplemented by observer notes. Transcripts were deidentified before analysis. Content analysis was conducted to explore these themes. An a priori set of codes was created based on the semistructured interview guide; for example, *Text messages acceptability* and *Text messages: preferred content*. Next, two of the study team members with experience and training in qualitative study methods (TAH and MEV) reviewed the transcripts, identified emergent themes, and then refined the initial codebook. For example, an additional code for *pandemic* was considered owing to the frequent mention of how the COVID-19 pandemic impacted behavior and motivation but ultimately not included as an independent code but rather

incorporated as a subcode to motivation for behavior change. After independently coding the 3 transcripts, the 2 reviewers compared the coding and clarified the codebook as needed. NVivo (version 12; QSR International) was used for qualitative analysis.

Results

Participant and Group Interview Characteristics

Participants (N=20) had a mean age of 15.7 (SD 1.3) years; 75% (15/20) had type 2 diabetes, and 25% (5/20) had prediabetes. The majority (14/20, 70%) of participants were non-Hispanic Black, and the remainder were non-Hispanic White (3/20, 15%), Asian (2/20, 10%), or mixed race (1/20, 5%); of the 20 participants, 2 (10%) participants were of Hispanic ethnicity. Among the participants with diabetes, 53% (8/15) were prescribed insulin, 93% (14/15) were prescribed metformin, and 13% (2/15) were prescribed liraglutide. The median most recent hemoglobin A_{1c} level was 6.1% (IQR 5.9%-6.2%) among participants with prediabetes and 7.3% (IQR 6.5%-10.4%) among participants with diabetes (Table 1).

In all, 8 group interviews, each consisting of 2-4 adolescents, were conducted from December 2020 to April 2021. Each group interview lasted for approximately 30 to 45 minutes. The participants had variable degrees of engagement, with many leaving their cameras off. However, all (20/20, 100%) participants responded to the entire set of interview questions and rated all text messages per session. Many used the chat feature in the videoconferencing platform to respond but spoke aloud when asked to do so.

Table 1. Participant characteristics.

Category	All participants (N=20)	Participants with prediabetes (n=5)	Participants with type 2 diabetes (n=15)
Sex, n (%)			
Female	11 (55)	3 (60)	8 (53)
Male	9 (45)	2 (40)	7 (47)
Race, n (%)			
Black	14 (70)	3 (60)	11 (73)
White	3 (15)	0 (0)	3 (20)
Asian	2 (10)	1 (20)	1 (7)
Mixed	1 (5)	1 (20)	0 (0)
Ethnicity, n (%)			
Non-Hispanic	18 (90)	5 (100)	13 (87)
Hispanic	2 (10)	0 (0)	2 (13)
Age (years), mean (SD)	15.7 (1.3)	15.6 (1.5)	15.7 (1.3)
BMI (kg/m^2), mean (SD)	40.5 (5.5)	40.5 (6.7)	40.5 (5.3)
Insulin use, n (%)			
No	12 (60)	5 (100)	7 (47)
Yes	8 (40)	0 (0)	8 (53)
Hemoglobin A_{1c} (%), median (IQR)	6.6 (6.1-9.1)	6.1 (5.9-6.2)	7.3 (6.5-10.4)

Themes

Overview

Thematic saturation was achieved with no new themes generated from later interview groups. Instead, previously identified themes were also present in the later groups. The interrater reliability of the 8 transcripts was high (κ=0.92). Several themes and subthemes emerged from focus group discussions that pertained to the development of text messaging content as well as the use of financial incentives in an intervention designed to motivate youth with overweight or obesity and prediabetes or type 2 diabetes to be more physically active.

Theme 1: Near-Continuous Use of Smartphones and Acceptability of Text Message Reminders

All but one (19/20, 95%) participant had smartphones and felt that text messaging was a good way to remind teens to be more active:

> *We always on our phone, so we gonna see it [and] texting is a really good way to sort of spread words. I mean, I know that I, personally, spend probably way too much time on my phone.* [Participant 19, group 8; female, aged 14 years]

The interruption via text message was felt to be a useful prompt to move more:

> *I feel like if you - if we got manual reminders, it could implant something in our head, and like an idea in our head to do it instead of forgetting about it throughout the day.* [Participant 19, group 8; female, aged 14 years]

Participants varied in the acceptable frequency of text message reminders, with a participant suggesting that messages as frequently as once per hour would be appropriate. However, most participants preferred 1-2 messages per day, either at noon or after school. They emphasized the need to know from whom the text was sent, so they did not mistake it for spam. Most felt that they used their phone more during the summer but had it with them at nearly all times, regardless of the time of year or day of the week.

Theme 2: Text Messages Should Be Short, Upbeat, Informative, and Relatable

Short and upbeat messages were strongly preferred. Table 2 highlights representative text messages and participant responses. Participants reported that they would most likely read and enjoy messages that were 1 sentence or phrase long and noted that they may not open the message to read beyond the message preview. Regardless of the originally intended tone (informative, encouraging, or funny), messages that had *upbeat* characteristics such as exclamation points, smiley faces, or encouraging words were felt to be most motivational. However, even if brief and encouraging, those stating a generally known fact (eg, *Exercise helps your body and your brain*) resulted in mixed responses. Importantly, a participant highlighted the need for caution when discussing self-esteem. Reflecting on the message *Did you know that being physically active can improve your self-esteem? Why not start right now? You got this* , she stated that this comment would cause her to question her own self-esteem:

> *While self-esteem is a great thing to focus on and have, I think if you point it out, it makes us feel a little bit insecure...If I got this sent to me and I was like - and I looked at it, I'd be like do I have low self-esteem?* [Participant 1, group 1; female, aged 16 years]

Participants reported satisfaction with texts that reported facts or specific suggestions on how to overcome barriers: *Feel like you're tight on time? Maybe it's in your head. A brisk walk actually changes the chemicals in your brain to make you feel more relaxed and less anxious* was felt to explain a bit of the science and to be memorable.

Another informative message (*Physical activity that gets your heart rate up releases endorphins that raise your energy level. Ready for your energy boost?*) was appreciated for providing a specific reason for exercising. Messages that gave examples of how to overcome specific barriers were also well-rated. For example, in response to a message that identified the common barrier of feeling embarrassed to exercise in front of others and suggested a solution (*It is completely normal to feel embarrassed to work out around others. Don't let that stop you. Exercise by yourself or with people you're comfortable with*), a participant rated the message highly:

> *...It acknowledges a common feeling that a lot of people feel when they're working out around other people. And then on top of that, it gives a suggestion as to how you can fix that feeling...* [Participant 20, group 8; male, aged 14 years]

There was agreement on the utility of sharing ideas to be physically active, but the preferred activities to suggest varied by participant. Several noted that they did not like sports, that "yoga sounds hard," exercise classes sounded like school ("Why must I have a class? Why can't we just go outside and just do whatever? Why does it have to be a class?" [Participant 13, group 6; male, aged 15 years]), and not everyone has room to or enjoys dancing at home. Suggestions about how to be physically active at home were appreciated, but participants differed in the perceived utility of including a link to a video or description of activities, with many stating that they would click the link, but others suggesting that clicking the link is "just kind of another thing to do."

Messages that mentioned school or sitting on the couch and watching television were highly relatable. A message that emphasized that being active can help with school performance resonated with a participant:

> *I like how it ties in the school thing. I know that I would like to do better in school. And I think that it's the same for a lot of people my age. So, I think that this one could really capture a lot of people.* [Participant 10, group 4; male, aged 18 years]

Table 2. Example text messages, tone, and feedback.

Message	Tone	Representative quotes
Treadmills get you nowhere . But seriously, walking is great exercise!	Funny	• "I like how it's kind of not comedic, but it's kind of like the exclamation point adds like a sense of - yeah, like upbeat...I like how the other one had like a fact because fun facts interest me and will grab my attention more" (participant 12, group 5; female, aged 13 years).
No matter how slowly you walk or jog, you are still lapping everybody on the couch !	Funny	• "I said great because think about like if we were all sitting on the couch or whatever being lazy, then someone got this text message, they could maybe motivate everybody else, like let's just go on a walk together" (participant 11, group 5; female, aged 16 years). • "...When you get this, let's say you're watching a movie. Everybody's on the couch and eating chips or whatever, and you see this emoji or you see this message. It's like a reminder to like go out, and it's like motivational" (participant 12, group 5; female aged 13 years).
Sometimes large gyms are not for everyone; make use of smaller spaces such as a bedroom or a kitchen to fit in a quick work out. At least it will smell better !	Funny	• "[It's] ok—I would change it to make use of the space you are most comfortable in" (participant 4, group 2; female, aged 14 years).
Exercise helps your body and your brain, so get to it !	Informative	• "I heard this before still, but I think it's like a short and simple nice quote to educate people on and to send a quick reminder because like that exercising can put you in a better mood and stuff like that" (participant 11, group 5; female, aged 16 years). • "And I like that it's short, but it doesn't give me motivation or anything. It's just like another text that would be sent, read, and not replied to, and wouldn't have any affect in my life" (participant 12, group 5; female, aged 13 years).
Feel like you are tight on time? Maybe it's in your head . A brisk walk actually changes the chemicals in your brain to make you feel more relaxed and less anxious .	Informative	• "I feel like this one's great as well because if you're ever feeling anxious, you can go back to this in your brain and remember that one time you got a text message telling you how to fix it. So I think this is good for any situation where you're ever feeling anxiety" (participant 19, group 8; female, aged 14 years). • "I think this one's great because it explains it. It explains a bit of the science" (participant 20, group 8; male, aged 14 years).
A for effort: being active can help you do better in school .	Informative	• "I like how it ties in the school thing. I know that I would like to do better in school. And I think that it's the same for a lot of people my age. So, I think that this one could really capture a lot of people" (participant 8, group 4; female, aged 14 years).
Improving your fitness is a slow process, but quitting will not speed it up! Keep up the great work!	Encouraging	• "I know a lot of people do better with motivation, so it'll help motivate you during that day. Whatever you're doing, you see this and you're like okay. Somebody believes in me..." (participant 12, group 5; female, aged 13 years).
Rise and shine . Do something today that your future self will thank you for. Get yourself pumped up!	Encouraging	• "I like this one. It's motivational and I think I'd like reading that in the morning...Yeah, this is a great thing to tell yourself or wake up to reading every day, in my opinion" (participant 18, group 7; female, aged 16 years). • "Yeah, I like that one, too. It's very motivational" (participant 16, group 7; male, aged 15 years).
Exercising with others can make it fun and help motivate you. Who will be your work out buddy today ?	Encouraging	• "...There's really nothing outstanding about it. I do like how it sort of – it tells you to get with a friend and do that sort of thing. I like that idea" (participant 10, group 4; male, aged 18 years). • "It's good, but I prefer to work out by myself" (participant 9, group 4; female, aged 17 years).

Participants imagined themselves receiving messages while sitting on the couch and *being lazy*, then felt motivated to stand up and walk around or even exercise during commercial breaks. A participant reflected as follows:

...Think about like if we were all sitting on the couch or whatever being lazy, then someone got this text message, they could maybe motivate everybody else, like let's just go on a walk together. [Participant 11, group 5; female, aged 16 years]

XSL•FO
RenderX

Another participant agreed:

> *I think that when you get this, let's say, you're watching a movie. Everybody's on the couch and eating chips or whatever, and you see this emoji or you see this message. It's like a reminder to like go out, and it's like motivational...* [Participant 12, group 5; female, aged 13 years]

Theme 3: Extrinsic Versus Intrinsic Motivation to Change Behavior

Participants frequently reported that they had a goal to exercise more, but they differed in their sources of motivation or encouragement to do so. Parents and physicians were often cited as the person setting physical activity goals for participants, and frequent reminders were felt to be particularly frustrating. A participant noted that "a lot of adults tell kids to exercise and that they need to get out more" by quoting the following:

> *And I get it. Not helpful when I'm in the middle of doing something, and then someone comes into my room and just like get outside. I'm just like why? I also tend to not exercise when there is no immediate goal...It needs to have a sensical purpose.* [Participant 1, group 1; female, aged 16 years]

Another participant expressed frustration about being reminded to exercise:

> *When I'm told over and over again to exercise and what will happen if I don't, it's – because I make sure that I'm exercising as frequent as possible...So when people...say why aren't you exercising or you need to exercise more, it can get annoying and it can make me not want to do it.* [Participant 12, group 5; female, aged 13 years]

A participant emphasized the value of a parent taking time to show concern when encouraging him to be more physically active:

> *It's like she actually sat down with me, instead of just telling me. She actually sat down. Actually, had a nice conversation about it, instead of just coming to my door and telling me what to do.* [Participant 8, group 2; male, aged 14 years]

Personal and family history of type 2 diabetes were major motivators for several participants to engage in a healthy lifestyle. A participant shared the following:

> *...My motivation is so I can get off of these pills I take, the metformin and whatnot...I've been doing absolutely everything I can because I have family members who have the severe type two diabetes, and I don't want that to be me...I don't want to lose my life due to health issues...I don't want to pass away when I'm 40 because I have serious health issues, so I want to live my life the right way and be normal for once.* [Participant 15, group 7; male, aged 16 years]

Another reflected by quoting the following:

> *Saw kind of the direction that my health was going in, and it was kind of like concerning, so I wanted to turn that around so that before it got too permanent or too bad or anything like that, so that was something that motivated me for sure.* [Participant 19, group 8; female, aged 14 years]

Theme 4: Effect of Financial Incentives May Depend on Intrinsic Motivation

Nearly all participants reported that their parents had offered rewards for behavior change, most commonly money or a desired item such as a video game or clothes. However, the perceived effectiveness and acceptability of this approach varied. Some reported that a monetary reward or desired object "kind of pushes you more and gives you a good boost of energy and motivates you a lot" (participant 11, group 5; female, aged 16 years) and that "I like the idea of getting something out of doing things" (participant 10, group 4; male, aged 18 years). On the other hand, another participant questioned the use of financial incentives when discussing her experience with an allowance: *"...When I started getting - becoming like older and more slightly anarchist, it was a bit of why am I doing this for capital reasons? I don't like this"* (participant 1, group 11; female, aged 16 years).

The perceived importance of the underlying behavior to change was a major factor in the persistence of behavior change. Participants reported feeling motivated to continue the behavior if habits were "*good*" for themselves or others, but if "[T]hey weren't helping people that much...I really saw no point in doing it" (participant 10, group 4; male, aged 18 years). Being physically active was categorized by some respondents as "just the right thing to do," which negated the use of financial incentives. In addition, the end goal was emphasized:

> *It's a good chance that you're going to meet your goal when you have the motivation, like something that you're working hard towards. Like for example, if I was - I know that I'm trying to work hard toward being healthy mentally and physically. Well, I know that we - all this hard work is eventually going to pay off. So, sometimes you've just got to - sometimes you've just got to think and have that mindset. If I work hard, eventually it's going to pay off in the end.* [Participant 11, group 5; female, aged 16 years]

Financial rewards were also seen as a way to overcome barriers even for goals that were previously intrinsically motivated:

> *...Last year before, pre-coronavirus, I was all-A student...And I didn't need any money to motivate me...when I saw the honor roll in my hand, that was my motivation...But this year, I did not get all As and all Bs...as motivation [my dad] said at the end of the year, if I was to bring home an...all As and Bs honor roll, that I would get a shopping spree or money or stuff like that...but that is kind of the motivation that I do need to keep my grades up.* [Participant 11, group 5; female, aged 16 years]

However, participants identified that goals that are *only* extrinsically motivated by money may not be achieved when additional barriers arise:

...My parents used to give me a prize if I got like 100 on a test or something like that, and it always motivated me to study and do well in school...it pretty much worked until COVID hit because my grades started going down because I wasn't that motivated. [Participant 12, group 5; female, aged 13 years]

Theme 5: Potential Benefits and Drawbacks of Loss-Framed Incentives

When asked about loss-framed incentives, using either money or physical objects, participants gave examples of times that their parents had threatened or actually removed objects for poor behavior. Most participants expressed frustration, stating that this approach would make them "sad," "mad," and "defeated or upset" and that it would be "unmotivating." However, some also acknowledged that this approach could be viewed as fair:

...I would understand why that got taken away from me. I know that it would be because I didn't do whatever I was supposed to do, so I personally wouldn't be angry because I know why that would get taken away from me. [Participant 11, group 5; female, aged 16 years]

Another participant, speaking about her father's threat of not allowing her to participate in an activity anymore if her grades fell, reflected the following:

...I felt neutral about the whole situation, but I was always - I think it helped me because I knew that that could be taken away because one thing about my dad's ultimatums is that he means business...So I felt - not scared, but I was like okay. I know what I need to do. [Participant 12, group 5; female, ages 13 years]

When evaluating preferences, perceived fairness, and effectiveness of loss- versus gain-framed incentives, opinions varied, with some participants reporting that either approach could work. Several participants acknowledged that the perception of loss would likely be highly motivating despite, or because of, the frustration it causes. A participant reflected the following:

...It is nice to have something earned but there should be some sort of consequence so you don't become lazy. Earning something would be more successful because you can see your accomplishment. [Participant 6, group 2; female, aged 17 years]

Some noted that they would feel highly motivated by the possibility of having something taken away, stating the following:

What motivates me more is like having something taken away, so then I would know that...I would get that back in the end after I work hard [and] the threat of having something taken away motivates me to do better, just so I could have it with me the whole time. [Participant 11, group 5; female, aged 16 years]

However, participants felt that the effectiveness of loss- versus gain-framed rewards would depend on the reward itself:

It depends on what the reward is and it depends on what's being taken away. So like if you took -

personally, like if you took my [video game system] away, I'd be like yeah, I'd choose that one. [Participant 1, group 1; female, aged 16 years]

Several others felt the following:

Positive reinforcement would be more effective and that the threat almost makes me want to revolt, because I don't like threats...that promise, like that shopping spree promise, it motivates me. I'm like I'm almost there. I can see the finish line. But threats, no. So the promise of having a reward, because the threat is too much for me and it does not make me want to do my best. It makes me want to do worse just to prove that person - I don't know, because it's a really catty thing with me if I'm threatened... [Participant 12, group 5; female, aged 13 years]

Importantly, although the behavior may change in the desired way because of the incentive, a participant questioned whether it would result in true motivation:

I think it's the [threat of having something taken that works better] because you're scared of doing it or not doing it, so you keep on doing it. And it's not necessarily motivation, but it's just like at the end of the day, you're still doing it, so it's good. [Participant 20, group 8; male, aged 14 years]

Content Revision

On the basis of the participant feedback, messages were refined by study team members for use in the BEAM trial. Those rated as *bad* by even a participant were edited to omit unfavorable content or discarded entirely if the overall concept was disfavored. For example, the message *Did you know that being physically active improve your self-esteem? Why not start right now? You got this* was omitted, and messages that were supportive of self-confidence and self-efficacy but that did not unintentionally imply that the individual had poor self-esteem, were substituted instead (*Ever feel like you're in a tough situation? Going for a walk can help you prepare to face that problem and overcome it*). On the basis of the favorable response to messages referencing feeling lazy or describing how being physically active may help with school performance, more messages with these themes were created. Messages with mixed responses were edited based on specific negative feedback or included if responses were positive and neutral. Additional encouraging messages were created to address problem solving to overcome barriers to being more physically active and to remind the value of a support person to help achieve activity goals; for example, *Does your step count goal seem like a stretch? Break it up! Every minute counts!* and *Who will be your workout buddy today? Bring a friend or family member with you on a walk or to the gym (blame us if you need to!)*. Messages were also shortened and adapted to fit the preferred timing in mid-day or afternoon (eg, *You have the power to start your day off strong! Wake up, have your favorite breakfast and go for a walk, run, or bike ride. Get moving and you'll be ready to face the day* was changed to *Tomorrow, you have the power to start your day off strong! Plan to wake up, be active, and you'll be ready to face the day*), and additional encouraging messages

were created (eg, *Is working toward your fitness goal a bit challenging? That's great! The more challenging a task, the* *more rewarding it will be in the end!*) . Additional specific lessons learned are summarized in Textbox 1.

Textbox 1. Lessons about the use of text messages and financial incentives for physical activity motivation among adolescents.

Acceptable message frequency

- 1-2 texts per day

Acceptable message timing

- Mid-day or afternoon (after school)

Ways to minimize the risk of messages being ignored

- Save the study's or team's phone number in contacts so that it is not identified as spam

- Shorten messages or put most important text in beginning of message

- Use exclamation points and emojis

Financial incentives for behavior change

- Potentially motivating in theory

- Familiar concept to adolescents

Loss-framing to promote behavior change

- Acceptability divisive: motivating but possibly too frustrating

---

Discussion

Principal Findings

Through virtual group interviews of adolescents with obesity and prediabetes or type 2 diabetes, we obtained end-user feedback to refine a bank of text messages for an mHealth-based physical activity intervention and identified several themes related to the use of text messaging and financial incentives to motivate youth to be more physically active. The participants' responses highlighted the challenge of developing message content that appeals to all end users [24], as well as the importance of keeping messages brief, upbeat, informative, and relatable. Adolescents' familiarity with rewards as a means to encourage behavior change allowed a rich discussion of their anticipated responses to financial incentives for physical activity motivation.

Our approach to intervention development is *person-based*, in which qualitative research is used to inform design by gaining insight into the perspective and psychosocial context of individuals who will use the intervention [25]. This qualitative assessment will be used not only in the intervention design but also in the evaluation of the intervention. Stakeholder involvement is an essential component of digital health interventions [26], but to date, text messaging interventions promoting healthy lifestyle changes for adolescents with obesity have been heterogeneous, with a limited description of whether, and how, the intervention was co-designed with end users [15,27]. One recent exception is the TEXTBITES intervention, in which Partridge et al [27] used an iterative mixed methods approach to develop a text message program for Australian adolescents with obesity. We took a similar approach to develop a text-message–based physical activity intervention for adolescents with overweight or obesity and prediabetes or type

2 diabetes (BEAM trial). Like TEXTBITES, our population will also include adolescents with obesity, but as reflected in this study, a large proportion of participants in our trial will be youth of minority race or ethnicity and from disadvantaged socioeconomic backgrounds towing to the higher prevalence of type 2 diabetes and prediabetes in these populations [28,29].

The likelihood of limited financial resources or safe spaces to engage in physical activity shaped our physical activity suggestions, which were intentionally free or low-cost and included in-home options. In addition, our population also likely differs from otherwise healthy adolescents in terms of overall stress and depressive symptoms; youth with type 2 diabetes report high levels of life stressors, which correlate with poor psychosocial functioning and impaired treatment adherence [30]. Thus, for our ultimate goal of helping adolescents with prediabetes and type 2 diabetes to become more physically active, we worked to develop messages that were both encouraging and contained activity suggestions that were perceived as realistic and achievable.

Our finding that adolescents preferred messages that were brief, upbeat, and informative was similar to previous reports [18,31]. In their TXT Me! intervention, Thompson et al [18] used pedometers and stand-alone text messages grounded in concepts from the Self-Determination Theory, including autonomy, competence, and relatedness, to promote increased physical activity among adolescents [18]. They used web-based surveys and telephone interviews with 30 persons, aged 14 to 17 years, to assess the acceptability of pedometer use and daily texts to help achieve a step-count goal. Similar to our findings, the adolescents in the study by Thompson et al [32] favored short messages that were positive, used exclamation points, did not nag, and focused on facts. In a pilot study of their intervention [32], they demonstrated feasibility, with an enrollment of 160

adolescents and complete data available in 86% of cases. Notably, they found that participants who were excluded owing to insufficient pedometer use or missing data collection were more likely to be older and African American. Postintervention feedback included the suggestion that other types of physical activity should be promoted in addition to walking and that a step count goal should be set for participants rather than having the goal be self-selected. In total, 80% (16/20) of the adolescents enjoyed receiving daily texts for 12 weeks, and 75% (15/20) chose noon or afternoon as the best time to receive texts. Notably, participation was not based on body weight or health conditions, including obesity, type 2 diabetes, or prediabetes. In contrast, Woolford et al [31] explored attitudes and preferences regarding automated SMS text messages among adolescents with obesity as part of a multidisciplinary weight management program. The messages included an explicit focus on topics central to weight management. As demonstrated in our study and in TXT Me!, adolescents reported that an automated SMS text messaging strategy would be acceptable and preferred positive upbeat messages that included exclamation points [31]. Again, the study by Woolford et al [31] did not explicitly focus on adolescents with obesity-related complications such as prediabetes or type 2 diabetes.

To our knowledge, ours is the first study to evaluate the acceptability of a text message–based intervention to increase physical activity in adolescents with obesity and prediabetes or type 2 diabetes. Because of the critical importance of lifestyle changes in improving health outcomes, youth with prediabetes or type 2 diabetes are likely to have already been instructed by multiple health care providers and their caregivers to be more physically active. It is notable that despite this commonly heard advice, adolescents still reported that daily or twice-daily text messages encouraging and reminding them about physical activity would be acceptable and potentially motivating.

In addition to specific feedback about the reviewed text messages, participants shared valuable insights about experiences when encouraged to exercise by caregivers and health care providers. Their responses highlighted the fine line required when showing concern about an adolescent's health and health behaviors. Although expressing genuine concern may be encouraging for some, repeated reminders may be perceived negatively by others. There is a danger that repeated text message reminders to *exercise* may also be perceived in this light. Our revised text message bank now places greater emphasis on being more *physically active* in any activity of their choice, rather than structured and repetitive *exercise*. Indeed, distinguishing between *exercise* (a planned, structured, purposeful, and repetitive behavior) and more general *physical activity* may help clarify expectations for patients, as increased nonexercise physical activity may be an acceptable goal for both patients and providers [33]. As part of the planned intervention, we will counsel participants' caregivers about the benefit of showing support for the adolescent's physical activity in ways that can be more naturally incorporated throughout their days, rather than insisting that the adolescent engages in narrowly defined exercise at specific times. The specific linkage of the health benefits of physical activity to diabetes-related outcomes may also prove motivational to youth already

experiencing an obesity complication, driving intrinsic motivation rather than relying primarily on extrinsic motivation. As described by the health belief model, the perception of health vulnerability associated with prediabetes or type 2 diabetes may serve as an additional motivation to act [34] on healthy lifestyle changes. This concept was suggested by some youth who referred to their health as a primary motivator to increase physical activity, but again, health care providers should balance using health as a motivator while not inducing shame or stigma that is commonly associated with obesity and type 2 diabetes [35].

Because of the challenges of maintaining engagement in mHealth and physical activity interventions as well as motivating adolescents to be more physically active, we also tested the impact of different financial incentive strategies in our BEAM trials. Specifically, we evaluated loss- versus gain-framed financial incentives to achieve step-count goals. Although the comparative efficacy of these financial incentive approaches has been evaluated in physical activity interventions in adults, it has not been assessed in youth [36], who may differ in their responses to the negativity of a loss-framed incentive. Among adolescents with type 1 diabetes, financial incentives appear to be an acceptable approach for promoting self-monitoring behaviors [37]. However, the acceptability of loss-framed incentives has not been explored. When evaluated in a clinical trial, loss-framed financial incentives led to more frequent blood glucose monitoring among adolescents with sub optimally controlled type 1 diabetes [38]. Participants in that trial endorsed the feasibility of daily financial incentives to motivate behavior change, with some reporting feeling motivated by the loss of money they believed was already their own. Notably, however, the increase in self-monitoring behaviors was transient, and the effect was extinguished after financial incentives were stopped. The possibility of financial incentives to crowd out intrinsic motivation has led to the concern that financial incentives may do more harm than good [39]; fortunately or unfortunately, this is less of a concern for health behaviors, many of which are associated with low baseline intrinsic motivation [40]. Our exploration of attitudes toward gain- and loss-framed incentives suggested that the acceptability of loss-framed incentives is mixed but that some adolescents may find them highly motivating. This study was not designed to quantify the differences in the anticipated motivation or acceptability of different financial incentive approaches. However, in the BEAM trial, we explore the heterogeneity of the treatment effect of the incentives in an effort to identify characteristics that predicted objective responsiveness to different financial incentive approaches.

Although not initially planned, owing to the COVID-19 pandemic, we conducted group interviews using a virtual format using videoconferencing technology. Virtual interviews had several benefits: (1) ease of recruitment, particularly for adolescents with financial or transportation barriers; (2) efficient and high-quality audio recording via the platform; and (3) availability of the chat feature, which allowed participants who may not otherwise have interrupted someone speaking to share their thoughts and engage in the discussion. The virtual format allowed participants to mute video or audio, which was done

at times the strain discussion progressed. However, the ability to retain control of their privacy, which is not practical in most traditional focus groups [41], may have encouraged participants to share more freely than they would have in an in-person setting. Technical challenges occasionally arose, including poor audio quality related to internet connectivity. Overall, the virtual format appears to be a promising way to engage adolescents in qualitative research in a way that minimizes participant burden while facilitating recruitment. Our successful engagement of participants in a remote format also provides further evidence of the feasibility and acceptability of mHealth interventions targeting adolescents [42,43].

Limitations

Attitudes and perspectives about text message content and financial incentives may vary across populations; therefore, our findings may not be generalizable to other adolescent subgroups, such as those with obesity but without comorbidities, or to individuals of different age groups or at different neurodevelopmental stages [36]. However, our participants represent a diverse group whose perspectives are not often elicited or reflected in research settings and represent the epidemiology of youth with prediabetes and type 2 diabetes, who are disproportionately from minority backgrounds [29]. As with any group interview or focus group study, particularly those including adolescents, social desirability bias may have influenced the responses [44]. We did not use single-sex groups, as has been recommended when conducting qualitative research with groups of unfamiliar adolescents [44]. However, our small group sizes may have limited the potential discomfort or embarrassment of offering differing opinions. Because the BEAM trial uses text messages in English, we did not include participants with limited English proficiency. We acknowledge that this has the potential to limit the intervention's reach among Hispanic youth, who have a higher prevalence of type 2 diabetes than non-Hispanic White youth [29]. Importantly, to adapt text message interventions for individuals with limited English proficiency, it is critical to embark on a *transcreation* process, in which the text messages are not simply translated but adapted in a way that is linguistically and culturally appropriate [45]. Thus, additional qualitative research is required to evaluate the acceptability and appropriateness of the adapted intervention.

The focus of this study was on the perspectives and preferences regarding text messages and financial incentives to motivate behavior change, which may not perfectly correlate with objectively measured behavior change; objective measurement will occur as part of the BEAM trial. Because of our study's sample size, we were unable to reliably characterize differences in attitudes and perceptions across patient characteristics, such as age, gender, or prediabetes versus diabetes; however, we will do so when evaluating the acceptability of the intervention in the BEAM trial. The use of virtual interviews made engaging participants challenging at times; this limited engagement often contributed to more limited discussion than may have occurred in face-to-face interviews and thus to the shorter actual duration of interviews than originally planned (30-45 vs 60 minutes). Finally, although participants reported that they found even frequent text messaging acceptable, their actual behavior may differ, as additional interruptions from push notifications and text messages from friends also occur. The BEAM trial will also evaluate the impact of message frequency.

Conclusions

In summary, among the participants in our study, all adolescents with obesity and prediabetes or type 2 diabetes preferred text messages that were short, upbeat, informative, and relatable. Through virtual group interviews, participants' feedback allowed for the creation of an end-user–refined bank of text messages that will be used in an mHealth physical activity intervention targeting the same population (BEAM trial). The perceived acceptability of loss-framed incentives was mixed, but the effect of incentive framing will be objectively measured in the BEAM trial. Overall, the ability to elicit end-user feedback increased the likelihood of acceptability of our intervention among the target population, and we will continue to engage participants throughout the trial to further refine our approach to intervention development.

Authors' Contributions

MEV was responsible for the conception and design of the study, interviews with participants, analysis and interpretation of data, and drafting and critical revision of the article. TAH assisted in interviewing participants, analysis and interpretation of data, and critical revision of the article. NM and AE assisted with the interviews and data collection. JM, LS, AK, and SA assisted with the study conception and design, analysis and interpretation, and critical revision of the article for important intellectual content. All the authors have read and approved the final manuscript. MEV is the guarantor of this work, has full access to all the data in the study, and takes responsibility for the integrity of the data and accuracy of the data analysis.

Conflicts of Interest

None declared.

References

1. Mayer-Davis EJ, Lawrence JM, Dabelea D, Divers J, Isom S, Dolan L, SEARCH for Diabetes in Youth Study. Incidence trends of type 1 and type 2 diabetes among youths, 2002-2012. N Engl J Med 2017;376(15):1419-1429 [FREE Full text] [doi: 10.1056/NEJMoa1610187] [Medline: 28402773]

2. Dart AB, Martens PJ, Rigatto C, Brownell MD, Dean HJ, Sellers EA. Earlier onset of complications in youth with type 2 diabetes. Diabetes Care 2014;37(2):436-443. [doi: 10.2337/dc13-0954] [Medline: 24130346]

3. Rhodes ET, Prosser LA, Hoerger TJ, Lieu T, Ludwig DS, Laffel LM. Estimated morbidity and mortality in adolescents and young adults diagnosed with type 2 diabetes mellitus. Diabet Med 2012;29(4):453-463. [doi: 10.1111/j.1464-5491.2011.03542.x] [Medline: 22150528]

4. Ogden CL, Fryar CD, Martin CB, Freedman DS, Carroll MD, Gu Q, et al. Trends in obesity prevalence by race and Hispanic origin-1999-2000 to 2017-2018. JAMA 2020;324(12):1208-1210 [FREE Full text] [doi: 10.1001/jama.2020.14590] [Medline: 32857101]

5. Abbasi A, Juszczyk D, van Jaarsveld CH, Gulliford MC. Body mass index and incident type 1 and type 2 diabetes in children and young adults: a retrospective cohort study. J Endocr Soc 2017;1(5):524-537 [FREE Full text] [doi: 10.1210/js.2017-00044] [Medline: 29264507]

6. Obesity and overweight. World Health Organization. 2021. URL: https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight [accessed 2021-10-19]

7. Vijayakumar P, Nelson RG, Hanson RL, Knowler WC, Sinha M. HbA1c and the prediction of type 2 diabetes in children and adults. Diabetes Care 2017;40(1):16-21 [FREE Full text] [doi: 10.2337/dc16-1358] [Medline: 27810987]

8. Love-Osborne KA, Sheeder JL, Nadeau KJ, Zeitler P. Longitudinal follow up of dysglycemia in overweight and obese pediatric patients. Pediatr Diabetes 2018;19(2):199-204. [doi: 10.1111/pedi.12570] [Medline: 28856775]

9. Andes LJ, Cheng YJ, Rolka DB, Gregg EW, Imperatore G. Prevalence of prediabetes among adolescents and young adults in the United States, 2005-2016. JAMA Pediatr 2020;174(2):e194498 [FREE Full text] [doi: 10.1001/jamapediatrics.2019.4498] [Medline: 31790544]

10. Weiss R, Taksali SE, Tamborlane WV, Burgert TS, Savoye M, Caprio S. Predictors of changes in glucose tolerance status in obese youth. Diabetes Care 2005;28(4):902-909. [doi: 10.2337/diacare.28.4.902] [Medline: 15793193]

11. Physical activity guidelines for Americans. 2nd edition. U.S. Department of Health and Human Services. 2018. URL: https://health.gov/sites/default/files/2019-09/Physical_Activity_Guidelines_2nd_edition.pdf [accessed 2022-03-23]

12. Kriska A, Delahanty L, Edelstein S, Amodei N, Chadwick J, Copeland K, et al. Sedentary behavior and physical activity in youth with recent onset of type 2 diabetes. Pediatrics 2013;131(3):e850-e856 [FREE Full text] [doi: 10.1542/peds.2012-0620] [Medline: 23400602]

13. Anderson M, Jiang J. Teens, social media and technology 2018. Pew Research Center. 2018. URL: https://www.pewresearch.org/internet/2018/05/31/teens-social-media-technology-2018/ [accessed 2022-03-23]

14. Silver L. Smartphone ownership is growing rapidly around the world, but not always equally. Pew Research Center. 2021. URL: https://www.pewresearch.org/global/2019/02/05/smartphone-ownership-is-growing-rapidly-around-the-world-but-not-always-equally/ [accessed 2021-10-19]

15. Partridge SR, Raeside R, Singleton A, Hyun K, Redfern J. Effectiveness of text message interventions for weight management in adolescents: systematic review. JMIR Mhealth Uhealth 2020;8(5):e15849 [FREE Full text] [doi: 10.2196/15849] [Medline: 32348264]

16. Patrick K, Norman GJ, Davila EP, Calfas KJ, Raab F, Gottschalk M, et al. Outcomes of a 12-month technology-based intervention to promote weight loss in adolescents at risk for type 2 diabetes. J Diabetes Sci Technol 2013;7(3):759-770 [FREE Full text] [doi: 10.1177/193229681300700322] [Medline: 23759410]

17. Jones HM, Al-Khudairy L, Melendez-Torres GJ, Oyebode O. Viewpoints of adolescents with overweight and obesity attending lifestyle obesity treatment interventions: a qualitative systematic review. Obes Rev 2019;20(1):156-169. [doi: 10.1111/obr.12771] [Medline: 30375160]

18. Thompson D, Cantu D, Bhatt R, Baranowski T, Rodgers W, Jago R, et al. Texting to increase physical activity among teenagers (TXT Me!): rationale, design, and methods proposal. JMIR Res Protoc 2014;3(1):e14 [FREE Full text] [doi: 10.2196/resprot.3074] [Medline: 24622344]

19. Patel MS, Asch DA, Rosin R, Small DS, Bellamy SL, Heuer J, et al. Framing financial incentives to increase physical activity among overweight and obese adults: a randomized, controlled trial. Ann Intern Med 2016;164(6):385-394 [FREE Full text] [doi: 10.7326/M15-1635] [Medline: 26881417]

20. Psihogios AM, Li Y, Butler E, Hamilton J, Daniel LC, Barakat LP, et al. Text message responsivity in a 2-way short message service pilot intervention with adolescent and young adult survivors of cancer. JMIR Mhealth Uhealth 2019;7(4):e12547 [FREE Full text] [doi: 10.2196/12547] [Medline: 30998225]

21. Pate RR, Saunders RP, O'Neill JR, Dowda M. Overcoming barriers to physical activity: helping youth be more active. ACSM Health Fit J 2011;15(1):7-12. [doi: 10.1249/fit.0b013e318201c8ee]

22. Smith TA, Perez JK, Friesen MA. Virtual focus groups as an answer to research during a pandemic: implications for nursing professional development. J Nurses Prof Dev. Preprint posted on April 28, 2021. [doi: 10.1097/NND.0000000000000750] [Medline: 33935191]

23. Brown G, Edmunds S. Doing pedagogical research in engineering. Loughborough, UK: Engineering Centre for Excellence in Teaching and Learning: Loughborough University; 2011:31-49.

24. Pollard CM, Howat PA, Pratt IS, Boushey CJ, Delp EJ, Kerr DA. Preferred tone of nutrition text messages for young adults: focus group testing. JMIR Mhealth Uhealth 2016;4(1):e1 [FREE Full text] [doi: 10.2196/mhealth.4764] [Medline: 26787115]

25. Yardley L, Morrison L, Bradbury K, Muller I. The person-based approach to intervention development: application to digital health-related behavior change interventions. J Med Internet Res 2015;17(1):e30 [FREE Full text] [doi: 10.2196/jmir.4055] [Medline: 25639757]

26. van Gemert-Pijnen JE, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A holistic framework to improve the uptake and impact of eHealth technologies. J Med Internet Res 2011;13(4):e111 [FREE Full text] [doi: 10.2196/jmir.1672] [Medline: 22155738]

27. Partridge SR, Raeside R, Latham Z, Singleton AC, Hyun K, Grunseit A, et al. 'Not to be harsh but try less to relate to 'the teens' and you'll relate to them more': co-designing obesity prevention text messages with adolescents. Int J Environ Res Public Health 2019;16(24):4887 [FREE Full text] [doi: 10.3390/ijerph16244887] [Medline: 31817167]

28. McGavock J, Wicklow B, Dart AB. Type 2 diabetes in youth is a disease of poverty. Lancet 2017;390(10105):1829. [doi: 10.1016/S0140-6736(17)32461-3] [Medline: 29082873]

29. Lawrence JM, Divers J, Isom S, Saydah S, Imperatore G, Pihoker C, SEARCH for Diabetes in Youth Study Group. Trends in prevalence of type 1 and type 2 diabetes in children and adolescents in the US, 2001-2017. JAMA 2021;326(8):717-727 [FREE Full text] [doi: 10.1001/jama.2021.11165] [Medline: 34427600]

30. Walders-Abramson N, Venditti EM, Ievers-Landis CE, Anderson B, El Ghormli L, Geffner M, Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) Study Group. Relationships among stressful life events and physiological markers, treatment adherence, and psychosocial functioning among youth with type 2 diabetes. J Pediatr 2014;165(3):504-8.e1 [FREE Full text] [doi: 10.1016/j.jpeds.2014.05.020] [Medline: 24948348]

31. Woolford SJ, Barr KL, Derry HA, Jepson CM, Clark SJ, Strecher VJ, et al. OMG do not say LOL: obese adolescents' perspectives on the content of text messages to enhance weight loss efforts. Obesity (Silver Spring) 2011;19(12):2382-2387 [FREE Full text] [doi: 10.1038/oby.2011.266] [Medline: 21869762]

32. Thompson D, Cantu D, Ramirez B, Cullen KW, Baranowski T, Mendoza J, et al. Texting to increase adolescent physical activity: feasibility assessment. Am J Health Behav 2016;40(4):472-483 [FREE Full text] [doi: 10.5993/AJHB.40.4.9] [Medline: 27338994]

33. Dasso NA. How is exercise different from physical activity? A concept analysis. Nurs Forum 2019;54(1):45-52. [doi: 10.1111/nuf.12296] [Medline: 30332516]

34. Rosenstock IM, Strecher VJ, Becker MH. Social learning theory and the health belief model. Health Educ Q 1988;15(2):175-183. [doi: 10.1177/109019818801500203] [Medline: 3378902]

35. Valentine V. The most important thing we give to people is hope: overcoming stigma in diabetes and obesity. Diabetes Spectr 2020;33(1):89-94 [FREE Full text] [doi: 10.2337/ds19-0055] [Medline: 32116459]

36. Kenyon CC, Flaherty C, Floyd GC, Jenssen BP, Miller VA. Promoting healthy childhood behaviors with financial incentives: a narrative review of key considerations and design features for future research. Acad Pediatr 2022;22(2):203-209. [doi: 10.1016/j.acap.2021.08.010] [Medline: 34403802]

37. Malik FS, Senturia KD, Lind CD, Chalmers KD, Yi-Frazier JP, Shah SK, et al. Adolescent and parent perspectives on the acceptability of financial incentives to promote self-care in adolescents with type 1 diabetes. Pediatr Diabetes 2020;21(3):533-551 [FREE Full text] [doi: 10.1111/pedi.12970] [Medline: 31863541]

38. Wong CA, Miller VA, Murphy K, Small D, Ford CA, Willi SM, et al. Effect of financial incentives on glucose monitoring adherence and glycemic control among adolescents and young adults with type 1 diabetes: a randomized clinical trial. JAMA Pediatr 2017;171(12):1176-1183 [FREE Full text] [doi: 10.1001/jamapediatrics.2017.3233] [Medline: 29059263]

39. Deci EL, Koestner R, Ryan RM. A meta-analytic review of experiments examining the effects of extrinsic rewards on intrinsic motivation. Psychol Bull 1999;125(6):627-700. [doi: 10.1037/0033-2909.125.6.627] [Medline: 10589297]

40. Promberger M, Marteau TM. When do financial incentives reduce intrinsic motivation? Comparing behaviors studied in psychological and economic literatures. Health Psychol 2013;32(9):950-957 [FREE Full text] [doi: 10.1037/a0032727] [Medline: 24001245]

41. Sim J, Waterfield J. Focus group methodology: some ethical challenges. Qual Quant 2019;53(6):3003-3022. [doi: 10.1007/s11135-019-00914-5]

42. Radovic A, McCarty CA, Katzman K, Richardson LP. Adolescents' perspectives on using technology for health: qualitative study. JMIR Pediatr Parent 2018;1(1):e2 [FREE Full text] [doi: 10.2196/pediatrics.8677] [Medline: 30740590]

XSL•FO
RenderX

43.   Ranney ML, Choo EK, Spirito A, Mello MJ. Adolescents' preference for technology-based emergency department behavioral interventions: does it depend on risky behaviors? Pediatr Emerg Care 2013;29(4):475-481. [doi: 10.1097/PEC.0b013e31828a322f] [Medline: 23528509]

44.   Daley AM. Adolescent-friendly remedies for the challenges of focus group research. West J Nurs Res 2013;35(8):1043-1059. [doi: 10.1177/0193945913483881] [Medline: 23618823]

45.   Ruvalcaba D, Nagao Peck H, Lyles C, Uratsu CS, Escobar PR, Grant RW. Translating/creating a culturally responsive Spanish-language mobile app for visit preparation: case study of "trans-creation". JMIR Mhealth Uhealth 2019;7(4):e12457 [FREE Full text] [doi: 10.2196/12457] [Medline: 30950803]

Abbreviations

BEAM: Behavioral Economics for Activity Motivation
GIF: graphic interchange format
mHealth: mobile health
NIH: National Institutes of Health
REDCap: Research Electronic Data Capture

XSL•FO
RenderX

Original Paper

Effects of a Novel Blood Glucose Forecasting Feature on Glycemic Management and Logging in Adults With Type 2 Diabetes Using One Drop: Retrospective Cohort Study

Steven D Imrisek[1], MA; Matthew Lee[1], MS; Dan Goldner[1], PhD; Harpreet Nagra[1], PhD; Lindsey M Lavaysse[1], PhD; Jamillah Hoy-Rosas[1], MPH; Jeff Dachis[1], MA; Lindsay E Sears[1], PhD

One Drop, New York, NY, United States

Corresponding Author:
Steven D Imrisek, MA
One Drop
166 Mercer St FL2
New York, NY, 10012
United States
Phone: 1 443 880 8235
Email: steven.imrisek@onedrop.today

Abstract

Background: Personalized feedback is an effective behavior change technique frequently incorporated into mobile health (mHealth) apps. Innovations in data science create opportunities for leveraging the wealth of user data accumulated by mHealth apps to generate personalized health forecasts. One Drop's digital program is one of the first to implement blood glucose forecasts for people with type 2 diabetes. The impact of these forecasts on behavior and glycemic management has not been evaluated to date.

Objective: This study sought to evaluate the impact of exposure to blood glucose forecasts on blood glucose logging behavior, average blood glucose, and percentage of glucose points in range.

Methods: This retrospective cohort study examined people with type 2 diabetes who first began using One Drop to record their blood glucose between 2019 and 2021. Cohorts included those who received blood glucose forecasts and those who did not receive forecasts. The cohorts were compared to evaluate the effect of exposure to blood glucose forecasts on logging activity, average glucose, and percentage of glucose readings in range, after controlling for potential confounding factors. Data were analyzed using analysis of covariance (ANCOVA) and regression analyses.

Results: Data from a total of 1411 One Drop users with type 2 diabetes and elevated baseline glucose were analyzed. Participants (60.6% male, 795/1311; mean age 50.2 years, SD 11.8) had diabetes for 7.1 years on average (SD 7.9). After controlling for potential confounding factors, blood glucose forecasts were associated with more frequent blood glucose logging ($P=.004$), lower average blood glucose ($P<.001$), and a higher percentage of readings in range ($P=.03$) after 12 weeks. Blood glucose logging partially mediated the relationship between exposure to forecasts and average glucose.

Conclusions: Individuals who received blood glucose forecasts had significantly lower average glucose, with a greater amount of glucose measurements in a healthy range after 12 weeks compared to those who did not receive forecasts. Glucose logging was identified as a partial mediator of the relationship between forecast exposure and week-12 average glucose, highlighting a potential mechanism through which glucose forecasts exert their effect. When administered as a part of a comprehensive mHealth program, blood glucose forecasts may significantly improve glycemic management among people living with type 2 diabetes.

KEYWORDS

XSL•FO
RenderX

Introduction

Diabetes currently affects an estimated 10.5% of Americans, while recent projections indicate its prevalence is increasing worldwide [1,2]. While complications from diabetes range from microvascular-related organ and peripheral tissue damage to death [1], the majority of people with diabetes do not adequately manage their blood glucose [3]. In recent years, mHealth apps have attempted to promote self-care behaviors that are critical for the management of type 2 diabetes (T2D) with mixed success. Compared to non–app users, mHealth app users with diabetes report higher levels of self-care behaviors [4]. A meta-analysis pooling results from randomized controlled trials (RCTs) of 9 mHealth apps found all 9 apps effective in improving diabetes-related outcomes, reducing hemoglobin A_{1c} (HbA_{1c}) by a mean 0.49% [5]. Meanwhile, several other reviews note studies with weaker or no effects for diabetes-related outcomes [6-10]. The fact that mHealth apps have realized such varied success raises the question of which components or features are most effective in driving outcomes.

While mHealth apps for diabetes have a range of different features [11], modules for logging diabetes-related data such as blood glucose are among the most common, with many apps also enabling the logging of food, physical activity, and medications [12]. Logging as a form of self-monitoring, delivered along with feedback, constitutes a behavior change technique, which is a systematic procedure included as an active component of an intervention designed to change behavior. Among mHealth apps, it has been noted that self-regulation techniques, such as self-monitoring, goal setting, and performance feedback, are the most frequently utilized [13,14]. Given the theoretical impact of such behavior change techniques on health behavior and clinical outcomes, mHealth apps have the opportunity to incorporate this logged health information and deliver personalized feedback to their users [15,16]. In a previous study, incorporating live feedback from a diabetes coach in response to hypoglycemic or hyperglycemic events showed success [17]. Further, a meta-analysis comparing apps with a feedback component versus those without this feature found that only apps delivering feedback were effective in reducing HbA_{1c} [7]. To our knowledge, mHealth apps with self-monitoring and a feedback component have exclusively focused on past behavior and outcomes. As mHealth apps scale and accumulate a larger repository of data, methods of providing immediate, specific, and personalized feedback about the future are a worthwhile avenue to explore. Data science techniques, such as artificial intelligence, machine learning, and predictive analytics, have been simultaneously described as the next frontier in mHealth apps and also as one of the greatest challenges facing them; these innovations may be the drivers of a personalized and automated feedback mechanism [18].

There are few existing examples of machine learning used to forecast future events for persons with diabetes. In one example, the need for pharmacological therapy was forecast for patients with gestational diabetes [19]. In another study, infections and hypoglycemic events were accurately forecast for individuals with type 1 diabetes (T1D) [20,21]. Although they indicated

that diabetes outcomes could be effectively forecast, these studies focused solely on the development and validation of predictive models. The application of predictive models within a diabetes intervention has not previously been tested, to our knowledge. In 2018, One Drop (Informed Data Systems Inc) validated a machine learning model for blood glucose forecasts and subsequently provided the tool to users with T2D in the One Drop app. When forecasts are delivered, they may be paired with behavioral suggestions, such as going for a walk and retesting blood glucose. Multiple studies have established the effectiveness of One Drop for people with diabetes; program participation has been associated with reductions in self-reported, estimated, and lab-tested HbA_{1c}, average blood glucose, self-reported hyperglycemic symptoms, diabetes distress, and self-efficacy, [22-24] with preliminary RCT data showing effects on lab-tested HbA_{1c}, diet, activity, and depression among persons diagnosed with T2D and hypertension. One Drop's blood glucose forecasts have demonstrated high accuracy and acceptability, with approximately 92% of users finding them helpful [25,26]. Three years after its inception, One Drop remains the sole mHealth app delivering blood glucose forecasts to its users. The effectiveness of these forecasts has yet to be established.

The current retrospective cohort study evaluated the impact of One Drop's 1- to 8-hour blood glucose forecasts on logging behavior and clinical outcomes among individuals with T2D and elevated average blood glucose who used the One Drop app over a 12-week period. First, we evaluated the effects of exposure to glucose forecasts on average blood glucose and percentage points in range (%PIR) by comparing participants who did or did not receive the forecasts. Second, we tested a potential behavioral mechanism through which the blood glucose forecasts exert their effect by examining their impact on glucose logging behavior. Lastly, we investigated a potential mediated relationship in which forecasts were associated with glucose management through the mechanism of glucose logging.

Methods

One Drop Intervention

One Drop is a multi-condition mHealth solution that can be tailored to each user's unique needs and preferences. The One Drop digital platform targets people with prediabetes, T1D or T2D, high blood pressure, high cholesterol, or combinations of these conditions. The One Drop mobile app can be used standalone or in conjunction with a monthly or yearly blood glucose test strip subscription, Bluetooth-enabled One Drop blood glucose meter, or connected devices (eg, Wi-Fi–enabled weight scales or Wi-Fi–enabled smart blood pressure monitors).

The One Drop mobile app is available for devices running the iOS, Android, or WatchOS operating systems. Uses can opt to enroll in the free or premium versions of the app. The free version includes extensive logging functionality with the capacity to log health data (eg, blood glucose, blood pressure, HbA_{1c}, and weight), intensity and duration of exercise, food eaten, and medications prescribed and taken. When users begin logging data actively (ie, manually through the app or with a

synced One Drop meter) or passively (via integrations with Apple HealthKit or Google Fit), detailed reports and visualizations become available, displaying summaries of the entered data and blood glucose trends over time. Messages of support, health-related insights, and educational content are also delivered to users' in-app inboxes or newsfeeds. The premium One Drop app subscription additionally provides users with on-demand access to health coaching with certified health professionals specializing in their conditions, machine learning–powered trends and forecasts, adjustable goal setting, and a personalized content library with hundreds of lessons.

Blood Glucose Forecasts

Blood glucose forecasts were introduced to the One Drop app as a free feature for users with T2D in September 2018 and became a premium feature in August 2020. These forecasts project the direction (ie, up, steady, or down) that a user's blood glucose will trend in the following 1 to 8 hours. Users automatically begin receiving blood glucose forecasts upon recording their first blood glucose reading and continue to receive them after each subsequent recording. When a forecast is generated, users receive a pop-up notification indicating the direction (rising, steady, or falling blood glucose) and duration (1-8 hours) of the forecast. These notifications can be paired with an actionable suggestion to help maintain healthy blood glucose levels. Figure 1 shows an example of a blood glucose forecast in the One Drop app.

Users who joined One Drop prior to September 2018 or did not have a paid subscription after August 2020 did not have access to the blood glucose forecasts. After forecasts were implemented in the program, users could become ineligible to receive forecasts if they failed to meet any of the prediction algorithm's requirements. Users did not receive forecasts if (1) they had extremely high glucose (>600 mg/dL); (2) they had extremely high glucose variability (>80 mg/dL forecast standard error); (3) their logging frequency was consistent with continuous glucose monitor (CGM) use (>50 readings in a 24-hour period); (4) they had ever recorded bolus insulin use; (5) they recorded basal insulin use prior to March 2019 (ie, the time when the model began serving predictions to these users).

Figure 1. Sample blood glucose forecast in the One Drop app.

Forecast pop-up (Android)

Forecast pop-up (iOS)

Forecast graph (iOS)
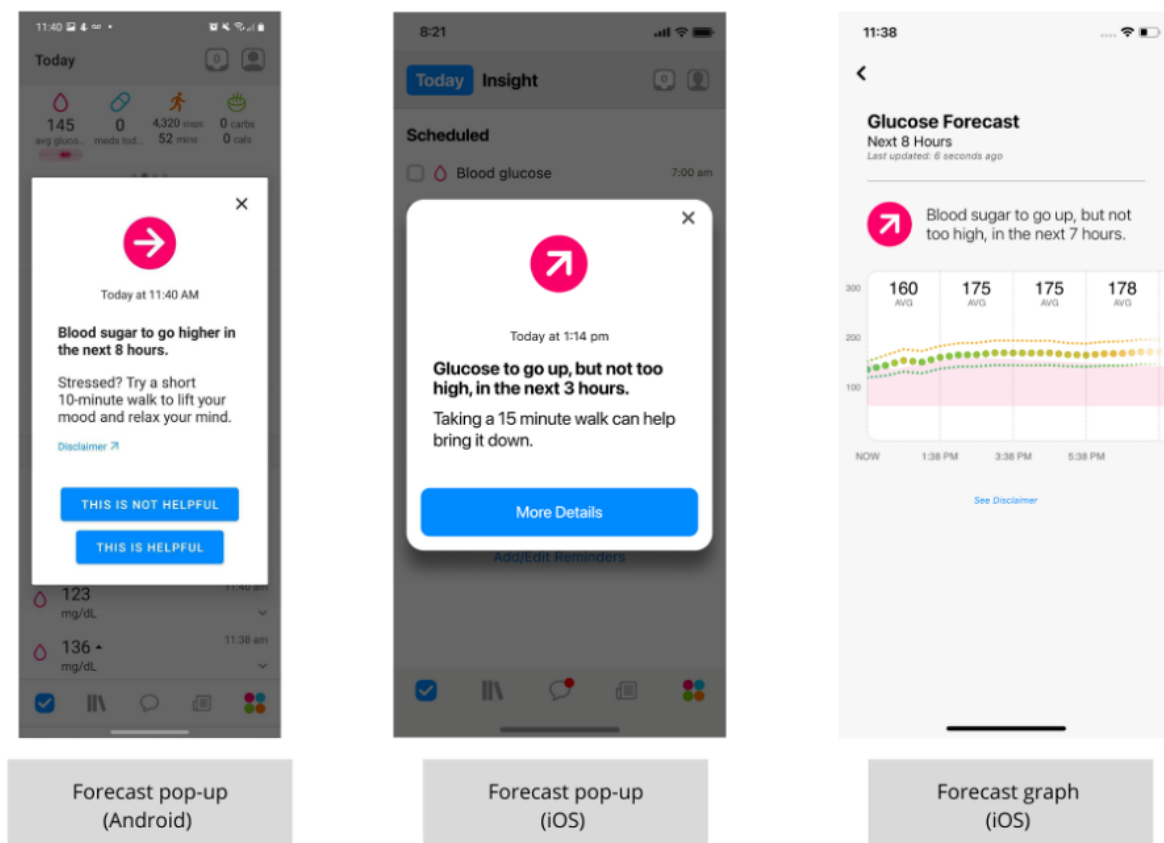
Study Design and Procedures

This study employed a retrospective cohort design, evaluating real-world outcomes over a 12-week period; participants were thus not recruited for study participation. There were 2 cohorts that were compared after statistically controlling for available potential confounders. The first cohort received at least one blood glucose forecast in weeks 1 through 11 and the second received no forecasts. Those included in the group who received no forecasts did not have a paid subscription after August 2020 or were ineligible to receive blood glucose forecasts based on the exclusion criteria.

On August 10, 2021, One Drop users with T2D who had one or more blood glucose measurements recorded 12 weeks following their first recorded reading were identified. Blood glucose readings were entered either manually through the app or passively through the One Drop blood glucose meter, another synced device, or integration with Apple Health Kit or Google Fit. The query for eligible users was limited to those who had started using One Drop and recorded their blood glucose for the first time in 2019 or later to minimize the possibility of comparing groups that participated in different iterations of One Drop. Additionally, only users with at-risk baseline blood glucose (estimated $HbA_{1c} \geq 7\%$) were queried. Users with a glucose logging frequency consistent with CGM use were excluded. The baseline measurement time point was defined by averaging the first 7 days of blood glucose readings, beginning with the first recorded blood glucose reading for that individual. Follow up (in week 12) consisted of measurements recorded from days 77 to 83.

Study Oversight

One Drop received an exemption for institutional review board approval and a waiver of informed consent from Solutions IRB, an independent ethics review company (Little Rock, AR and Yarnell, AZ) to study all deidentified data owned by One Drop. User data are stored in a secure cloud-based server. All One Drop users must actively agree to an end user license agreement upon creation of their accounts, granting One Drop permission to use data entered in the app for analysis, reporting, and research purposes.

Measurements

Group

The total number of forecasts received between weeks 1 and 11 was summed in order to group users according to whether they had received any blood glucose forecasts during the study period. Those with zero forecasts in that time period were placed in the "did not receive forecasts" group (n=177). Those with ≥1 forecast were placed in the "received forecasts" group (n=1234).

User Characteristics

Date of birth, gender, diabetes type, insulin use, and year of diagnosis are self-reported in the One Drop app, though not all users provide these data. Age was calculated as the number of months between a user's date of birth and the date of their first recorded blood glucose measurement divided by 12. Users taking insulin were identified based on whether they had recorded taking a dose of basal or bolus insulin on or before the date of their first blood glucose log. The number of years diagnosed with diabetes was calculated as the difference between the user-reported year of diagnosis and the year of a user's first recorded blood glucose measurement.

Logging Activity

Logging activity was measured as the number of blood glucose entries recorded in each user's first week, as well as the number of entries in the 11-week period prior to the follow-up week.

Blood Glucose Variability Measurement

Glycemic variability is commonly calculated as the standard deviation of an individual's glucose values over time [26,27]. The standard deviation of a user's blood glucose recordings during the first week was calculated to express individual baseline blood glucose variability. Users were required to have at least 3 readings recorded in week 1 to have a blood glucose variability metric computed.

Average Glucose Measurement

One Drop's database consists of real-world data; both biologically impossible (eg, 0 mg/dL) and implausible (eg, above 600 mg/dL, which is beyond the measuring capacity of a glucometer) readings can be entered. The range of plausible measurements was defined as 30 mg/dL to 600 mg/dL. Readings outside of this range were not included in average glucose calculations. For baseline average glucose, an average of all plausible blood glucose measurements in week 1 was calculated. Similarly, for follow-up average glucose, all plausible blood glucose recordings in a user's week 12 were averaged. In order to identify the at-risk population in terms of A_{1c}, average glucose values were translated to an estimated percentage of glycated hemoglobin ($eHbA_{1c}$) using the following formula: $eHbA_{1c}$ = (average glucose + 46.7) / 28.7 [28]. The American Diabetes Association recommends a goal of <7% HbA_{1c} for most people with diabetes; achieving this level is associated with a reduced risk for diabetes-related complications [29]. Users with an $eHbA_{1c}$ of ≥7%, corresponding to ≥154.2 mg/dL average glucose, were classified as at risk.

To visualize potential interactions, a multi-categorical variable was created to further classify those with $eHbA_{1c} \geq 7\%$ into four categories, indicating an increasing risk of complications from elevated blood glucose concentration: (1) $8\% > eHbA_{1c} \geq 7\%$; (2) $9\% > eHbA_{1c} \geq 8\%$; (3) $10\% > eHbA_{1c} \geq 9\%$; and (4) $eHbA_{1c} \geq 10\%$.

%PIR Measurement

Research has demonstrated that blood glucose levels falling below 70 mg/dL or rising above 180 mg/dL are associated with increased risk for diabetes-related complications [30]. Percentage of blood glucose points in range (%PIR) is a metric adapted from the CGM-specific metric time in range, applied to measurements obtained from manual blood glucose meters. A 10% change in %PIR has been associated with a change in HbA_{1c} of 0.4% [31].

Blood glucose values were considered in range if they fell between 70-180 mg/DL. Each user's %PIR was calculated by dividing the number of blood glucose measurements in range by the total number of recorded blood glucose measurements, for both week 1 and week 12.

Cohort Selection

There were 1411 users included in the analysis. Users were deemed eligible for analysis if (1) they reported a diagnosis of T2D; (2) their first week of One Drop participation was between the years 2019 to 2021; (3) they recorded ≥3 blood glucose measurements in their first week; (4) they recorded ≥1 blood

glucose measurement in week 12; (5) they had a self-reported year of diagnosis; and (6) their calculated week-1 HbA$_{1c}$ was 7.0%.

Users averaging more than 7 blood glucose measurements per day for the first 11 weeks of the study period were assumed to be using a CGM (>539 measurements; 7 measurements times 7 days times 11 weeks) and were excluded.

Analyses

All analyses were performed using SPSS Version 28 (IBM Corp). Our predetermined α level was .05 for all statistical tests. Between-group differences in the year users started One Drop, age, gender, years diagnosed with T2D, insulin use, number of week-1 blood glucose recordings, sum of week-1 to week-11 blood glucose recordings, baseline average glucose, and baseline individual blood glucose variability were assessed. Differences were tested with 2-tailed independent-samples t tests for continuous variables and chi-square tests for categorical variables. Descriptive statistics were also computed for these variables. A gender of "other" was reported by 4 users in the group who did not receive forecasts and zero users in the group who received forecasts; this value was treated as missing and excluded from the chi-square analysis assessing between-group differences in gender.

Variables were omitted from models if high missingness was observed (greater than 50%), but descriptive statistics for the variable are still reported. Age was the only variable meeting this threshold (1143/1411, 81% missing).

We specified 2 analysis of covariance (ANCOVA) models to determine the forecast group effect on blood glucose outcomes. Covariates were selected for ANCOVAs if their baseline values were significantly different in the groups who received and did not receive forecasts. The first ANCOVA tested the group effect on week-12 average glucose, controlling for years diagnosed, insulin use, baseline blood glucose variability, and baseline average glucose. The second ANCOVA tested the group effect on week-12 %PIR, controlling for years diagnosed, insulin use, baseline blood glucose variability, and baseline %PIR. Interactions between the group variable and covariates were tested; significant interactions were held and interpreted, while nonsignificant interactions were dropped from the final reported models.

The secondary analysis sought to find mechanisms through which exposure to blood glucose forecasts resulted in greater reductions in average glucose concentration in week 12; it was hypothesized that blood glucose logging could be one such mechanism. This hypothesized model is illustrated in Figure 2. To test this hypothesis, 3 separate linear regression models were specified to establish that the direct effect of group on blood glucose logging behavior and the direct effect of group and logging behavior on week-12 average glucose were all significant.

PROCESS is a free software add-on for SPSS that includes over 70 predefined models [32]. Mediation models in PROCESS incorporate ordinary least squares regression and estimate indirect effects and their confidence intervals through a bootstrapping procedure that is robust against nonnormal sample distributions [33]. Model 4 was specified to estimate the indirect effect of group on week-12 average glucose via blood glucose logging with 5000 bootstrap samples. All models included years diagnosed, insulin use, baseline blood glucose variability, and baseline average glucose as covariates.

Figure 2. Hypothesized model of how blood glucose logging mediates the effect of group on week-12 average glucose.
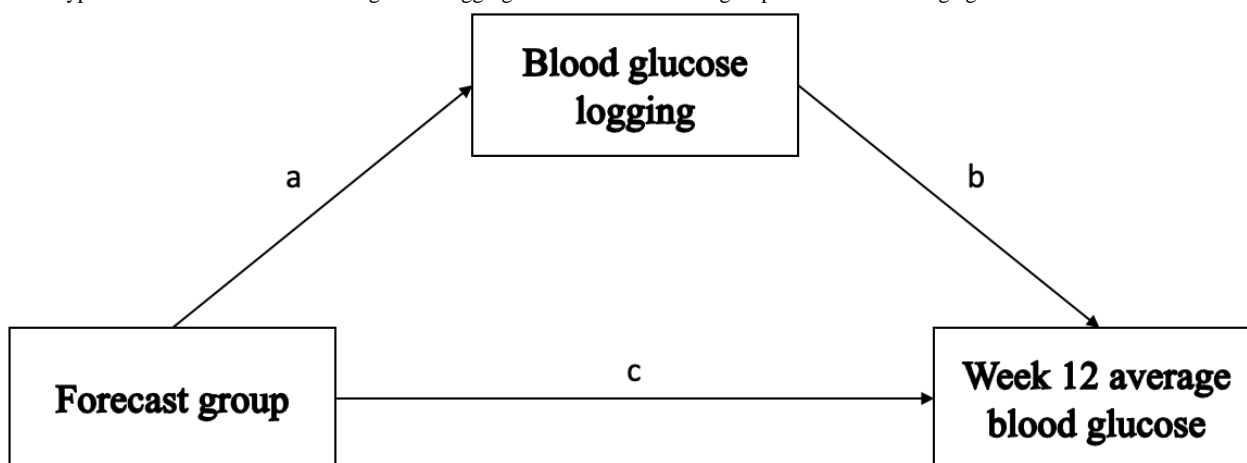
Results

A total of 1411 users were included in the analyses. The users were 60.6% male (795/1311), aged 12 to 84 years old (mean age 50.2 years, SD 11.8), diagnosed with T2D for <1 to 46 years (mean 7.1 years, SD 7.9), and recorded between 3 and 78 blood glucose logs (mean 14.5, SD 9.2) in their first week and between 3 and 532 (mean 122.0, SD 86.1) logs in the 11 weeks before follow up.

The groups were significantly different in several baseline variables. Compared to users who received forecasts, those who did not receive forecasts had a higher average likelihood of reporting insulin use (14.1% versus 6.2%; χ^2_1=14.8; P<.001), more years diagnosed with T2D (10.4 years, SD 9.1 versus 6.6 years, SD 7.6; t_{1409}=6.00; P<.001), higher baseline average glucose (256.16 mg/dL, SD 82.36 versus 206.23 mg/dL, SD 48.37; t_{1409}=11.55; P<.001), higher baseline blood glucose variability (58.64 mg/dL, SD 29.63 versus 43.91 mg/dL, SD

23.42, t_{1409}=7.55; P<.001) and a lower baseline percentage of blood glucose logs in range (26.96%, SD 28.91% versus 41.98%, SD 29.9%; t_{1409}=–6.27; P<.001). The groups did not

differ in the year they began using One Drop (P=.21), age (P=.07), gender (P=.24), or number of week-1 blood glucose logs (P=.08). Descriptive statistics and P values from tests of baseline differences are presented in Table 1.

Table 1. Sample characteristics with tests of difference by group.

Characteristics	Total (N=1411)	Received forecasts (n=1234)	Did not receive forecasts (n=177)	P value[a]
Year started One Drop, n (%)				.21
2019	681 (48.3)	597 (48.4)	84 (47.5)	
2020	614 (43.5)	530 (42.9)	84 (47.5)	
2021	116 (8.2)	107 (8.7)	9 (5.1)	
Gender, n (%)[b]				.24
Male	795 (60.6)	701 (61.2)	94 (56.6)	
Female	512 (39.1)	440 (38.4)	72 (43.4)	
Other	4 (0.3)	4 (0.3)	0 (0)	
Insulin use, n (%)	101 (7.2)	76 (6.2)	25 (14.1)	<.001
Age (years), mean (SD)	50.2 (11.8)	49.8 (11.4)	54.5 (14.7)	.07
Years diagnosed with T2D[c], mean (SD)	7.1 (7.9)	6.6 (7.6)	10.4 (9.1)	<.001
Blood glucose logs, mean (SD)				
Week-1 blood glucose logs	14.5 (9.2)	14.7 (9.4)	13.4 (7.9)	.08
Week-1 to week-11 blood glucose logs	122.0 (86.1)	124.1 (87.0)	107.2 (79.0)	.01
Glycemic management, mean (SD)				
Week-1 average blood glucose (mg/dL)	212.50 (56.27)	206.23 (48.37)	256.16 (82.36)	<.001
Week-1 blood glucose variability (mg/dL)	45.76 (24.76)	43.91 (23.42)	58.64 (29.63)	<.001
Week-1 points in range (%)	40.10 (30.18)	41.98 (29.90)	26.96 (28.91)	<.001

[a]From chi-square test or 2-tailed independent-samples t test.

[b]"Other" was treated as a missing value and excluded from the chi-square analysis.

[c]T2D: type 2 diabetes

Primary Outcome 1a: Average Glucose

The ANCOVA revealed significant mean differences between the groups in week-12 average glucose when controlling for baseline average glucose and covariates (F_7=40.75, P<.001). All model covariates except insulin use (P=.16) were significant (years diagnosed, baseline average glucose, and baseline blood glucose variability; all P<.001). Additionally, significant interaction effects for group × baseline average glucose (F_1=5.28, P=.02) and group × baseline blood glucose variability (F_1=15.12, P<.001) were observed.

To explore the group × baseline average glucose interaction, ANCOVA models were specified to evaluate the group effect at different levels of baseline eHbA$_{1c}$. Baseline average glucose was split into eHbA$_{1c}$ risk levels for interpretability. This interaction is visualized in Figure 3. Users receiving forecasts ended week 12 with significantly lower average glucose than those not receiving forecasts when baseline eHbA$_{1c}$ was ≥10%

(mean difference –54.52mg/dL; –1.9% eHbA$_{1c}$, P=.002). Nonsignificant results within the other three categories may be attributed to low power (1-β<.4). Among those with ≥8% eHbA$_{1c}$, reductions in week-12 eHbA$_{1c}$ ranged from –0.86% to –1.9%.

The second interaction, group × baseline glucose variability, was evaluated by performing a median split on baseline blood glucose variability and specifying ANCOVA models for each level. Values below the median were categorized as "low variability" and values above the median were categorized as "high variability." Values at the median were pruned. Among users with high baseline blood glucose variability, those receiving forecasts experienced significant reductions in week-12 average glucose (mean difference –53.22mg/dL; –1.85% eHbA$_{1c}$, P<.001) relative to those not receiving forecasts. Figure 4 visualizes the group × baseline glucose variability interaction.

Figure 3. Interaction diagram of the effects of group and baseline average glucose on week-12 average glucose.
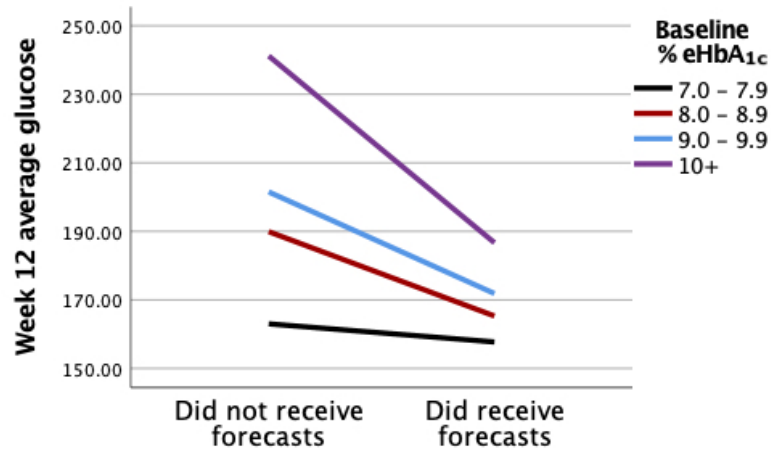
Figure 4. Interaction diagram of the effects of group and baseline glucose variability on week-12 average glucose.
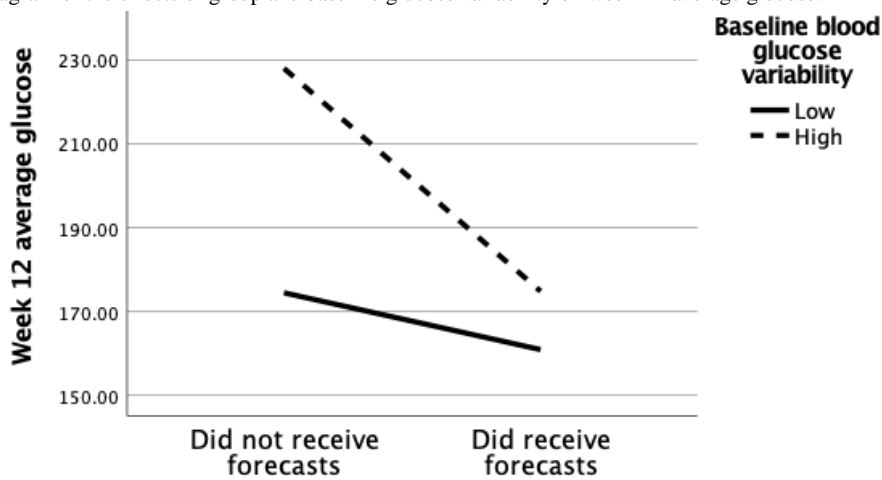
Primary Outcome 1b: %PIR

The ANCOVA revealed a significant mean difference between groups in week-12 %PIR when controlling for covariates (F_6=40.27, P<.001). All model covariates except insulin use (P=.3) were significant (years diagnosed, baseline %PIR, and baseline blood glucose variability; all P<.001). Additionally, a significant interaction effect between group × baseline %PIR (F_1=4.84, P=.03) was observed.

The group × baseline %PIR interaction was evaluated by performing a median split on baseline %PIR and specifying ANCOVA models for each level. Values below the median were categorized as "low %PIR" and values above the median were categorized as "high %PIR." Values at the median were pruned. Among users with low baseline %PIR, those receiving forecasts experienced a significant increase in %PIR (mean difference .45%, P<.001) compared to those not receiving forecasts. A visualization of the group × baseline %PIR interaction is presented in Figure 5.

Figure 5. Interaction diagram of the effects of group and baseline average percentage points in range on week-12 average glucose.
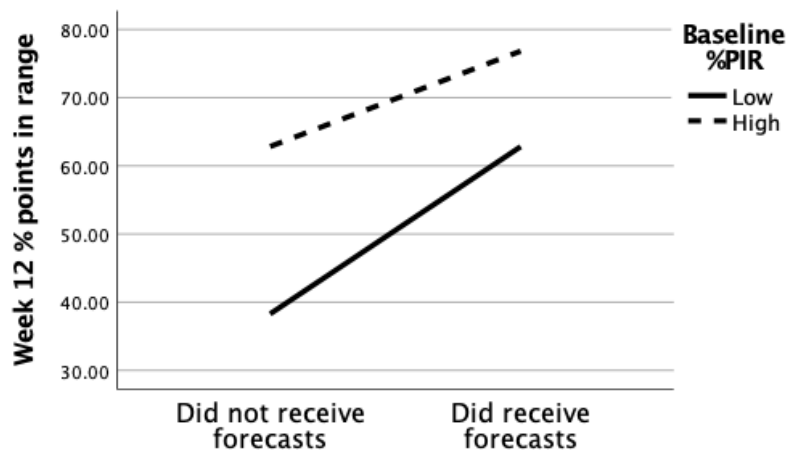
Secondary Analysis: Mediation of Group Effect on Average Glucose by Blood Glucose Logging Behavior

As reported above, the results suggest that users receiving blood glucose forecasts experienced greater reductions in week-12 average glucose than those not receiving forecasts. We thus proceeded with our secondary analysis.

The forecast group was significantly and positively associated with total blood glucose logs (path a; b=20.72, t_{1405}=2.86, P=.004). Total blood glucose logs were significantly associated with week-12 average glucose (path b; b=–0.13, t_{1405}=–6.86, P<.001). The total effect of group on week-12 average glucose was also significant (path c; b=–21.74, t_{1405}=–4.27, P<.001).

As all 3 paths were significant, we proceeded by regressing week-12 average glucose on group, controlling for total blood glucose logs. The direct effect was reduced, but remained significant (b=–19.22, t_{1404}=–3.82, P<.001).

Results from the bootstrapping procedure produced an estimated indirect effect (path c') of group on week 12 average glucose through total blood glucose logs with a 99% CI that did not include 0, indicating a significant mediation effect. While the indirect effect was significant, the direct effect also remained significant, indicating that blood glucose logging is a partial mediator of the relationship. Mediation results are summarized in Table 2. The conceptual model is presented in Figure 6, along with unstandardized path coefficients.

Table 2. Results of mediation analysis.

Mediation analysis[a]	b (SE)	P value
Model		
Path from group to blood glucose logging	20.72 (7.24)	.004
Path from group to week-12 average glucose	–21.74 (5.09)	<.001
Path from blood glucose logging to week-12 average glucose	–0.13 (0.02)	<.001
Effect		
Direct effect of group on week-12 average glucose	–19.22 (5.03)	<.001
Indirect effect of group on week-12 average glucose	–2.52 (0.91; 99% CI –5.30 to –0.48)	

[a]Model summary: R^2=0.18; P<.001.

Figure 6. Mediation analysis. Path values are unstandardized regression coefficients. The indirect effect was calculated using 5000 bootstrap samples with a 99% CI.
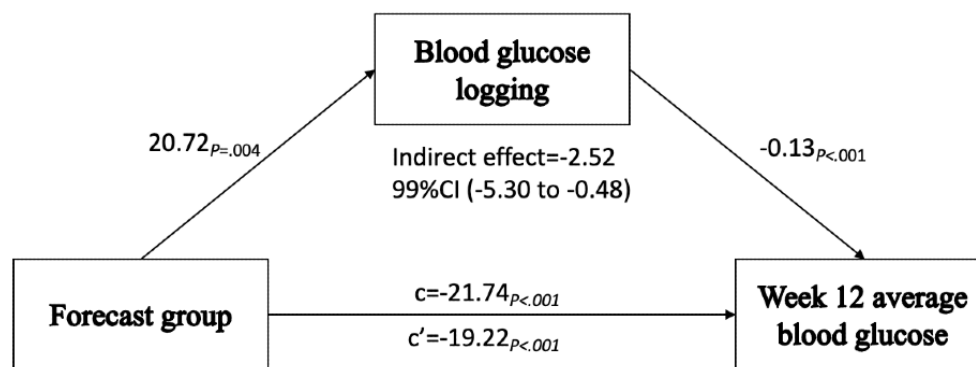
Discussion

In this retrospective cohort study, One Drop users with T2D who received blood glucose forecasts had significantly lower average glucose after 12 weeks than those who did not receive the forecasts, after accounting for group differences at baseline. This effect was most pronounced for users with high baseline blood glucose or high baseline blood glucose variability. Additionally, among users who had low baseline %PIR, those who received blood glucose forecasts had significantly higher %PIR after 12 weeks than those who did not receive blood glucose forecasts. Over the course of the study period, participants who received forecasts logged their glucose significantly more frequently than those who did not receive forecasts. Our secondary analysis suggests that the forecasts

encouraged users to log their blood glucose more often, which in turn was associated with lower blood glucose at week 12.

These results have potential implications for the health care costs of individuals with diabetes. The average yearly cost of medical care for persons with diabetes is US $9600 [34]. A systematic review found that mHealth interventions for T2D were cost-effective [35]. When adjusted for inflation, a one-point reduction in HbA_{1c} is associated with a US $1376.51 reduction in patient costs [36]. In this study, among users with ≥8% $eHbA_{1c}$, the reduction in week-12 average glucose would translate to an estimated patient cost savings of US $1183.80 to $2615.37 per year. Among those with high baseline blood glucose variability, glucose reductions would translate to an estimated patient cost savings of US $2546.54 per year. Among those with low baseline %PIR, exposure to forecasts was

associated with a 45% increase in %PIR. This increase in %PIR is associated with an eHbA$_{1c}$ reduction of 1.8%, representing a potential US $2477.72 cost savings [31,36]. These cost savings are incremental increases for those receiving forecasts compared to those not receiving forecasts. Previous research highlighting One Drop's association with reductions in lab-tested HbA$_{1c}$ was conducted prior to the advent of blood glucose forecasts; therefore, actual cost savings for those participating in this study's iteration of One Drop may be even higher.

Strengths and Limitations

The data generated for this study were collected from users of an mHealth app, and thus have real-world generalizability; however, the rapid evolution of the product, the available data, and a lack of experimental controls are limitations. First, there may have been covariates to consider that were not available for analysis, such as age, race, ethnicity, socioeconomic status, health motivation, CGM use, and other factors that may have differed across the groups and impacted outcomes. The impact of these variables on the relationship between blood glucose forecasts and diabetes outcomes is a potential avenue for future research.

Additionally, the groups systematically differed at baseline due to prespecified criteria that excluded some users from receiving forecasts. Those who received forecasts had fewer years diagnosed with T2D, lower glucose, higher %PIR, lower glucose variability, and were less likely to be taking insulin than those who did not receive forecasts. While we controlled for these variables, the bias inherent to this study design may still have been present. The results should be interpreted with this potential for selection bias in mind.

Finally, because the One Drop users included in this study participated at different times over a three-year period, it is possible that they participated in different iterations of the One Drop app that differentially impacted their app experiences, creating potential confounders. The One Drop app is continually updated and improved based on clinical science, behavior science, and research performed internally and externally. Further, participation in this study was limited to 12 weeks. While other studies of mHealth interventions have evaluated glucose outcomes at 3 months [37,38], insight into the sustained impact of forecasts on glucose beyond a 12-week period is limited. To address these limitations, which are characteristic of real-world evidence, future long-term, prospective randomized studies are needed to confirm the causal impact of forecasts on self-monitoring behavior and glucose management.

While the study design and the nature of real-world data likely introduced bias in the results, real-world studies confer unique benefits that extend beyond the confines of a controlled study. Studies using real-world data exchange the internal validity of an RCT for external validity [39], allowing our results to be generalized to other populations with T2D using mHealth apps. The stringent requirements for inclusion in RCTs may exclude participants that would normally be seen in a real-world clinical

setting [40]. When used in conjunction with evidence-based clinical practice, real-world evidence has shown that mHealth apps can lead to significant improvements in glycemic management over the course of 1 year [41]. Aside from supporting an existing care network, mHealth apps may also have a niche in providing care for hard-to-reach populations [42].

Blood Glucose Forecasts

A major innovation in data-powered health insights is the predictive modeling of specific outcomes, such as blood glucose levels. Although predictive models do not necessarily reveal causes and effects, these models have been used for discovery, hypothesis testing, risk prediction, and the identification of counterfactuals and effective interventions [43]. Despite promising evidence on machine learning models, such as one study that demonstrated a significantly reduced glycemic response when a machine learning model was paired with a dietary intervention, blood glucose forecasts remain a nascent technique. There are currently no agreed-upon protocols for machine learning models in precision health [44,45], and a number of different models have been used as frameworks for machine learning training and development [46]. Further, there is no well-defined approach to estimate carbohydrate intake, the effect of stress and activity on blood glucose level, or the portability of machine learning models to capture inter- and intraindividual variability [45,47].

Until now, the majority of blood glucose forecast research has been focused on T1D [48]. This has limited the scope and real-world potential for blood glucose forecasts, as most (90.9%) diabetes cases in the United States have been diagnosed as T2D [49]. Blood glucose forecast research for T2D has mainly focused on forecasting the future incidence of disease or adverse glycemic events [50]. In addition, blood glucose forecast studies for either T1D or T2D have largely been limited to a short forecast horizon of 2 hours or less [48]. The current study advances the literature in studying a forecast horizon of 8 hours in an at-risk T2D population.

Conclusion

One Drop is one of the first mHealth apps to provide blood glucose forecasts to its users; our findings are the first to provide evidence for the effectiveness of delivering blood glucose forecasts as part of an mHealth intervention. The results suggest that exposure to blood glucose forecasts may be effective for individuals with T2D who have a high level of blood glucose, with forecast exposure associated with reduced glucose, a higher percentage of blood glucose %PIR, and increased self-monitoring of blood glucose. Further, blood glucose logging was a partial mediator of the relationship between forecast exposure and glucose reduction, highlighting a potential mechanism through which forecast exposure is associated with reduced glucose. Taken together, this novel evidence highlights the potential for One Drop blood glucose forecasts to improve glycemic management in individuals with T2D.

Conflicts of Interest

All listed authors are employees of Informed Data Solutions, Inc.

References

1. National diabetes statistics report. Centers for Disease Control and Prevention. Atlanta, GA: Centers for Disease Control and Prevention; 2020. URL: https://www.cdc.gov/diabetes/data/statistics-report/index.html [accessed 2022-04-28]
2. Khan MAB, Hashim MJ, King JK, Govender RD, Mustafa H, Al Kaabi J. Epidemiology of Type 2 Diabetes - Global Burden of Disease and Forecasted Trends. J Epidemiol Glob Health 2020 Mar;10(1):107-111 [FREE Full text] [doi: 10.2991/jegh.k.191028.001] [Medline: 32175717]
3. American Diabetes Association. 5. Facilitating Behavior Change and Well-being to Improve Health Outcomes. Diabetes Care 2021 Jan;44(Suppl 1):S53-S72. [doi: 10.2337/dc21-S005] [Medline: 33298416]
4. Kebede MM, Pischke CR. Popular Diabetes Apps and the Impact of Diabetes App Use on Self-Care Behaviour: A Survey Among the Digital Community of Persons With Diabetes on Social Media. Front Endocrinol (Lausanne) 2019;10:135 [FREE Full text] [doi: 10.3389/fendo.2019.00135] [Medline: 30881349]
5. Hou C, Carter B, Hewitt J, Francisa T, Mayor S. Do Mobile Phone Applications Improve Glycemic Control (HbA1c) in the Self-management of Diabetes? A Systematic Review, Meta-analysis, and GRADE of 14 Randomized Trials. Diabetes Care 2016 Nov;39(11):2089-2095. [doi: 10.2337/dc16-0346] [Medline: 27926892]
6. Maharaj A, Lim D, Murphy R, Serlachius A. Comparing Two Commercially Available Diabetes Apps to Explore Challenges in User Engagement: Randomized Controlled Feasibility Study. JMIR Form Res 2021 Jun 16;5(6):e25151 [FREE Full text] [doi: 10.2196/25151] [Medline: 34132640]
7. Cui M, Wu X, Mao J, Wang X, Nie M. T2DM Self-Management via Smartphone Applications: A Systematic Review and Meta-Analysis. PLoS One 2016 Nov;11(11):e0166718 [FREE Full text] [doi: 10.1371/journal.pone.0166718] [Medline: 27861583]
8. Doupis J, Festas G, Tsilivigos C, Efthymiou V, Kokkinos A. Smartphone-Based Technology in Diabetes Management. Diabetes Ther 2020 Mar 25;11(3):607-619 [FREE Full text] [doi: 10.1007/s13300-020-00768-3] [Medline: 31983028]
9. Frazetta D, Willet K, Fairchild R. A systematic review of smartphone application use for type 2 diabetic patients. OJNI 2012;16(3):2041 [FREE Full text]
10. Eberle C, Löhnert M, Stichling S. Effectiveness of Disease-Specific mHealth Apps in Patients With Diabetes Mellitus: Scoping Review. JMIR Mhealth Uhealth 2021 Feb 15;9(2):e23477 [FREE Full text] [doi: 10.2196/23477] [Medline: 33587045]
11. Angelini S, Alicastro G, Dionisi S, Di Muzio M. Structure and Characteristics of Diabetes Self-management Applications: A Systematic Review of the Literature. Comput Inform Nurs 2019 Jul;37(7):340-348. [doi: 10.1097/CIN.0000000000000526] [Medline: 31136332]
12. Jimenez G, Lum E, Car J. Examining Diabetes Management Apps Recommended From a Google Search: Content Analysis. JMIR Mhealth Uhealth 2019 Jan 16;7(1):e11848 [FREE Full text] [doi: 10.2196/11848] [Medline: 30303485]
13. Direito A, Dale LP, Shields E, Dobson R, Whittaker R, Maddison R. Do physical activity and dietary smartphone applications incorporate evidence-based behaviour change techniques? BMC Public Health 2014 Jun 25;14(1):646 [FREE Full text] [doi: 10.1186/1471-2458-14-646] [Medline: 24965805]
14. Middelweerd A, Mollee JS, van der Wal CN, Brug J, Te Velde SJ. Apps to promote physical activity among adults: a review and content analysis. Int J Behav Nutr Phys Act 2014 Jul 25;11(1):97 [FREE Full text] [doi: 10.1186/s12966-014-0097-9] [Medline: 25059981]
15. Park H, Cormier E, Gordon G, Baeg J. Identifying Health Consumers' eHealth Literacy to Decrease Disparities in Accessing eHealth Information. Comput Inform Nurs 2016 Feb;34(2):71-6; quiz 99. [doi: 10.1097/CIN.0000000000000205] [Medline: 26657619]
16. van Deursen AJAM, van Dijk JAGM. Internet skills performance tests: are people ready for eHealth? J Med Internet Res 2011 Apr 29;13(2):e35 [FREE Full text] [doi: 10.2196/jmir.1581] [Medline: 21531690]
17. Downing J, Bollyky J, Schneider J. Use of a Connected Glucose Meter and Certified Diabetes Educator Coaching to Decrease the Likelihood of Abnormal Blood Glucose Excursions: The Livongo for Diabetes Program. J Med Internet Res 2017 Jul 11;19(7):e234 [FREE Full text] [doi: 10.2196/jmir.6659] [Medline: 28698167]
18. Istepanian RS, Al-Anzi T. m-Health 2.0: New perspectives on mobile health, machine learning and big data analytics. Methods 2018 Dec 01;151:34-40. [doi: 10.1016/j.ymeth.2018.05.015] [Medline: 29890285]
19. Velardo C, Clifton D, Hamblin S, Khan R, Tarassenko L, Mackillop L. Toward a Multivariate Prediction Model of Pharmacological Treatment for Women With Gestational Diabetes Mellitus: Algorithm Development and Validation. J Med Internet Res 2021 Mar 10;23(3):e21435 [FREE Full text] [doi: 10.2196/21435] [Medline: 33688832]
20. Woldaregay AZ, Launonen IK, Årsand E, Albers D, Holubová A, Hartvigsen G. Toward Detecting Infection Incidence in People With Type 1 Diabetes Using Self-Recorded Data (Part 1): A Novel Framework for a Personalized Digital Infectious Disease Detection System. J Med Internet Res 2020 Aug 12;22(8):e18911 [FREE Full text] [doi: 10.2196/18911] [Medline: 32784178]

XSL•FO

RenderX

21. Daskalaki E, Nørgaard K, Züger T, Prountzou A, Diem P, Mougiakakou S. An early warning system for hypoglycemic/hyperglycemic events based on fusion of adaptive prediction models. J Diabetes Sci Technol 2013 May 01;7(3):689-698 [FREE Full text] [doi: 10.1177/193229681300700314] [Medline: 23759402]

22. Osborn CY, van Ginkel JR, Marrero DG, Rodbard D, Huddleston B, Dachis J. One Drop | Mobile on iPhone and Apple Watch: An Evaluation of HbA1c Improvement Associated With Tracking Self-Care. JMIR Mhealth Uhealth 2017 Nov 29;5(11):e179 [FREE Full text] [doi: 10.2196/mhealth.8781] [Medline: 29187344]

23. Kumar S, Moseson H, Uppal J, Juusola JL. A Diabetes Mobile App With In-App Coaching From a Certified Diabetes Educator Reduces A1C for Individuals With Type 2 Diabetes. Diabetes Educ 2018 Jun 24;44(3):226-236. [doi: 10.1177/0145721718765650] [Medline: 29575982]

24. Osborn CY, van Ginkel JR, Rodbard D, Heyman M, Marrero DG, Huddleston B, et al. One Drop | Mobile: An Evaluation of Hemoglobin A1c Improvement Linked to App Engagement. JMIR Diabetes 2017 Aug 24;2(2):e21 [FREE Full text] [doi: 10.2196/diabetes.8039] [Medline: 30291059]

25. Goldner D, Heyman M, Hirsch A. 49-LB: Reported Utility of Automated Blood Glucose Forecasts. 2019 Presented at: 79th Scientific Session of the American Diabetes Association; Jun 7, 2019; San Francisco. [doi: 10.2337/db19-49-LB]

26. Suh S, Kim JH. Glycemic Variability: How Do We Measure It and Why Is It Important? Diabetes Metab J 2015 Aug;39(4):273-282 [FREE Full text] [doi: 10.4093/dmj.2015.39.4.273] [Medline: 26301188]

27. Frontoni S, Di Bartolo P, Avogaro A, Bosi E, Paolisso G, Ceriello A. Glucose variability: An emerging target for the treatment of diabetes mellitus. Diabetes Res Clin Pract 2013 Nov;102(2):86-95. [doi: 10.1016/j.diabres.2013.09.007] [Medline: 24128999]

28. Nathan D, Kuenen J, Borg R, Zheng H, Schoenfeld D, Heine R. Translating the A1C assay into estimated average glucose values. Diabetes Care 2008 Aug;31(8):1473-1478 [FREE Full text] [doi: 10.2337/dc08-0545] [Medline: 18540046]

29. American Diabetes Association. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2021. Diabetes Care 2021 Jan;44(Suppl 1):S111-S124. [doi: 10.2337/dc21-S009] [Medline: 33298420]

30. Beck R, Bergenstal R, Riddlesworth T, Kollman C, Li Z, Brown AS, et al. Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials. Diabetes Care 2019 Mar;42(3):400-405 [FREE Full text] [doi: 10.2337/dc18-1444] [Medline: 30352896]

31. Cutruzzolà A, Irace C, Parise M, Fiorentino R, Pio Tripodi PF, Ungaro S, et al. Time spent in target range assessed by self-monitoring blood glucose associates with glycated hemoglobin in insulin treated patients with diabetes. Nutr Metab Cardiovasc Dis 2020 Sep 24;30(10):1800-1805. [doi: 10.1016/j.numecd.2020.06.009] [Medline: 32669240]

32. Hayes A. Introduction to mediation, moderation, and conditional process analysis: A regression-based approach. New York, NY: The Guilford Press; May 06, 2017.

33. Preacher KJ, Hayes AF. Asymptotic and resampling strategies for assessing and comparing indirect effects in multiple mediator models. Behav Res Methods 2008 Aug;40(3):879-891. [doi: 10.3758/brm.40.3.879] [Medline: 18697684]

34. American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2017. Diabetes Care 2018 May;41(5):917-928 [FREE Full text] [doi: 10.2337/dci18-0007] [Medline: 29567642]

35. Rinaldi G, Hijazi A, Haghparast-Bidgoli H. Cost and cost-effectiveness of mHealth interventions for the prevention and control of type 2 diabetes mellitus: A systematic review. Diabetes Res Clin Pract 2020 Apr;162:108084. [doi: 10.1016/j.diabres.2020.108084] [Medline: 32061819]

36. Grabner M, Abbott S, Nguyen M, Chen Y, Quimbo R. Estimated Cost Savings Associated With A1c Reductions In A Large Us Commercial Health Plan. Value Health 2013 May;16(3):A160. [doi: 10.1016/j.jval.2013.03.801]

37. Agarwal P, Mukerji G, Desveaux L, Ivers NM, Bhattacharyya O, Hensel JM, et al. Mobile App for Improved Self-Management of Type 2 Diabetes: Multicenter Pragmatic Randomized Controlled Trial. JMIR Mhealth Uhealth 2019 Jan 10;7(1):e10321 [FREE Full text] [doi: 10.2196/10321] [Medline: 30632972]

38. Zimmermann G, Venkatesan A, Rawlings K, Scahill MD. Improved Glycemic Control With a Digital Health Intervention in Adults With Type 2 Diabetes: Retrospective Study. JMIR Diabetes 2021 Jun 02;6(2):e28033 [FREE Full text] [doi: 10.2196/28033] [Medline: 34075880]

39. Luce B, Drummond M, Jönsson B, Neumann PJ, Schwartz JS, Siebert U, et al. EBM, HTA, and CER: clearing the confusion. Milbank Q 2010 Jun;88(2):256-276 [FREE Full text] [doi: 10.1111/j.1468-0009.2010.00598.x] [Medline: 20579285]

40. Blonde L, Khunti K, Harris SB, Meizinger C, Skolnik NS. Interpretation and Impact of Real-World Clinical Data for the Practicing Clinician. Adv Ther 2018 Nov 24;35(11):1763-1774 [FREE Full text] [doi: 10.1007/s12325-018-0805-y] [Medline: 30357570]

41. Tu Y, Chang Y, Chiou H, Lai K. The Effects of Continuous Usage of a Diabetes Management App on Glycemic Control in Real-world Clinical Practice: Retrospective Analysis. J Med Internet Res 2021 Jul 15;23(7):e23227 [FREE Full text] [doi: 10.2196/23227] [Medline: 34264192]

42. Steinman L, van Pelt M, Hen H, Chhorvann C, Lan CS, Te V, et al. Can mHealth and eHealth improve management of diabetes and hypertension in a hard-to-reach population? -lessons learned from a process evaluation of digital health to support a peer educator model in Cambodia using the RE-AIM framework. mHealth 2020 Oct;6:40-40 [FREE Full text] [doi: 10.21037/mhealth-19-249] [Medline: 33437836]

43. Pearson TA, Califf RM, Roper R, Engelgau MM, Khoury MJ, Alcantara C, et al. Precision Health Analytics With Predictive Analytics and Implementation Research: JACC State-of-the-Art Review. J Am Coll Cardiol 2020 Jul 21;76(3):306-320 [FREE Full text] [doi: 10.1016/j.jacc.2020.05.043] [Medline: 32674794]

44. Zarkogianni K, Litsa E, Mitsis K, Wu P, Kaddi CD, Cheng C, et al. A Review of Emerging Technologies for the Management of Diabetes Mellitus. IEEE Trans Biomed Eng 2015 Dec;62(12):2735-2749 [FREE Full text] [doi: 10.1109/TBME.2015.2470521] [Medline: 26292334]

45. Prosperi M, Min JS, Bian J, Modave F. Big data hurdles in precision medicine and precision public health. BMC Med Inform Decis Mak 2018 Dec 29;18(1):139 [FREE Full text] [doi: 10.1186/s12911-018-0719-2] [Medline: 30594159]

46. Kavakiotis I, Tsave O, Salifoglou A, Maglaveras N, Vlahavas I, Chouvarda I. Machine Learning and Data Mining Methods in Diabetes Research. Comput Struct Biotechnol J 2017;15:104-116 [FREE Full text] [doi: 10.1016/j.csbj.2016.12.005] [Medline: 28138367]

47. Zeevi D, Korem T, Zmora N, Israeli D, Rothschild D, Weinberger A, et al. Personalized Nutrition by Prediction of Glycemic Responses. Cell 2015 Nov 19;163(5):1079-1094 [FREE Full text] [doi: 10.1016/j.cell.2015.11.001] [Medline: 26590418]

48. Contreras I, Vehi J. Artificial Intelligence for Diabetes Management and Decision Support: Literature Review. J Med Internet Res 2018 May 30;20(5):e10775 [FREE Full text] [doi: 10.2196/10775] [Medline: 29848472]

49. Bullard KM, Cowie CC, Lessem SE, Saydah SH, Menke A, Geiss LS, et al. Prevalence of Diagnosed Diabetes in Adults by Diabetes Type - United States, 2016. MMWR Morb Mortal Wkly Rep 2018 Mar 30;67(12):359-361 [FREE Full text] [doi: 10.15585/mmwr.mm6712a2] [Medline: 29596402]

50. Saunajoki AE, Auvinen JP, Bloigu AH, Timonen MJ, Keinänen-Kiukaanniemi SM. Evaluating the 1-h post-load glucose level to predict future type 2 diabetes. Diabetes Res Clin Pract 2020 Feb;160:108009. [doi: 10.1016/j.diabres.2020.108009] [Medline: 31926844]

Abbreviations

%PIR: percent of blood glucose points in range
ANCOVA: analysis of covariance
CGM: continuous glucose monitor
eHbA$_{1c}$: estimated percentage of glycated hemoglobin
HbA$_{1c}$: glycated hemoglobin
mHealth: mobile health
RCT: randomized controlled trial
T1D: type 1 diabetes
T2D: type 2 diabetes

<u>Original Paper</u>

Algorithm-Enabled, Personalized Glucose Management for Type 1 Diabetes at the Population Scale: Prospective Evaluation in Clinical Practice

David Scheinker[1,2,3,4], PhD; Angela Gu[3], MS; Joshua Grossman[3], MS; Andrew Ward[3], PhD; Oseas Ayerdi[3], MS; Daniel Miller[3], PhD; Jeannine Leverenz[2], MS, RN, CDCES; Korey Hood[1,4], PhD; Ming Yeh Lee[2], MD, PhD; David M Maahs[1,4,5], MD, PhD; Priya Prahalad[1,4], MD, PhD

[1]Department of Pediatrics, Division of Pediatric Endocrinology, Stanford University, Stanford, CA, United States

[2]Lucile Packard Children's Hospital, Stanford University, Stanford, CA, United States

[3]Department of Management Science and Engineering, Stanford University School of Engineering, Stanford, CA, United States

[4]Stanford Diabetes Research Center, Stanford University, Stanford, CA, United States

[5]Department of Health Research and Policy, Stanford University, Stanford, CA, United States

Corresponding Author:
Priya Prahalad, MD, PhD
Department of Pediatrics, Division of Pediatric Endocrinology
Stanford University
300 Pasteur Dr.
Room G313
Stanford, CA, 94025
United States
Phone: 1 6507211811
Fax: 1 6507258375
Email: <u>prahalad@stanford.edu</u>

Abstract

Background: The use of continuous glucose monitors (CGMs) is recommended as the standard of care by the American Diabetes Association for individuals with type 1 diabetes (T1D). Few hardware-agnostic, open-source, whole-population tools are available to facilitate the use of CGM data by clinicians such as physicians and certified diabetes educators.

Objective: This study aimed to develop a tool that identifies patients appropriate for contact using an asynchronous message through electronic medical records while minimizing the number of patients reviewed by a certified diabetes educator or physician using the tool.

Methods: We used consensus guidelines to develop timely interventions for diabetes excellence (TIDE), an open-source hardware-agnostic tool to analyze CGM data to identify patients with deteriorating glucose control by generating generic flags (eg, mean glucose [MG] >170 mg/dL) and personalized flags (eg, MG increased by >10 mg/dL). In a prospective 7-week study in a pediatric T1D clinic, we measured the sensitivity of TIDE in identifying patients appropriate for contact and the number of patients reviewed. We simulated measures of the workload generated by TIDE, including the average number of time in range (TIR) flags per patient per review period, on a convenience sample of eight external data sets, 6 from clinical trials and 2 donated by research foundations.

Results: Over the 7 weeks of evaluation, the clinical population increased from 56 to 64 patients. The mean sensitivity was 99% (242/245; SD 2.5%), and the mean reduction in the number of patients reviewed was 42.6% (182/427; SD 10.9%). The 8 external data sets contained 1365 patients with 30,017 weeks of data collected by 7 types of CGMs. The rates of generic and personalized TIR flags per patient per review period were, respectively, 0.15 and 0.12 in the data set with the lowest average MG (141 mg/dL) and 0.95 and 0.22 in the data set with the highest average MG (207 mg/dL).

Conclusions: TIDE is an open-source hardware-agnostic tool for personalized analysis of CGM data at the clinical population scale. In a pediatric T1D clinic, TIDE identified 99% of patients appropriate for contact using an asynchronous message through electronic medical records while reducing the number of patients reviewed by certified diabetes care and education specialists by 43%. For each of the 8 external data sets, simulation of the use of TIDE produced fewer than 0.25 personalized TIR flags per

XSL•FO
RenderX

patient per review period. The use of TIDE to support telemedicine-based T1D care may facilitate sensitive and efficient guideline-based population health management.

Introduction

Background

For patients with type 1 diabetes (T1D) receiving insulin therapy, the American Diabetes Association (ADA) recommends the use of continuous glucose monitors (CGMs) as the standard of care along with quarterly clinic visits with hemoglobin A_{1c} (HbA_{1c}) laboratory testing [1]. However, most people with T1D remain on self-monitored blood glucose because of patient, clinician, or insurance preference and do not meet the current HbA_{1c} targets [2]. The long feedback cycle and the use of relatively little data when self-monitoring are barriers to timely detection and personalized response to deteriorating glucose control. An individual self-monitoring their glucose levels in line with the 2018 ADA standard of care recommendations generates glucose readings 6-10 times per day and receives feedback from their care team every 1-4 months based on a clinic visit or an HbA_{1c} test [3]. In contrast, CGMs record glucose levels once every 5-15 minutes (96-288 times per day). The initiation and continued use of CGMs have increased and are associated with improved clinical outcomes and patient-reported quality of life measures [1-9]. In a US pediatric T1D registry, the use of CGMs increased from 4% in 2013 to 33% in 2017 [6].

Numerous commercial and open-source platforms provide individual-level visualizations and analyses of CGM data [10-13]. Recent studies by the Advanced Technologies and Treatments for Diabetes consensus on CGM and the ADA and European Association for the Study of Diabetes consensus on precision medicine in diabetes found that although the use of CGMs offers an opportunity to use high-frequency data to identify deteriorating glucose control and tailor personalized management strategies, no standardized, validated methods currently exist outside of automated insulin delivery systems [4,14]. Patient-level tools, such as manufacturer or data aggregator platforms, require physicians or certified diabetes care and education specialists (CDCESs) to examine the data of each individual to identify those people whose glucose management may need improvement. Population-level tools that analyze and present data for the entire population to facilitate prioritizing patients are less common. LibreView (Abbott Laboratories) enables whole-population data review but is proprietary, works only with Libre sensors, and provides access primarily to prespecified metrics [12]. A hardware-agnostic tool would be more appropriate to support care for a population in which patients use a variety of CGMs. An open-source tool would facilitate external evaluation and the development and comparison of alternative models. A tool that calculates *personalized* metrics for each patient based on

their historical data would facilitate the tracking of temporal changes in glucose management. To the best of our knowledge, no validated, hardware-agnostic, open-source tool is available to facilitate the delivery of timely, population-level, personalized care through telehealth.

Numerous efforts have been made to improve T1D management using remote monitoring, the most successful of which relied on asynchronous messages sent to patients [15]. However, not all studies demonstrated significant and sustained improvement [15]. The implementation of clinical decision support (CDS) has faced a variety of challenges and has led to structured recommendations for their successful design and deployment [16]. Two of the primary areas of focus are that the CDS should improve, rather than disrupt, the appropriate workflows and that it should be designed with an iterative approach [16]. A recent multi-institution, cluster randomized clinical trial on the use of a CDS to improve the management of heart disease showed no significant improvements [17]. There was insufficient evaluation and redesign of the system based on feedback from its intended users [18]. The lack of iterative design and the resulting challenges to the workflow are common in the design of clinical software following the waterfall approach, a structured top-down approach in which the intent is to test and finalize the tool before deployment [19]. The agile approach, a more iterative approach based on rapid deployment and iterative redesign, is a popular alternative [19].

Objectives

We sought to design timely interventions for diabetes excellence (TIDE), a decision support tool to identify patients appropriate for asynchronous contact using a secure message through electronic medical record (EMR). To facilitate successful deployment and sustained use, we sought to fit into and improve current workflows by reducing the number of patients requiring review by a physician or the CDCES. We followed the agile approach to deploy the earliest viable version of TIDE in clinical practice and update it based on feedback from physicians and CDCESs.

Methods

Study Design

This study followed the Guidelines for Developing and Reporting Machine Learning Predictive Models in Biomedical Research [20]. The first phase was hardware-agnostic algorithm design based on the data collected using a variety of CGM hardware. Data were obtained from a convenience sample of eight external data sets: 6 from clinical trials and 2 donated by research foundations [21-28]. The second phase was the design of TIDE, an interactive visual interface presenting CGM data for the entire clinical population, based on iterative feedback

XSL•FO

RenderX

from physicians and CDCESs at an academic pediatric T1D clinic. One physician and CDCES used TIDE for 4 weeks and provided feedback based on which TIDE was comprehensively redesigned. Following this, they used the redesigned version for 5 weeks, during which minor improvements were made and errors were fixed. The third phase was a prospective evaluation over the course of 7 weeks of the sensitivity of TIDE for identifying patients who are appropriate for asynchronous contact using a secure message through the EMR and the difference in the number of patients requiring review with and without the use of TIDE. In the final phase, we simulated several measures of the workload generated by TIDE on the same convenience sample of 8 external data sets used to design the algorithms.

Setting

TIDE was developed at an academic pediatric T1D clinic caring for youth newly diagnosed with T1D who initiated CGM use within 1 month of onset and enrolled in a weekly remote monitoring program. All patients used Dexcom G6 (Dexcom) monitors, from which data were uploaded and made available to physicians and CDCESs through the Dexcom Clarity Clinic Portal [10]. Participants consented to participate in a longitudinal study evaluating the initiation of CGM early in the course of diabetes and the effects of weekly CGM data review as part of a larger ongoing study, for which the details of the consent process, eligibility criteria, screening, and enrollment process have been reported [8]. Each week, a CDCES used the Dexcom Clarity Clinic Portal to review each patient's data and send an asynchronous message through the EMRs to those patients who they determined required glucose management guidance. This study was approved by the Stanford University institutional review board. The leadership of the clinic, study authors PP and DMM, who serve on relevant national organizations governing diabetes technology, approved the use of TIDE in clinical care.

Generic and Personalized Metrics

A metric is *generic* if it is calculated the same way for each patient, for example, mean glucose (MG), and *personalized* if it is calculated for each patient based on their historical data; for example, the month-to-month change in MG. Consensus guidelines were used to generate a large set of generic CGM-based metrics from which clinicians could select the metrics to be tracked in TIDE [29]. The metrics included the number of days the CGM was active and collected more than a minimum percentage of valid readings (ACT), MG, percentage of time in range (TIR) defined as readings 70 to 180 mg/dL, percentage of time extremely hypoglycemic (eHyp) defined as readings <54 mg/dL, and percentage of time hypoglycemic (Hyp) defined as readings <70 mg/dL. Following the same consensus guidelines, each metric was calculated for each day for the entire day from 0:00 to 24:00, daytime 6:00 AM to midnight, and nighttime midnight to 6:00 AM. A complete list of generic metrics is provided in Table S1 in Multimedia Appendix 1. For each generic metric, a personalized metric was defined as the change from a baseline period to a review period (eg, the month-to-month change in the MG). The *review period* is the timeframe over which the metrics are calculated. It is defined relative to the day on which the data are being reviewed

(eg, the last full week). The *baseline period* is the timeframe over which the baseline value for each personalized metric is calculated (eg, the last full month before the review period). For each metric, "a flag is triggered" when the metric exceeds a prespecified target value.

Algorithms to calculate generic and personalized metrics and to generate flags as a function of the review period, baseline period, and target value were developed and tested using data from 8 external data sets. The data sets were identified based on an internet search and the professional contacts of the authors: 6 previously published clinical trials and observational data donated by Tidepool and OpenAPS (Table S2 in Multimedia Appendix 1). Data use agreements were signed with Tidepool and OpenAPS, each stipulating that the data may be used for this research project and that those donating the data would not take part in the study design or the reporting of results and would be acknowledged in writing. The data sets had 168,723 patient days of included CGM readings collected with seven types of CGMs: Freestyle Navigator, Dexcom STS, Medtronic Paradigm or Guardian, iPro2, iPro2 Professional CGM, Freestyle Libre Pro Flash, and Dexcom G4. The algorithms with annotated codes and an overview of their design, TIDE, and synthetic CGM data for use with TIDE are available on GitHub [30,31].

Iterative Design of an Interactive Tool

The design of an initial version of TIDE was based on a convenience sample of informal interviews and observations used to establish the current state, achieve buy-in from stakeholders, and solicit suggestions for and perceived problems with the proposed workflow. The initial version of TIDE was designed to require a one-time setup followed by repeated use. During the one-time setup, based on their clinical practice and population, clinicians select the metrics to be displayed, the review period over which the generic metrics are calculated, and a baseline period based on which the personalized metrics are calculated. Two pediatric endocrinologists, study authors DMM and PP, and a CDCES, study author JL, identified the consensus glucose metrics currently being used in the clinic to evaluate patient glucose management: ACT was measured as the number of valid readings as a percentage of the maximum number of readings possible (the number of 5-minute intervals during the review period), MG, TIR, eHyp, and Hyp. The review period was set to 1 week ending on the last Sunday before the data review. The targets were initially set as follows: ACT >75%, TIR >70%, eHyp <1%, and Hyp <4%. No target was set for the MG. The valid wear threshold was used by the CDCES to determine whether to reach out to the patient to discuss their use of the CGM and to assist with challenges in obtaining additional sensors. When the valid wear threshold was not met, TIDE presented the metrics and flags as usual, and the CDCES used their judgment to determine whether patient data required further review.

During each of the first 4 weeks of the use of TIDE, the physician and study author PP logged into the Dexcom Clarity Clinic Portal and downloaded patient ID numbers, CGM readings, and CGM timestamps for all patients in the study. The physician used TIDE to identify patients with flags, reviewed

the output of TIDE for appropriateness and patient safety, and forwarded the list of patients flagged by TIDE to CDCES (study author JL). For each flagged patient, the CDCES opened Dexcom Clarity and reviewed detailed patient data, opened the EMR and sent a secure message to the patient, and, if a dose adjustment was made, the dose was updated in the patient's chart. After these 4 weeks, PP and JL suggested changes that were incorporated into TIDE between weeks 4 and 5. During weeks 5 to 9, the tool was used by the study authors PP and JL to provide clinical care and identify minor adjustments required to improve usability or correct errors. Minor adjustments and corrections were made immediately, usually within 24 hours of identification.

Prospective Evaluation

The primary measures were the sensitivity of TIDE for identifying patients appropriate for asynchronous contact using a secure message through EMRs and the reduction in the number of patients reviewed by the CDCES with the use of TIDE. For 7 weeks, a CDCES reviewed the CGM data of each patient in the population and determined those appropriate for asynchronous contact. Sensitivity was defined as the number of appropriate patients flagged by TIDE divided by the number of appropriate patients. The reduction in the number of patients reviewed using TIDE was the number of patients not flagged by TIDE as a percentage of the total population.

The secondary outcomes calculated were as follows: the average amount of time required for per-patient review and contact as measured by the CDCES using TIDE, specificity (the number of patients not flagged by TIDE divided by the number of patients not appropriate for asynchronous contact), positive predictive power (the number of patients appropriately flagged by TIDE divided the number of patients flagged by TIDE), and negative predictive power (the number of patients not appropriate for asynchronous contact not flagged by TIDE divided by the number of patients not flagged by TIDE).

Validation on External Data Sets

The primary determinant of the workload associated with the use of TIDE is the number of patients for whom flags are generated in each review period, equivalent to the rate at which flags are generated per patient per review period. To evaluate the workload associated with the use of TIDE in other settings, we simulated the rate at which generic and personalized flags would be generated for populations with varying levels of glucose management. Patient ID numbers, CGM readings, and CGM timestamps were extracted from each of the 8 external data sets for all patient days that met the inclusion criteria and at least 70% valid CGM readings. Metrics MG, TIR, eHyp, and Hyp Flag and the thresholds for these metrics were chosen based on consensus guidelines [29]. The thresholds for generic metrics were MG >170 mg/dL, TIR <60%, eHyp >1%, and Hyp >3%. Flag thresholds for personalized metrics were chosen based on

the clinical experience of the study authors DMM and PP, as TIR less than baseline TIR minus 10 percentage points and MG greater than baseline MG plus 10 mg/dL. The duration of each measurement period was 1 week starting on Sunday. Personalized flags were calculated for patients with at least 4 weeks of data. For each personalized metric, the baseline period was the last week in the patient data that preceded the week being analyzed. The rate at which flags were generated was measured for each type of flag, each patient, and each dataset. For each data set, the rates at which flags were generated and the percentage of patients for whom at least one MG or TIR flag was generated every week were calculated. The rates of generic and personalized flags for MG and TIR were compared using a 2-tailed paired t test. The number of patients for whom an MG or TIR flag was generated every week was recorded.

Results

Iterative Design of an Interactive Tool

The first version of TIDE displayed the metrics that triggered a flag in red and those that did not trigger a flag in green (Figure 1). After the feedback from the first 4 weeks of its use, the primary changes to the interface were as follows: the columns displaying MG, the number of readings, and the number of 5-minute intervals during the review period were removed to minimize the number of patients who received flags that did not require dose adjustments while not missing those who required dose adjustments; the criterion for TIR target was changed from 70% to 60%; a personalized metric was added to compare each patient's TIR in the previous week to their TIR in the previous 4 weeks with a target of an increase in TIR or a drop in TIR of no more than 10% points; the color-coding was revised so only metrics that triggered a flag were highlighted; the wording of the display names of the metrics was changed to be more interpretable; a feature was added to allow the person using the tool to specify whether to use data from the most recent 7 days or from the default review period of 7 days ending on the previous Sunday; the patient data, previously presented on a single tab, were split tab into four tabs that displayed all patients, patients with alerts, patients with no data, and patients with data but no alerts; and the visual presentation was made more compact to display more patients per page (Figure 1).

The primary change in the workflow was that the step of downloading each patient's data from Dexcom Clarity was replaced with a Python script that downloaded all patient data (Figure 2). The participation of the physician in the review process was no longer necessary as part of the workflow but was continued to ensure patient safety and quality of care. The ultimate intended workflow, initiated months after the completion of this study, is for the CDCES to use TIDE without the participation of physicians.

Figure 1. Initial and revised timely interventions for diabetes excellence (TIDE) interface. TBR: time below range; TIR: time in range.

Figure 2. Workflow illustrated with examples of weekly and monthly cadence of data collection, data transfer, and provider review. CDCES: certified diabetes care and education specialists; CGM: continuous glucose monitor; EMR: electronic medical record; TIDE: timely interventions for diabetes excellence.
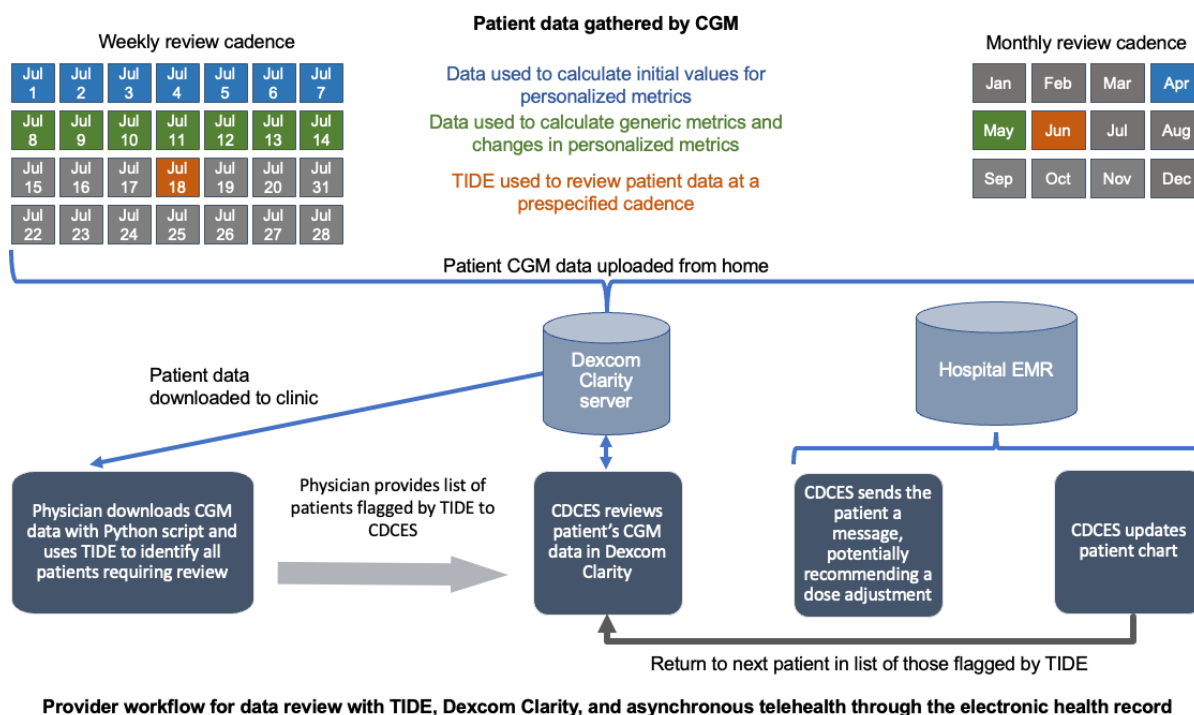
Prospective Evaluation

Over the last 7 weeks of the study, the number of patients increased from 56 to 64, totaling 427 patient weeks. The sensitivity of TIDE for identifying patients appropriate for contact using an asynchronous message through the EMR was 94% in the first week, 96% in the last week, and 100% in all other weeks (mean 99%, SD 2.5%; Table 1). The average

XSL•FO
RenderX

reduction in the number of patients reviewed by the CDCES was 42.8% (182/427; SD 10.9%), that is, the fraction of patients not flagged for review by TIDE (Table 1).

For patients identified by TIDE as requiring review, the mean duration of the data review process averaged 4.5 minutes per patient (1.5 minutes to access the data in Dexcom Clarity and review it for patterns, 1 minute to log into the patient's record and document changes, 2 minutes to send the patient a message using a secure EMR-based messaging platform). The weekly specificity, positive predictive power, and negative predictive power of TIDE are shown in Table 1.

Table 1. Outcomes including sensitivity identifying patients appropriate for asynchronous contact through the medical record and the reduction in the number of patients reviewed.

Week of review	February 7, 2020	February 14, 2020	February 21, 2020	February 28, 2020	March 6, 2020	March 13, 2020	March 20, 2020
Patients in study, N	56	58	59	62	64	64	64
Patients flagged by TIDE[a], n	29	29	36	39	39	37	36
Patients reviewed, %	52	50	61	63	61	58	56
Reduction in patients reviewed[b], %	*48*	*50*	*39*	*37*	*39*	*62*	*63*
True positive flags[c], %	29	21	31	27	30	34	34
True negative flags[d], %	23	17	19	15	9	16	19
False positive flags[e], %	23	33	36	40	39	33	31
False negative flags[f], %	2	0	0	0	0	0	2
Insufficient CGM[g] data, %	9	10	10	6	8	9	9
Sensitivity[b], %	*94*	*100*	*100*	*100*	*100*	*100*	*96*
Specificity, %	50	34	34	26	19	32	38
Positive predictive value, %	55	39	46	40	43	51	52
Negative predictive value, %	93	100	100	100	100	100	92

[a]TIDE: timely interventions for diabetes excellence.

[b]Primary objective (italicized).

[c]Flagged by TIDE and appropriate for asynchronous contact.

[d]Not flagged by TIDE and not appropriate for asynchronous contact.

[e]Flagged by TIDE and not appropriate for asynchronous contact.

[f]Not flagged by TIDE and appropriate for asynchronous contact.

[g]CGM: continuous glucose monitor.

Validation on External Data Sets

There were 1424 patients with at least 1 day of CGM data that met the inclusion criteria in the 8 external data sets. There were 168,723 patient days with CGM readings across 30,076 weeks. The patient with the most included days had 1028 days over 154 weeks, whereas the patient with the fewest days had 1 day. The mean weekly ACT was 5.1 (IQR 4.0-6.33), MG was 170.7 (IQR 148.8-189.2), mean percentage of TIR 70 to 180 mg/dL was 56.6% (IQR 45.1%-68.4%), eHyp <54 mg/dL was 1.9% (IQR 0.25%-2.32%), and Hyp <70 mg/dL was 3.3% (IQR 1.50%-4.60%). Across data sets, the minimum and maximum number of patients included were 12 and 450, respectively; the number of CGM days per patient was 9.8 and 256.8, respectively; MG was 141.3 (SD 21.3) and 207.0 (SD 35.3), respectively; mean percentage TIR was 38.2% (SD 14.2%) and 74.2% (SD 13.3%), respectively; Hyp was 2.1% (SD 2.3%) and 4.6% (SD 3.8%), respectively; and eHyp was 0.5% (SD 0.9%) and 3.7% (SD 4.9%), respectively (Table 2).

Data sets were numbered by increasing mean MG. The analysis of personalized MG and TIR flags included 1100 patients with at least 4 weeks of data. The median frequency was significantly higher for generic TIR flags than for personalized TIR flags, 0.47 (IQR 0.12-0.83) versus 0.19 (IQR 0.12-0.26) flags per patient per week ($P<.001$), respectively, as was the SD of the frequency of flags (0.36 vs 0.11, respectively; $P<.001$; Figure 3). The median frequency of flags was significantly higher for generic MG than for personalized MG, 0.31 (IQR 0.05-0.71) versus 0.30 (IQR 0.22-0.37) flags per patient per week ($P<.001$), as was the SD of the frequency of flags 0.35 versus 0.12 ($P<.001$; Figure 3). In the two data sets with the highest mean MG, data sets 7 and 8, respectively, 49.7% (97/212) and 81% (26/32) of patients had a generic MG or TIR flag every week. Across all data sets, 15.64% (172/1100) of patients had a generic MG or TIR flag every week, and 0% (1/1100) of patients had a personalized MG or TIR flag every week (Table 3).

Table 2. Continuous glucose monitor (CGM) data in external data sets.

Data set	Patients, n	CGM days, n (number per patient)	CGM weeks, n (number per patient), n	Days active, mean (SD)	Glucose (mg/dL), mean (SD)	Time in range[a] (%), mean (SD)	Percentage of time hypoglycemic[b], mean (SD)	Percentage of time extremely hypo-glycemic[c], mean (SD)
1	85	21,236 (249.8)	3372 (39.7)	6.3	141.3 (21.3)	74.2 (13.3)	3.1 (2.4)	2 (3.1)
2	12	315 (26.2)	63 (5.2)	5	152.9 (23.3)	66.4 (13.2)	4 (3)	1.7 (2.4)
3	120	30,815 (256.8)	4546 (37.9)	6.8	158.3 (26.7)	65.9 (16)	2.1 (2.3)	0.5 (0.9)
4	225	48,805 (216.9)	7670 (34.1)	6.4	162.3 (24.1)	62.1 (14.1)	3 (2.6)	0.9 (1.4)
5	450	54,535 (121.2)	11,936 (26.5)	4.6	162.6 (28)	62.4 (16.3)	2.9 (3.1)	1 (2.3)
6	180	1682 (9.3)	378 (2.1)	4.4	176.6 (33.3)	50.4 (15.6)	3.6 (3.2)	3.4 (4.3)
7	219	10,025 (45.8)	1727 (7.9)	5.8	184.9 (44.4)	45.1 (16.6)	4.6 (3.8)	3.7 (4.9)
8	133	1310 (9.8)	384 (2.9)	3.4	207 (35.3)	38.2 (14.2)	2.9 (3.7)	1.6 (3.6)

[a]Percentage of readings that were 70 to 180 mg/dL.

[b]Percentage of readings <70 mg/dL.

[c]Percentage of readings <54 mg/dL.

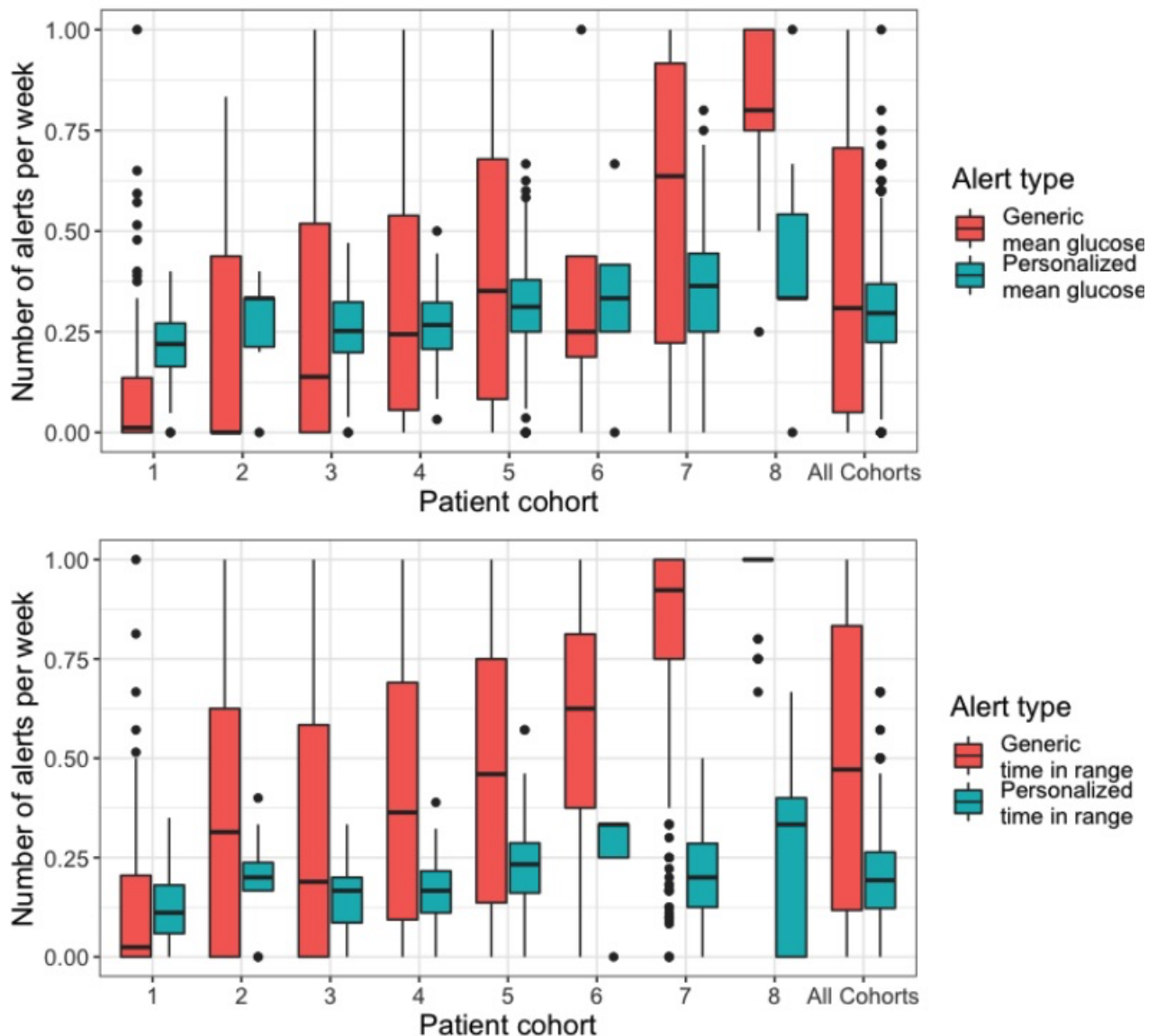**Figure 3.** Frequency of generic and personalized flags in external cohorts.

Table 3. Frequency of generic and personalized flags based on continuous glucose monitor data in external data sets.

Data set	Patients, n	Patients with at least 4 weeks of data, n (%)	Glucose flags, n (flags per patient per week)		Time in range flags[a], n (flags per patient per week)		Patients with mean glucose or time in range flag every week, n (%)	
			Generic[b]	Personalized[a]	Generic[c]	Personalized[d]	Generic	Personalized
1	85	78 (92)	329 (0.1)	725 (0.22)	493 (0.15)	493 (0.12)	1 (1)	0 (0)
2	12	10 (83)	13 (0.22)	14 (0.24)	19 (0.33)	19 (0.16)	1 (10)	0 (0)
3	120	120 (100)	1417 (0.31)	1128 (0.25)	1535 (0.34)	1535 (0.15)	4 (3.3)	0 (0)
4	225	225 (100)	2595 (0.34)	2002 (0.26)	3204 (0.42)	3204 (0.16)	9 (4)	0 (0)
5	450	436 (97)	4137 (0.35)	3498 (0.29)	4895 (0.41)	4895 (0.21)	31 (7.1)	0 (0)
6	180	4 (2)	6 (0.38)	4 (0.25)	9 (0.56)	9 (0.19)	1 (25)	0 (0)
7	219	195 (89)	967 (0.58)	525 (0.31)	1360 (0.81)	1360 (0.18)	97 (49.7)	0 (0)
8	133	32 (24)	116 (0.84)	47 (0.34)	131 (0.95)	131 (0.22)	26 (81.3)	1 (3.1)

[a]Personalized mean glucose (MG) flag triggered when MG>MG+10 mg/dL in baseline period.

[b]Generic mean glucose flag triggered when mean bigeneric glucose >170 mg/dL.

[c]Generic time in range flag triggered when the percentage of readings of 70-180 mg/dL was <60%.

[d]Personalized time in range (TIR) flag triggered when TIR<TIR−10% points in baseline period.

Discussion

Principal Findings

We designed TIDE as an open-source hardware-agnostic tool for the personalized analysis of CGM data at the clinic population scale. In a pediatric T1D clinic, TIDE identified 99% of patients appropriate for contact using an asynchronous message through the EMR while reducing the number of patients reviewed by certified diabetes educators by 43%. For each of the 8 external data sets, simulation of the use of TIDE produced fewer than 0.25 personalized TIR flags per patient per review period. TIDE and the underlying algorithms are free open-source software available on GitHub [30,31]. Upon request, we will help clinicians customize the tool to their setting and deploy it in practice.

TIDE was developed with an iterative agile approach to support asynchronous contact with patients, the form of contact found to be most effective by a systematic review of T1D telemetry systems [15]. An initial version of TIDE was produced quickly, and few significant design decisions were made before physicians and CDCESs used TIDE to provide feedback. Physicians and CDCESs identified their preferences for a rule-based approach over less-interpretable approaches such as machine learning, time-series analysis, or alternative statistical smoothing techniques. On the basis of physician and CDCES feedback, TIDE was designed to identify how a patient's glucose management differs from validated recommendations and to produce interpretable flags to facilitate recommendations. As TIDE uses consensus guidelines, it may be more broadly applicable than a model trained on a small or nonrepresentative subset of the population would be. The use of TIDE to identify patients for asynchronous messaging fits well with the CDCES workflow. The CDCES could send a message to each patient identified by TIDE and move immediately to the next patient, rather than spending time scheduling an appointment or trying to contact the patient or family. The primary challenges of the agile approach and asynchronous messaging are that additional resources may be required to ensure that patient care is not adversely affected during the deployment of an early stage tool or because of patients ignoring messages. In this study, during the initial testing period, a physician reviewed the output of TIDE to ensure that the quality of care was not compromised, and the CDCES tracked whether patients read their messages and followed up accordingly.

The use of generic and personalized flags has complementary benefits. For patients with average glucose management, the generic flags provide a standardized approach to care based on the most recent consensus guidelines. For patients with very well or very poorly managed glucose levels, personalized flags based on patient progress may be more informative. If a person with MG 208 (the mean in one of the external data sets) consistently reduced their glucose by 5 mg/dL per review period, a generic metric may trigger a flag for numerous consecutive review periods, whereas a personalized metric would indicate improvement. During the first major revision of TIDE, a personalized metric was added to track the TIR to help CDCESs identify changes in patient management that did not cross the threshold of a personalized metric. With any flags, particularly in pediatric and young adult populations, it is important to further test the optimal timing and frequency (ie, the dose) to strike the correct balance of receiving action-oriented guidance while not further burdening the person.

Nonendocrinologists care for numerous people with T1D [32]. Clinicians who are not aware of the most recent consensus guidelines or who are not comfortable with diabetes technology, such as CGM data, may not have the resources to provide patients with appropriate care recommendations. Programs to provide telemedicine-based care or train nonspecialists are associated with better outcomes but require resources and time investment that limit participation and scope [33,34]. The use

of a relatively simple tool with metrics and targets based on the consensus guidelines may be useful for nonspecialist clinicians to inform the care of such patients.

Strengths and Limitations

A strength of this study is the evaluation across 8 external datasets of the potential applicability of TIDE. Most T1D clinics in the United States see patients 3 to 12 times per year primarily in person [3]. In this study, reviewing a patient's data with TIDE and sending the patient a message required an average of 4.5 minutes. In a clinic in which patients use CGM and 15-minute-long in-person visits, eliminating an average of 1 in-person visit per patient per year would provide sufficient time for an average of 3 message-based contacts. Using TIDE to support such a workflow requires that TIDE flags an average of 0.25 patients per month for review, equivalent to 3 reviews per patient per year. In a simulation of the use of TIDE for populations with differing average levels of glucose management, the personalized TIR metric flagged no more than 0.22 patients per review period, even for the population with an average MG level of 207 mg/dL. As TIDE flags patients based on deteriorating glucose control, patient contacts would be targeted to address the need rather than per a fixed schedule. Each patient would be more likely to receive care when their control deteriorates. On an average, patients with worse control may receive more contacts than those with better control. Such deployments of TIDE are ongoing with two partner clinics, one in the United States and another in Australia, each caring for ≥1000 patients with T1D and using CGMs.

This study has several limitations. The workflow presented requires downloading data and toggling between the tool and Dexcom Clarity and is not integrated with the EMR. Integration of CGM data with the EMR will facilitate integration with current telehealth workflows and allow the tool to incorporate data on the timing of each patient's previous and upcoming visits into the recommendations. The specificity of this tool was significantly lower than its sensitivity. However, specificity is less relevant than the direct measure of the primary outcome and time savings associated with the use of TIDE. Specificity may be improved by using the data on which patients did and did not require a review to tune the algorithm for which patients

should be flagged. Improvements are ongoing to streamline, standardize, and scale the data review; to improve the sensitivity and specificity of the tool; and to incorporate the tool into the EMR [35]. There was a 43% reduction in the number of patients reviewed each week; however, reviewing patients weekly is not currently the standard of care and may represent increased time spent for most diabetes clinicians. The reduction in the number of patients requiring review in a different setting may change with the cadence of the review and the criteria for review. This study was conducted as a novel proof-of-concept intervention to create new knowledge and generate data on the performance of an automated tool. The metrics and thresholds were not derived from a systematic hypothesis-based approach or a survey of patients, families, and clinicians. The thresholds used to create the tool were based on consensus guidelines with the input of a group of experts in diabetes technology, and the revised version of the tool used feedback from 4 weeks of use in clinical care.

Future Studies

Subsequent efforts to deploy TIDE in other settings may benefit from a formal quality improvement framework with an established aim, predefined targets for metrics, implementation criteria, and well-defined iteration cycles. Subsequent research is ongoing to explicitly incorporate measurements of the additional time necessary for clinical decision-making based on the review of the data, examine the operational requirements to expand the number of individuals monitored with the help of this tool, and identify if the use of such a tool may allow a clinic with fixed resources to provide care for more patients through a more efficient use of clinician time [35].

Conclusions

We developed and deployed TIDE, a tool that uses metrics based on consensus guidelines, to identify 99% of patients appropriate for contact using an asynchronous message while reducing the number of patients requiring review by a physician or certified diabetes educator by 43%. Further investigation is necessary to understand the potential of automated analyses of CGM data to support broader access to personalized and timely glucose management.

Conflicts of Interest

Multimedia Appendix 1
Full list of generic metrics, sources of data for retrospective analysis, and timely interventions for diabetes excellence screenshots.
[PDF File (Adobe PDF File), 222 KB - diabetes_v7i2e27284_app1.pdf]

References

1. American Diabetes Association Professional Practice Committee, Draznin B, Aroda VR, Bakris G, Benson G, Brown FM, et al. 7. Diabetes technology: standards of medical care in diabetes-2022. Diabetes Care 2022 Jan 01;45(Suppl 1):S97-112. [doi: 10.2337/dc22-S007] [Medline: 34964871]
2. Foster NC, Beck RW, Miller KM, Clements MA, Rickels MR, DiMeglio LA, et al. State of type 1 diabetes management and outcomes from the T1D exchange in 2016-2018. Diabetes Technol Ther 2019 Feb;21(2):66-72 [FREE Full text] [doi: 10.1089/dia.2018.0384] [Medline: 30657336]
3. Chiang JL, Maahs DM, Garvey KC, Hood KK, Laffel LM, Weinzimer SA, et al. Type 1 diabetes in children and adolescents: a position statement by the American Diabetes Association. Diabetes Care 2018 Sep;41(9):2026-2044 [FREE Full text] [doi: 10.2337/dci18-0023] [Medline: 30093549]
4. Danne T, Nimri R, Battelino T, Bergenstal RM, Close KL, DeVries JH, et al. International consensus on use of continuous glucose monitoring. Diabetes Care 2017 Dec;40(12):1631-1640 [FREE Full text] [doi: 10.2337/dc17-1600] [Medline: 29162583]
5. DeSalvo DJ, Miller KM, Hermann JM, Maahs DM, Hofer SE, Clements MA, T1D Exchange and DPV Registries. Continuous glucose monitoring and glycemic control among youth with type 1 diabetes: international comparison from the T1D exchange and DPV initiative. Pediatr Diabetes 2018 Nov;19(7):1271-1275 [FREE Full text] [doi: 10.1111/pedi.12711] [Medline: 29923262]
6. Miller KM, Hermann J, Foster N, Hofer SE, Rickels MR, Danne T, T1D Exchange and DPV Registries. Longitudinal changes in continuous glucose monitoring use among individuals with type 1 diabetes: international comparison in the German and Austrian DPV and U.S. T1D exchange registries. Diabetes Care 2020 Jan;43(1):e1-e2 [FREE Full text] [doi: 10.2337/dc19-1214] [Medline: 31672703]
7. Prahalad P, Yang J, Scheinker D, Desai M, Hood K, Maahs DM. Hemoglobin A1c trajectory in pediatric patients with newly diagnosed type 1 diabetes. Diabetes Technol Ther 2019 Aug;21(8):456-461 [FREE Full text] [doi: 10.1089/dia.2019.0065] [Medline: 31180244]
8. Prahalad P, Zaharieva DP, Addala A, New C, Scheinker D, Desai M, et al. Improving clinical outcomes in newly diagnosed pediatric type 1 diabetes: teamwork, targets, technology, and tight control-the 4T study. Front Endocrinol (Lausanne) 2020;11:360 [FREE Full text] [doi: 10.3389/fendo.2020.00360] [Medline: 32733375]
9. Prahalad P, Addala A, Scheinker D, Hood KK, Maahs DM. CGM initiation soon after type 1 diabetes diagnosis results in sustained CGM use and wear time. Diabetes Care 2020 Jan;43(1):e3-e4 [FREE Full text] [doi: 10.2337/dc19-1205] [Medline: 31558548]
10. Dexcom Clarity. URL: https://clarity.dexcom.com [accessed 2021-05-01]
11. Kumar RB, Goren ND, Stark DE, Wall DP, Longhurst CA. Automated integration of continuous glucose monitor data in the electronic health record using consumer technology. J Am Med Inform Assoc 2016 May;23(3):532-537 [FREE Full text] [doi: 10.1093/jamia/ocv206] [Medline: 27018263]
12. Abbot LibreView. URL: https://www.libreview.com/ [accessed 2021-05-01]
13. Nimri R, Muller I, Atlas E, Miller S, Fogel A, Bratina N, et al. MD-Logic overnight control for 6 weeks of home use in patients with type 1 diabetes: randomized crossover trial. Diabetes Care 2014 Nov;37(11):3025-3032. [doi: 10.2337/dc14-0835] [Medline: 25078901]
14. Chung WK, Erion K, Florez JC, Hattersley AT, Hivert MF, Lee CG, et al. Precision medicine in diabetes: a consensus report from the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia 2020 Sep;63(9):1671-1693 [FREE Full text] [doi: 10.1007/s00125-020-05181-w] [Medline: 32556613]
15. Eberle C, Stichling S. Telemetric interventions offer new opportunities for managing type 1 diabetes mellitus: systematic meta-review. JMIR Diabetes 2021 Mar 16;6(1):e20270 [FREE Full text] [doi: 10.2196/20270] [Medline: 33724201]
16. Greenes RA, Bates DW, Kawamoto K, Middleton B, Osheroff J, Shahar Y. Clinical decision support models and frameworks: seeking to address research issues underlying implementation successes and failures. J Biomed Inform 2018 Feb;78:134-143 [FREE Full text] [doi: 10.1016/j.jbi.2017.12.005] [Medline: 29246790]

17.   Adusumalli S, Westover JE, Jacoby DS, Small DS, VanZandbergen C, Chen J, et al. Effect of passive choice and active choice interventions in the electronic health record to cardiologists on statin prescribing: a cluster randomized clinical trial. JAMA Cardiol 2021 Jan 01;6(1):40-48 [FREE Full text] [doi: 10.1001/jamacardio.2020.4730] [Medline: 33031534]

18.   Maddox TM. Clinical decision support in statin prescription-what we can learn from a negative outcome. JAMA Cardiol 2021 Jan 01;6(1):48-49. [doi: 10.1001/jamacardio.2020.4756] [Medline: 33026415]

19.   Jackson S, Yaqub M, Li C. The agile deployment of machine learning models in healthcare. Front Big Data 2019 Jan 8;1:7 [FREE Full text] [doi: 10.3389/fdata.2018.00007] [Medline: 33693323]

20.   Luo W, Phung D, Tran T, Gupta S, Rana S, Karmakar C, et al. Guidelines for developing and reporting machine learning predictive models in biomedical research: a multidisciplinary view. J Med Internet Res 2016 Dec 16;18(12):e323 [FREE Full text] [doi: 10.2196/jmir.5870] [Medline: 27986644]

21.   OpenAPS. URL: https://openaps.org [accessed 2022-03-16]

22.   Haymond MW, DuBose SN, Rickels MR, Wolpert H, Shah VN, Sherr JL, T1D Exchange Mini-dose Glucagon Study Group. Efficacy and safety of mini-dose glucagon for treatment of nonsevere hypoglycemia in adults with type 1 diabetes. J Clin Endocrinol Metab 2017 Aug 01;102(8):2994-3001. [doi: 10.1210/jc.2017-00591] [Medline: 28591776]

23.   Tidepool. URL: https://tidepool.org [accessed 2022-03-16]

24.   Aleppo G, Ruedy KJ, Riddlesworth TD, Kruger DF, Peters AL, Hirsch I, REPLACE-BG Study Group. REPLACE-BG: a randomized trial comparing continuous glucose monitoring with and without routine blood glucose monitoring in adults with well-controlled type 1 diabetes. Diabetes Care 2017 Apr;40(4):538-545 [FREE Full text] [doi: 10.2337/dc16-2482] [Medline: 28209654]

25.   JDRF CGM Study Group. JDRF randomized clinical trial to assess the efficacy of real-time continuous glucose monitoring in the management of type 1 diabetes: research design and methods. Diabetes Technol Ther 2008 Aug;10(4):310-321. [doi: 10.1089/dia.2007.0302] [Medline: 18828243]

26.   Weinstock RS, DuBose SN, Bergenstal RM, Chaytor NS, Peterson C, Olson BA, T1D Exchange Severe Hypoglycemia in Older Adults With Type 1 Diabetes Study Group. Risk factors associated with severe hypoglycemia in older adults with type 1 diabetes. Diabetes Care 2016 Apr;39(4):603-610. [doi: 10.2337/dc15-1426] [Medline: 26681721]

27.   Bergenstal RM, Gal RL, Connor CG, Gubitosi-Klug R, Kruger D, Olson BA, T1D Exchange Racial Differences Study Group. Racial differences in the relationship of glucose concentrations and hemoglobin A1c levels. Ann Intern Med 2017 Jul 18;167(2):95-102. [doi: 10.7326/M16-2596] [Medline: 28605777]

28.   Nwosu BU, Maranda L, Cullen K, Greenman L, Fleshman J, McShea N, et al. A randomized, double-blind, placebo-controlled trial of adjunctive metformin therapy in overweight/obese youth with type 1 diabetes. PLoS One 2015;10(9):e0137525 [FREE Full text] [doi: 10.1371/journal.pone.0137525] [Medline: 26367281]

29.   Maahs DM, Buckingham BA, Castle JR, Cinar A, Damiano ER, Dassau E, et al. Outcome measures for artificial pancreas clinical trials: a consensus report. Diabetes Care 2016 Jul;39(7):1175-1179 [FREE Full text] [doi: 10.2337/dc15-2716] [Medline: 27330126]

30.   CGM Algorithms. SURF. 2020. URL: https://github.com/joshuagrossman/a1c [accessed 2022-03-16]

31.   SURF-TIDE. GitHub. 2021 Sep 15. URL: https://github.com/jferstad/SURF-TIDE [accessed 2022-03-16]

32.   Lipman TH, Hawkes CP. Racial and socioeconomic disparities in pediatric type 1 diabetes: time for a paradigm shift in approach. Diabetes Care 2021 Jan;44(1):14-16. [doi: 10.2337/dci20-0048] [Medline: 33444165]

33.   Malasanos TH, Burlingame JB, Youngblade L, Patel BD, Muir AB. Improved access to subspecialist diabetes care by telemedicine: cost savings and care measures in the first two years of the FITE diabetes project. J Telemed Telecare 2005;11 Suppl 1:74-76. [doi: 10.1258/1357633054461624] [Medline: 16036002]

34.   Zhou C, Crawford A, Serhal E, Kurdyak P, Sockalingam S. The impact of project ECHO on participant and patient outcomes: a systematic review. Acad Med 2016 Oct;91(10):1439-1461. [doi: 10.1097/ACM.0000000000001328] [Medline: 27489018]

35.   Ferstad JO, Vallon JJ, Jun D, Gu A, Vitko A, Morales DP, et al. Population-level management of type 1 diabetes via continuous glucose monitoring and algorithm-enabled patient prioritization: Precision health meets population health. Pediatr Diabetes 2021 Nov;22(7):982-991. [doi: 10.1111/pedi.13256] [Medline: 34374183]

Abbreviations

ACT: number of days continuous glucose monitor active
ADA: American Diabetes Association
CDCES: certified diabetes care and education specialist
CDS: clinical decision support
CGM: continuous glucose monitor
eHyp: extreme hypoglycemic
EMR: electronic medical record
Hyp: hypoglycemic
MG: mean glucose
T1D: type 1 diabetes

XSL•FO
RenderX

TIDE: timely interventions for diabetes excellence
TIR: time in range

XSL•FO
RenderX

Original Paper

Managing Diabetes Using Mobiab: Long-Term Case Study of the Impact of a Mobile App on Self-management

Václav Burda[1], MSc; Miloš Mráz[2], MD, PhD; Jakub Schneider[1], PhD; Daniel Novák[1], PhD

[1]Department of Cybernetics, Faculty of Electrical Engineering, Czech Technical University in Prague, Prague, Czech Republic

[2]Department of Diabetes, Diabetes Centre, Institute for Clinical and Experimental Medicine, Prague, Czech Republic

Corresponding Author:
Václav Burda, MSc
Department of Cybernetics
Faculty of Electrical Engineering
Czech Technical University in Prague
Karlovo namesti 13
Prague, 12135
Czech Republic
Phone: 420 224357666
Email: burdavac@fel.cvut.cz

Abstract

Background: This paper describes the development of a mobile app for diabetes mellitus (DM) control and self-management and presents the results of long-term usage of this system in the Czech Republic. DM is a chronic disease affecting large numbers of people worldwide, and this number is continuously increasing. There is massive potential to increase adherence to self-management of DM with the use of smartphones and digital therapeutics interventions.

Objective: This study aims to describe the process of development of a mobile app, called Mobiab, for DM management and to investigate how individual features are used and how the whole system benefits its long-term users. Using at least 1 year of daily records from users, we analyzed the impact of the app on self-management of DM.

Methods: We have developed a mobile app that serves as an alternative form to the classic paper-based protocol or diary. The development was based on cooperation with both clinicians and people with DM. The app consists of independent individual modules. Therefore, the user has the possibility to use only selected features that they find useful. Mobiab was available free of charge on Google Play Store from mid-2014 until 2019. No targeted recruitment was performed to attract users.

Results: More than 500 users from the Czech Republic downloaded and signed up for the mobile app. Approximately 80% of the users used Mobiab for less than 1 week. The rest of the users used it for a longer time and 8 of the users produced data that were suitable for long-term analysis. Additionally, one of the 8 users provided their medical records, which were compared with the gathered data, and the improvements in their glucose levels and overall metabolic stability were consistent with the way in which the mobile app was used.

Conclusions: The results of this study showed that the usability of a DM-centered self-management smartphone mobile app and server-based systems could be satisfactory and promising. Nonetheless, some better ways of motivating people with diabetes toward participation in self-management are needed. Further studies involving a larger number of participants are warranted to assess the effect on long-term diabetes management.

KEYWORDS

Introduction

This paper describes the development of a mobile app for diabetes mellitus (DM) self-management and discusses the results of its long-term usage by selected users after 5 years.

The design of the app (called Mobiab) consisted of a holistic process involving end-user requirements, expert involvement, incorporation of behavioral change theory, data security, and data privacy considerations.

XSL•FO
RenderX

DM is a chronic disease affecting large numbers of people throughout the world, and this number is continuously increasing. According to the International Diabetes Federation, there are 537 million adults worldwide has diagnosed with DM [1,2]. In the Czech Republic, in 2020, nearly 1 million people live with this disease; that is, almost 10% of the population of the country [1,3]. There are two main types of DM: type 1 DM and type 2 DM and other types such as gestational diabetes, secondary diabetes, and other forms of DM [4,5]. Type 1 DM is characterized by an absolute lack of insulin secretion from pancreatic β-cells and is responsible for approximately 5%-10% of cases [4-6]. Type 2 DM is characterized by progressive loss of insulin secretion from the pancreatic β-cells with an underlying background of insulin resistance resulting in hyperglycemia, which further leads to the development of acute and chronic complications [4,5,7]. Type 2 DM accounts for approximately 90%-95% of cases [4,5]. Self-management is essential for attaining optimal long-term glucose control, and requires careful recording of food intake, glycemic values, insulin doses, and other information. A typical part of self-management is using paper-based protocols or diaries for recording diabetes-related values [8]. This can be problematic and complicated because the person with DM has to remember or look up caloric values in different meals.

There is massive potential to increase involvement with self-management of DM using smartphones and digital therapeutics interventions. Mobile health (mHealth) applications can also reduce barriers to the availability of the health care system; for example, time constraints or limited access to care providers [9]. Smartphone apps for diabetes might have an extensive outreach, as more than 6.37 billion people in the world use smartphones [10], and approximately 0.5 billion of them already use some mobile app for diet, physical activities, and chronic disease management [11]. There are numerous mobile apps dealing with DM. For the term "diabetes," there are more than 200 mobile apps available on the Google Play platform alone [12]. However, despite the large number of apps in this field, only a few had been evaluated in health outcome studies [12] and just 5 were associated with clinically significant improvements in hemoglobin A_{1c} (HbA_{1c}) levels (Glucose Buddy, Diabeo Telesage, Blue Star, WellTang, Gather Health) [12]. These studies did not assess other parameters such as blood pressure and body weight [12]. The authors of one study identified and compared 19 mobile apps in terms of the availability of features for DM self-management [13]. Few of them have been designed on the basis of a behavioral model and have been endorsed by health care professionals. In addition, it is important to have appropriate integration without compromising user safety and privacy. The use of mobile apps can improve DM management and can contribute to education of persons with DM and motivate them to maintain healthy behavior. Several small-scale studies have shown promising results in terms of targeting blood glucose, medication intake, weight loss, and quality of life [14-17]. To our best knowledge, there is no published full report on a case study of diabetes self-management over a 5-year period.

The aims of this study are to (1) explore how long-term usage of such a system may benefit its users, (2) describe the process of development of a mobile app focused on self-management of people with DM, and (3) evaluate the demand for individual features or modules.

Methods

Requirement Analysis

We developed the Mobiab system within the context of OLDES (www.oldes.eu), a European Union (EU) multicenter project involving 4 companies, 2 universities, and 2 university hospitals. The OLDES project focused on developing information technology for the purposes of eHealth applications [18]. We defined the essential requirements for a system on the basis of interviews and discussions with diabetologists from the university hospital in Prague, representatives from the national Czech diabetes association, and people living with diabetes, who were recruited from an outpatient clinic at the university hospital. This approach enabled us to involve the needs of health professionals and people with DM during the design and development of the app. Additional information was gathered by searching public scientific databases using the following combinations of keywords: "mobile app," "diabetes," "diabetes management," "patient adherence, empowerment," "mobile health," and "self-management." Several paper-based diabetes diaries were used to define the main functionalities that were to be integrated [19].

Architecture and System Functionalities

The Mobiab system offers an alternative to a paper-based diary—an Android mobile app and a web portal aimed at supporting DM self-management. Compared with a paper-based diary, the main benefit is the immediate feedback for inputted data in the form of graphs and basic statistics showing the user's compliance with diet or providing self-monitoring of blood glucose levels. The Mobiab system was designed in a client-server architecture with a storage system on the server. Mobiab requires an internet connection on mobile devices. In the beginning—that is, in 2014—this approach was restricted by lower availability of internet connection [20]. However, this is no longer a problem, now that internet connection is much more widely available.

The concept underlying Mobiab consists of a mobile app, data collection from medical devices, and data storage (Figure 1). All medical data are collected on a mobile phone and are stored on the server. We prepared a prototype of a Bluetooth connection to selected medical devices from ForaCare Suisse AG. The connection works fully automatically—records of measurements are downloaded and are stored without any action by the user. With users' consent, the collected behavior data and medical data are then available on a desktop computer to selected physicians. Common security standards and privacy policies have been followed in the design and development of the Mobiab system. Communication between the smartphone or computer and the server is encrypted via the HTTPS protocol. After the app download, registration or login is initially required. The login screen requires a unique email address and password to access the app functionality. An expert group consisting of endocrinologists, health researchers, nutrition nurses, and app

developers provided valuable decisions for the design and development of Mobiab.

Figure 1. Scheme of system architecture. API: application programming interface.
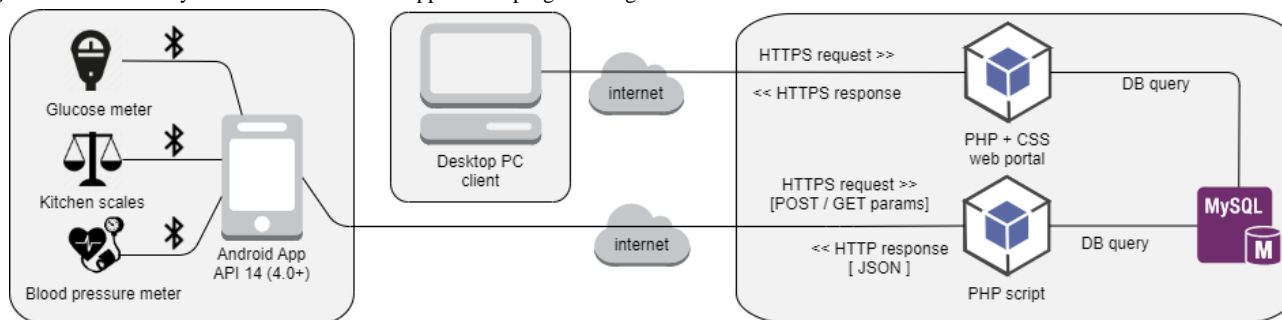
Description of the Mobile App and the Web Interface

The mobile app consists of individual modules that are independent of each other and need only the basis of the app (Figure 2). The main advantage of applying a modular approach is that other functionalities can easily be added, and particular users can select only certain modules that are suited to their needs. For example, people with type 2 DM and those who do not use insulin can turn off the insulin module. All entered values in the modules are visualized intuitively and enable the user to monitor the changes continuously. A description of the modules with their main features is provided below.

Figure 2. Scheme of the mobile app and individual modules.
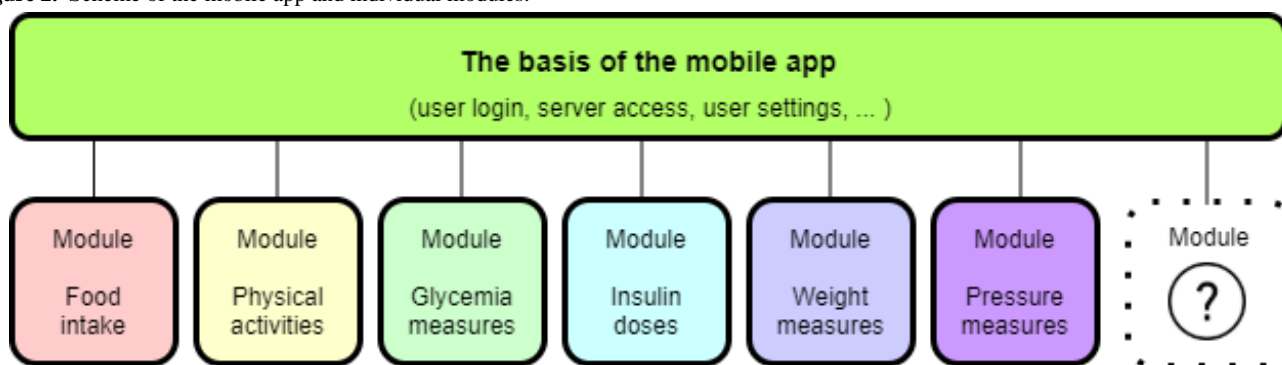
Food Intake and Physical Activities

Food intake is the most complex module and provides the functionality for recording food that is consumed. This module now contains a food database with more than 9000 Czech food items. The database has gradually been expanded and checked for data accuracy by other users. There are several approaches to food consumption logging:

- Search in the whole database
- Search in favorite items
- Browse all food items and filter by categories
- Browse user's meals or simply take a photo of the food.

The user enters the amount of food after searching for the specific food item. The time stamp for the consumption and the food category is predefined by the current time; however, this can be changed by the user. To enable the user to change their mind, the description of the nutrition, and the size of the portion (in grams), and the carbohydrates (in grams) are displayed before the final dialog is saved. The changes in values are facilitated by an intuitive visualization of all measured medical data (Figure 3).

The physical activities module was designed similarly to the food intake module: the database contains more than 400 activities that can be browsed by categories or searched by name. It is necessary to select one activity and to enter the duration of the activity for logging. The caloric expenditure is computed with the user's weight and the duration of the activity. Owing to this approach, the computed caloric expenditure may not always match the real expenditure and should be considered solely a guide.

Figure 3. Screenshots of the mobile app: food intake, glycemia monitoring, and insulin doses.
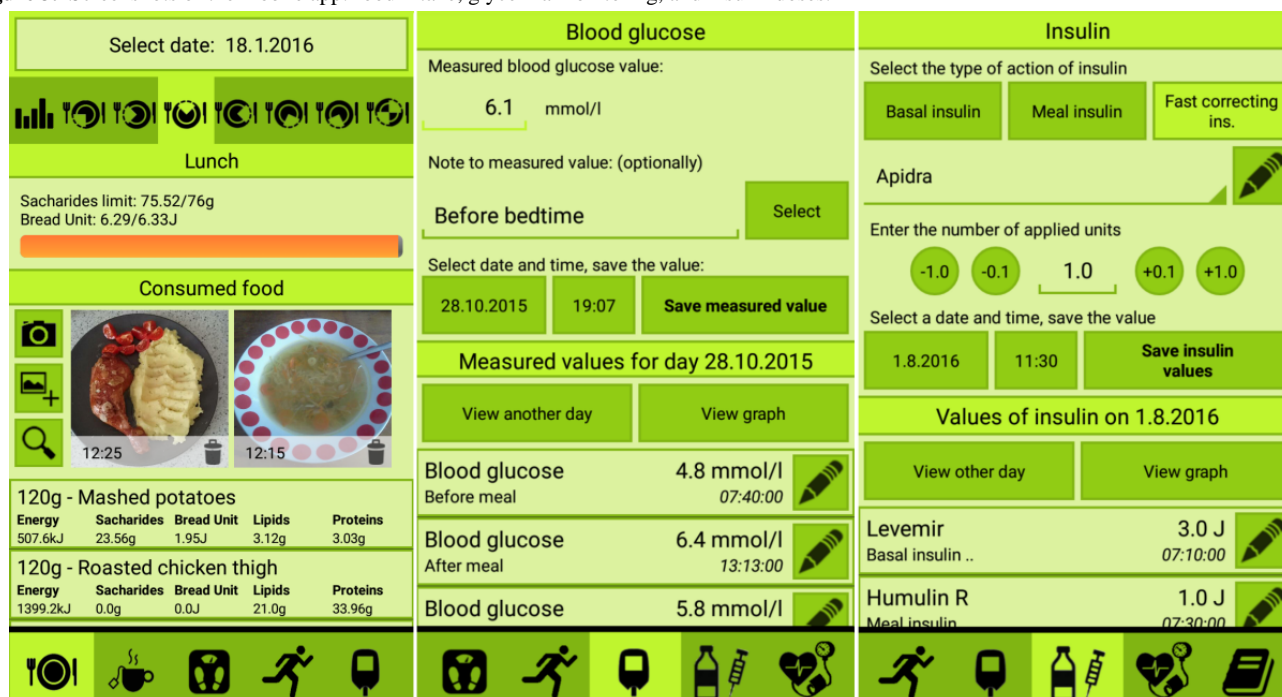
Glycemic Monitoring and Insulin Dosage

The Glycemic Monitoring module has a simple design for easy usage. It has an input part for entering values; for example, glucose levels, the date and time of measurement, and notes. The second part of the module is an overview of the values for the selected day, or a graph for the selected time range (Figure 3). The insulin applications module is more complex than the previous modules. As shown (Figure 3), the user first chooses from among 3 types of insulin (basal, prandial, and fast correcting), then selects a specific brand name of insulin (user editable), the number of applied units, and the date and time of application. The overview section is the same as in the Glycaemia Monitoring module.

Data

Data were collected through Mobiab over a period of 5 years (from January 2016), although Mobiab had been available on Google Play Store from mid-2014 only until 2019. No advertisement was used to recruit users, they found the mobile app in an organic reach. Over this period, over 500 users from the Czech Republic, who used the app for different lengths of time. Approximately 200 users did not report any DM, approximately 150 users reported type 1 DM, and approximately 175 users reported type 2 DM. Approximately 80% of the users used the mobile app for less than one week. The remaining 20% of the users used Mobiab for a longer time with a decreasing usage trend as it was also noted previously [21]. However, only those satisfying at least one of the following conditions were selected for the analysis:

1. At least 3600 records of food intakes
2. At least 360 records of glycaemia measurements
3. At least 360 records of insulin doses
4. At least 1080 records of physical activities
5. At least 360 records of weight measurements
6. At least 360 records of pressure measurements.

Meeting one of these conditions was considered to provide evidence of long-term usage. Details about users (Table 1) and the number of records and records per day (Table 2) are shown in tables.

Table 1. Basic users' statistics.

User ID	Sex	Birth year	Height (cm)	Diabetes mellitus type	Active days, n
ID 1141	Male	1962	173	Type 2	1749
ID 1196	Male	1960	178	Type 2	1261
ID 1224	Female	1976	162	Type 1	1623
ID 1289	Female	1941	162	No diabetes	1626
ID 1412	Female	1976	162	Type 2	96
ID 1432	Male	1958	175	Type 1	804
ID 1545	Male	1967	188	Type 2	881
ID 1558	Male	1967	170	Type 2	247

XSL•FO
RenderX

Table 2. Number of records and daily averages.

Patient ID	Food entries, n (daily mean)	Glycemic measures, n (daily mean)	Insulin doses, n (daily mean)	Physical activities, n (daily mean)	Weight measures, n (daily mean)	Pressure measures, n (daily mean)
ID 1141	34425 (19.67)	—[a]	—	13,515 (7.73)	1690 (0.97)	1478 (0.85)
ID 1196	—	1164 (0.92)	—	—	—	—
ID 1224	9470 (5.83)	1932 (1.19)	2166 (1.33)	4562 (2.81)	—	449 (0.33)
ID 1289	15,729 (9.67)	—	—	—	—	—
ID 1412	—	466 (4.85)	—	—	—	—
ID 1432	3757 (5.86)	799 (0.99)	1199 (1.53)	2982 (4.18)	—	—
ID 1545	—	857 (0.97)	697 (0.79)	—	—	859 (0.98)
ID 1558	—	538 (2.18)	—	—	—	—

[a]—: not available.

In total, 8 users (5 male, 3 female) fulfilled the inclusion criteria for long-term analysis, 5 of whom stated that they had type 2 DM, 2 had type 1 DM, and 1 was without DM. The average age of all users was approximately 57 years. All 8 users were invited to provide medical records, but only one user (ID 1141) was willing to share them. We were particularly interested in the development of the following clinical parameters during use of the app: hemoglobin A_{1c} (HbA$_{1c}$), glycemia, triglycerides, and cholesterol (total, low-density lipoprotein, and high-density lipoprotein cholesterol). The summary of records for the whole 7 years of the user who provided medical records are presented in Table 3. The frequency of the laboratory's clinical parameters is sufficient to draw a conclusion about the progress in DM treatment [22]. In addition to these medical records, user ID 1141 provided personal health state remarks that are presented in the case study results.

The analysis of the data had to use two approaches owing to missing user medical records: the first approach is an analysis of usage of the application, including any beneficial trends for DM management, and the second approach is to make a direct comparison between the medical records and the entered values and trends of the user ID 1141.

Table 3. Selected medical records of user ID 1141.

Date	Hemoglobin A_{1c} levels (mmol/mol)	Glycemia (blood glucose measured in terms of mmol/L)	Total cholesterol (mmol/L)	Low-density lipoprotein cholesterol (mmol/L)	High-density lipoprotein cholesterol (mmol/L)	Triglycerides (mmol/L)
January 1, 2014	—[a]	4.6	4.3	2.82	1.15	1.07
April 17, 2016	—	18.17	—	—	—	—
April 26, 2016	90	7.9	4.17	2.62	1.4	0.85
July 21, 2016	36	4.7	—	—	—	—
November 11, 2016	29	5	4.58	2.39	1.49	0.67
March 6, 2017	32	4.8	3.81	1.98	1.66	0.53
July 17, 2017	34	4.5	4.05	—	—	0.81
April 23, 2018	35	5.3	3.73	2.08	1.48	0.51
September 17, 2018	34	5	4.11	2.52	1.55	0.73
February 4, 2019	—	4.9	3.96	2.54	1.18	0.93
June 17, 2019	35	4.9	3.66	2.03	1.46	0.6
November 4, 2019	35	5.1	4.26	2.57	1.39	0.99
March 19, 2020	36	4.7	3.3	1.65	1.44	0.5
July 13, 2020	35	5.1	3.78	2.09	1.44	0.65
November 13, 2020	36	5.2	3.77	2.01	1.62	0.64
March 22, 2021	35	5.4	3.71	1.98	1.53	0.78

[a]—:not available.

Ethical Considerations

Ethics approval from the ethics committee of our university was not required for this study. All users agreed to use anonymized data for purposes of research and data analysis during sign-up process, which is required for the app usage.

Results

Analysis of Usage

At first, we analyzed the long-term food intake. Users ID 1141 and ID 1289 recorded their food intake regularly. They were strictly taking their diet plan and followed energy and sugar intake limits. User ID 1141 still uses the mobile app, and his performance is described in detail in the following section. Two other users, ID 1224 and ID 1432, enter data irregularly every few days.

Nevertheless, ID 1224 used the app for over 4 years, and ID 1432 used it for 2 years. Interestingly, both of these users has type 1 DM, and they used the app much more regularly for entering glycemic values and insulin dosage than for food intake recording. The glycemic records (Figure 4) show a slight decrease in blood glucose levels after a few months of usage of Mobiab. A more important fact for our study's purposes is that users ID 1224 and ID 1289 carried out long-term recordings and were engaged for more than 2 years, and users ID 1432 and ID 1545 were engaged for more than 4 years. Additionally, the other users, ID 1412 and ID 1558, were involved with Mobiab for a shorter time, for 3 months and 8 months, respectively, but during that time they regularly included several measurements per day.

Figure 4. Records of blood sugar in the first year of app use.
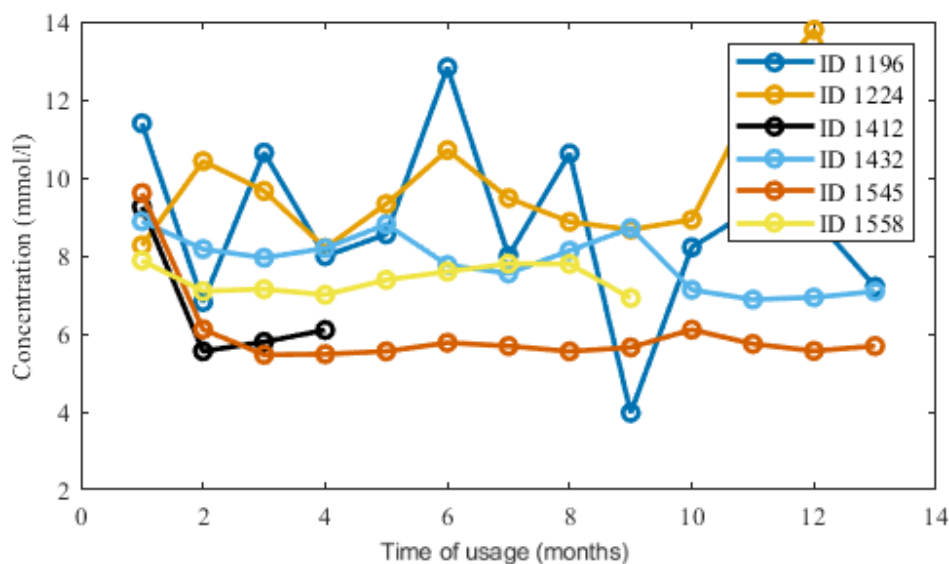
Case Study of App Use With Type 2 DM

User ID 1141 (male, 60 years old, type 2 DM) was selected for the case study because he was willing to share his medical records and other information about his health and lifestyle. This person had been diagnosed as having type 2 DM randomly during an emergency examination on April 17, 2016. Before that, he had already been treated for high blood pressure and for hyperlipidemia. After the diagnosis of DM, he has been treated with medication (Glucophage XR, 500 mg) and he had been looking for some supporting mobile app. He started dieting and the records show that he has followed the diet constantly for the whole time that he has used the app. In total, he has entered over 34,000 food records. Positive results were soon obtained. With regular exercise (stationary exercise bike and walking) he reduced his weight from 127 kg to 84 kg, and his waist circumference decreased from 141 cm to 107 cm within 1 year. In the last 3 years, these values have increased moderately, as of March 2021, his weight was 101 kg because he has not been able to exercise intensely owing to joint pain and he stopped entering new waist circumference values (Figure 5). His blood pressure and cholesterol levels have also improved and then stabilized (Figure 6). All these results are in accordance with his medical records (Figure 7). Unfortunately, the person does not self-monitor blood glucose, and only periodical medical records of his glycemic levels are available (Figure 8). Based on the usage quality questionnaire and a semistructured interview, he was very satisfied with the mobile app and appreciated how easy the app was to use. As of this writing, he is still using Mobiab, and he will complete 8 years of usage in April 2022.

Figure 5. Weight and waist circumference records for the entire period of app usage.

Figure 6. Blood pressure records for the entire period of app usage.

Figure 7. Medical records for hemoglobin A$_{1c}$ and glycemia.

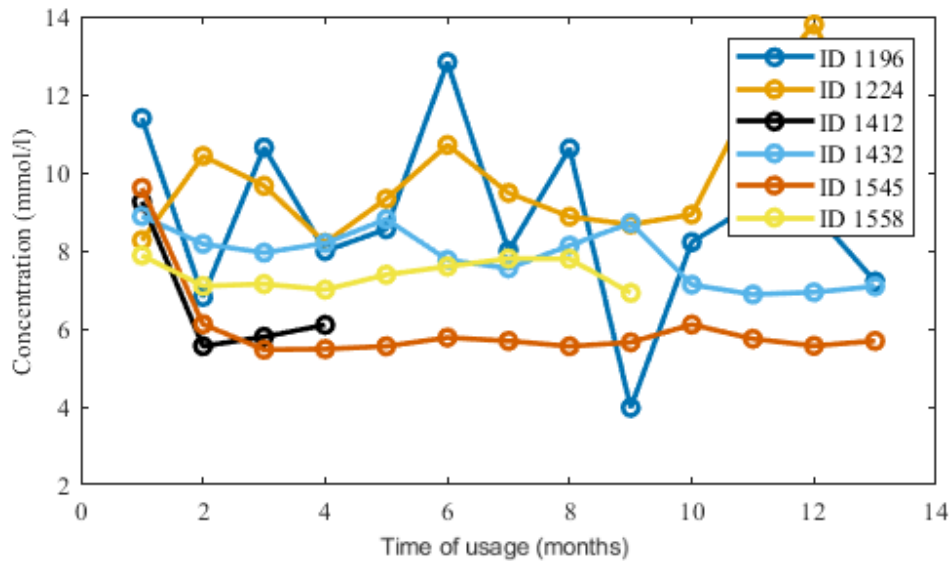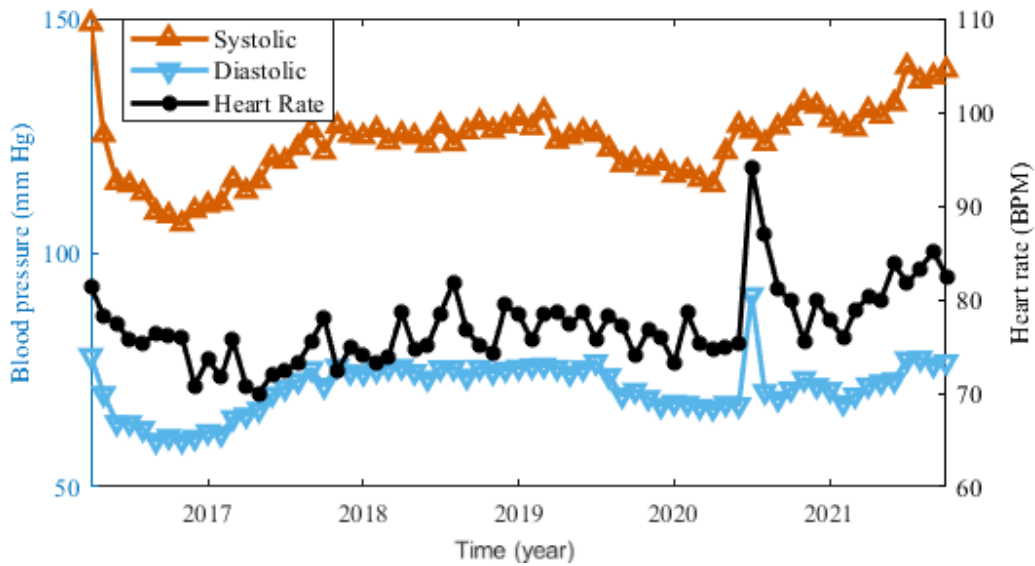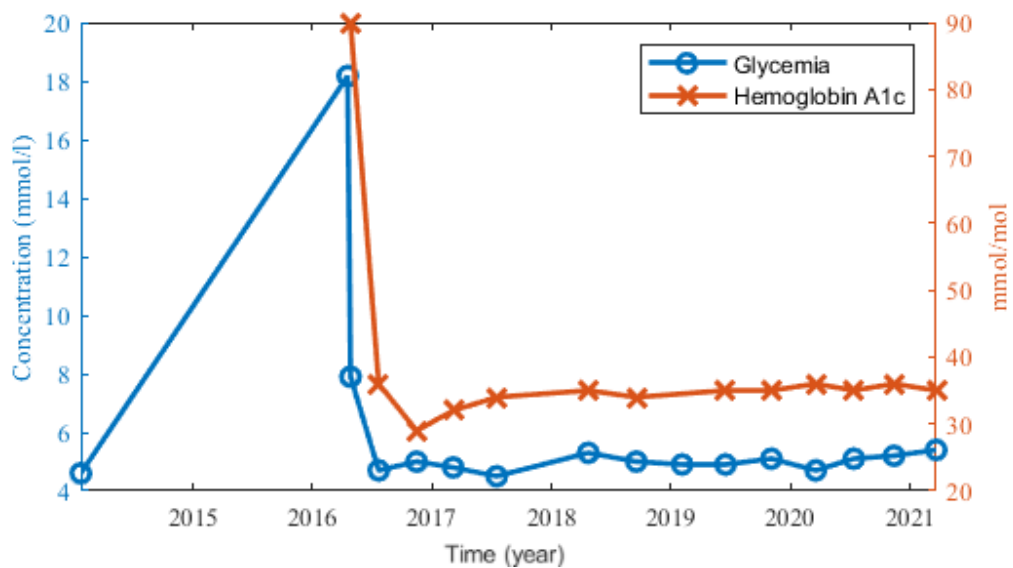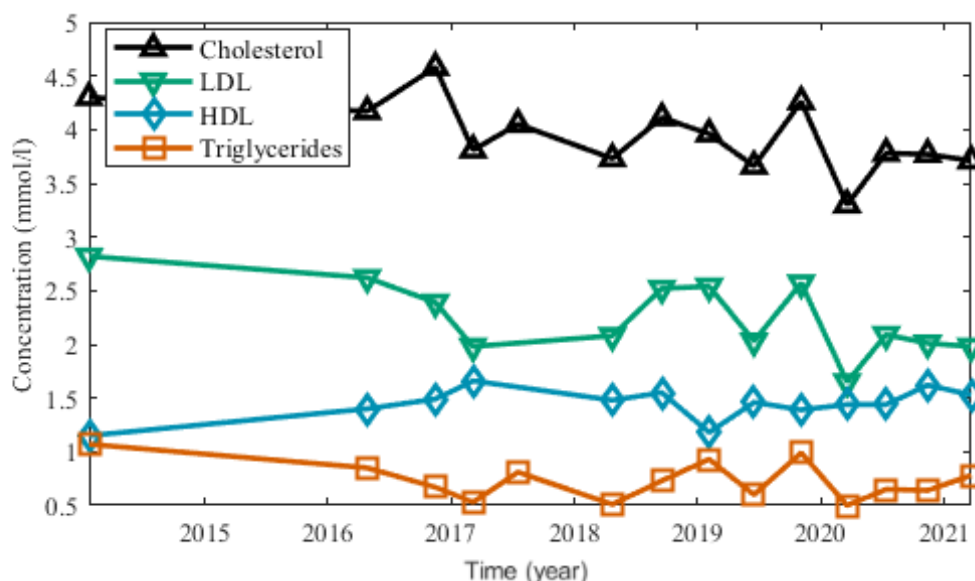**Figure 8.** Medical records for cholesterol and triglycerides. HDL: high-density lipoprotein, LDL: low-density lipoprotein.

Discussion

Principal Findings

The main goal of the Mobiab system is exploring benefits of long-term usage of technology for DM self-management. The system simplifies manual entering and documenting of measured values associated with treatment monitoring and self-management of DM and provides a user-friendly summary of their self-management efforts. The Mobiab system contributes to the user's education and a better understanding of the disease by providing continuous recordings of all essential data, including food intake, caloric expenditure, blood glucose levels, insulin dosage, body weight, and blood pressure. In addition, we might argue that the Mobiab system contributes to long-term outcomes of DM management, as demonstrated in several use cases. Several studies have suggested the usefulness of electronic self-management systems in managing DM [23]. For example, smartphone apps have been shown to improve glycemic control, specifically in younger people with DM [24]. Another randomized controlled trial showed that DM intervention using smartphones led to improved clinical outcomes [25]. The US Food and Drug Administration has now approved several (BlueStar) mobile apps for DM management [25], and the new German Digital Health Applications (in German: "Digitale Gesundheitsanwendungen") scheme has also been approved [26]. These data confirm an increasing trend to introduce digital therapeutics intervention into daily clinical practice [27]. A further benefit of smartphone apps is that anonymized data can be collected from a larger population.

The collection of medical data using Mobiab was beneficial to users with both diabetes types. Previously, it had been necessary for people with DM to record medical values manually in a diabetes diary. Using Mobiab, user ID 1141 has already been able to record his food consumption, exercises, weight changes, and blood pressure continuously for 1749 days. In addition, the user achieved positive changes in blood glucose levels (Figure 7) and weight control (Figure 5) within a concise time. Although we cannot quantify the exact contribution of the Mobiab app to

these improvements, the benefits for user ID 1141 have been considerable. A positive impact of the assistance of the mobile app on diet and blood glucose levels were also confirmed in a study focusing on mySugr app benefits [28].

Some systems applied training participants ranging from telephone [29] to face-to-face support [30]. The design of the app followed the user-centered design and the final design was also commented on by the expert group. At the end, no personal training was offered to participants, since we assumed that the app is easy and intuitive to use. However, the onboarding procedure explaining the main app functionalities started after installing and launching the app.

Only a few technology-related issues were reported. The main comments stemmed from the use of the app without an internet connection, mainly at the beginning of the app launch. While there was considerable effort to ensure complete app functionality without the internet connection by caching all parameters as in the case of earlier systems [31]; after several updates, it was decided to remove this feature. This is in line with most of the current solutions based on cloud architecture, which requires a stable connection to guarantee smooth operation [32]. Further, no similar studies analyzed the number of calls that participants or clinicians made for technological support [33].

The Mobiab data set is highly variable in terms of the usage of the modules. Not every user used the same set of modules (Table 1). This is a limiting factor for a complex analysis of the health impacts. However, this variability of usage of the modules should not be classified as an app issue because it only indicates the well-known highly heterogeneous needs of people with diabetes [34]. The hypothesis that engaged participants used more modules reflecting their higher discipline was not confirmed in our study. Nevertheless, the Mobiab developers will continue to make modules more attractive to users and convince people with DM that it would also be beneficial to use a broader range of modules; for example, to provide overviews of complex data and explain the impacts on their health. We believe that a broad selection of modules is

advantageous for people with DM, thus contributing to personalized DM self-management, increasing the participants' engagement and long-term outcomes [35-37]. Furthermore, several studies discussed the usefulness of using the Chronic Care Model to improve clinical and behavioral outcomes applying eHealth technology. Consequently, we have identified several improvements that might reduce the burden of the disease and increase engagement by expanding the modular architecture [38-40]. Combination of general and tailored educational content might help cope with medical jargon and misleading information from different sources. In addition, tracking mood on a daily or weekly basis might be important to provide insight for better glycemic control and to prevent depression and diabetes distress [41,42].

However, there is a concern about placing too much confidence in managing DM using mHealth apps [29,30,43]. These pilot studies have pointed out that some people with type 2 DM do not believe in the benefits of these apps resulting in a low level of usage [30,44-46]. When discussing self-management of diabetes with the use of a mobile app, several research papers have emphasized the need for education, peer support, interactive content, blood glucose monitoring, dietary tracking, and realistic goal setting [22,47-50]. Another important concept for increasing the efficacy of interventions is the establishment of a 2-way communication between the patient and care team [51]. We supported this type of communication by developing a stand-alone web-based clinical portal for physicians.

However, the long-term usage of apps developed for managing DM using self-management tools remains low [44]. Our own experience suggests that our app can achieve good outcomes, but it is not straightforward enough to motivate people with diabetes to self-manage their condition consistently in the long term. Long-term engagement with mHealth systems does not necessarily require daily interaction; routine DM management could lead to the reduction of using the technology [21].

Most of the studies referenced in this paper were single-center pilots validating short-term results of the examined mobile apps. Undoubtedly, more clinical trials with extended follow-up periods are needed to evaluate the long-term effect of diabetes-related mobile apps on glucose management and quality of life, and sustainability of self-management using the mHealth ecosystem [52]. A clinical study for validating the impact of the Mobiab system on self-management behavior and for exploring the usability of the system is currently under development.

Strengths and Limitations

A major strength of this study is the involvement of 5 persons with type 2 DM, 2 persons with type 1 DM, and 1 person without DM, each of whom could use the system for a long time and enter a significant amount of data. However, the small number of participants is a limitation of our study. A very small set of users is insufficient to thoroughly test and validate the self-management compliance of the Mobiab system. In addition, even this small number of participants did not use all the modules that the system provides.

Another limitation is the integration of only one glucometer. We implemented seamless glucose data transfer using a specific glucose meter (Fora Diamond MINI) and blood pressure monitor (Fora Active P30 Plus). Technical documentation and cooperation with manufacturers would be needed to connect other devices.

A further limitation is the web-based portal for physicians. A total of 5 clinicians in our expert advisory group indicated that clinicians already use some commercial software (eg, Medtronic CareLink), and that the use of different software is an unnecessary complication. The solution would be to have a communication interface to connect the mobile app to an already established system. Data integration with existing hospital information systems was not implemented as a part of our work, because we had no specification of the communication interface. However, this integration activity remains open for future work, when new versions of the hospital system are incorporated with application programming interface functionality.

Conclusions

The results of this study have shown that the usability of a smartphone app and server-based systems are potentially satisfactory and promising. The collection of long-term data on diabetes and overall metabolic management can be supported by a modular app such as Mobiab. Our system, based on the needs and requirements of its intended users, has attempted to maximize the potential to enhance self-management and increase user adherence. In this study, 8 users evaluated app functionality in long-term monitoring. A case study has presented and analyzed the particularly successful involvement with the system. However, we cannot yet claim that the Mobiab app provides people with diabetes a well-utilized tool for their self-management to help prevent complications. An assessment of the effectiveness of the app in improving self-management over time requires further studies involving a larger number of participants. Some redesign of the mobile app will probably be required owing to continuous changes in the development of mobile apps. However, the principles of the modules and functions work well and will likely be preserved.

XSL•FO

RenderX

Conflicts of Interest

None declared.

References

1. Brož J, Malinovská J, Nunes MA, Kučera K, Rožeková K, Žejglicová K, et al. Prevalence of diabetes and prediabetes and its risk factors in adults aged 25-64 in the Czech Republic: A cross-sectional study. Diabetes Res Clin Pract 2020 Dec;170:1-9. [doi: 10.1016/j.diabres.2020.108470] [Medline: 32998019]

2. International Diabetes Federation. URL: https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html [accessed 2022-01-16]

3. Zhruba milion Čechů trpí cukrovkou a nemocných neustále přibývá. Státní zdravotní ústav. URL: http://www.szu.cz/zhruba-milion-cechu-trpi-cukrovkou-a-nemocnych-neustale [accessed 2022-01-16]

4. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes Care 2010 Jan;33 Suppl 1:S62-S69 [FREE Full text] [doi: 10.2337/dc10-S062] [Medline: 20042775]

5. American Diabetes Association. Abridged for Primary Care Providers. Clin Diabetes 2021 Jan;39(1):14-43 [FREE Full text] [doi: 10.2337/cd21-as01] [Medline: 33551551]

6. Holt RIG, DeVries JH, Hess-Fischl A, Hirsch IB, Kirkman MS, Klupa T, et al. The management of type 1 diabetes in adults. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia 2021 Dec;64(12):2609-2652 [FREE Full text] [doi: 10.1007/s00125-021-05568-3] [Medline: 34590174]

7. Riddle MC, Cefalu WT, Evans PH, Gerstein HC, Nauck MA, Oh WK, et al. Consensus report: definition and interpretation of remission in type 2 diabetes. Diabetologia 2021 Nov;64(11):2359-2366. [doi: 10.1007/s00125-021-05542-z] [Medline: 34458934]

8. Donsa K, Beck P, Höll B, Mader JK, Schaupp L, Plank J, et al. Impact of errors in paper-based and computerized diabetes management with decision support for hospitalized patients with type 2 diabetes. A post-hoc analysis of a before and after study. Int J Med Inform 2016 Jun;90:58-67. [doi: 10.1016/j.ijmedinf.2016.03.007] [Medline: 27103198]

9. Adu MD, Malabu UH, Malau-Aduli AEO, Malau-Aduli BS. The development of My Care Hub Mobile-Phone App to Support Self-Management in Australians with Type 1 or Type 2 Diabetes. Sci Rep 2020 Jan 08;10(1):7 [FREE Full text] [doi: 10.1038/s41598-019-56411-0] [Medline: 31913296]

10. How Many People Have Smartphones Worldwide. BankMyCell. URL: http://www.bankmycell.com/blog/how-many-phones-are-in-the-world [accessed 2022-01-16]

11. Hood M, Wilson R, Corsica J, Bradley L, Chirinos D, Vivo A. What do we know about mobile applications for diabetes self-management? A review of reviews. J Behav Med 2016 Dec;39(6):981-994. [doi: 10.1007/s10865-016-9765-3] [Medline: 27412774]

12. Veazie S, Winchell K, Gilbert J, Paynter R, Ivlev I, Eden KB, et al. Rapid Evidence Review of Mobile Applications for Self-management of Diabetes. J Gen Intern Med 2018 Jul;33(7):1167-1176 [FREE Full text] [doi: 10.1007/s11606-018-4410-1] [Medline: 29740786]

13. Izahar S, Lean QY, Hameed MA, Murugiah MK, Patel RP, Al-Worafi YM, et al. Content Analysis of Mobile Health Applications on Diabetes Mellitus. Front Endocrinol (Lausanne) 2017;8:318 [FREE Full text] [doi: 10.3389/fendo.2017.00318] [Medline: 29230195]

14. Frøisland DH, Årsand E. Integrating visual dietary documentation in mobile-phone-based self-management application for adolescents with type 1 diabetes. J Diabetes Sci Technol 2015 May;9(3):541-548 [FREE Full text] [doi: 10.1177/1932296815576956] [Medline: 25901020]

15. Turner-McGrievy GM, Beets MW, Moore JB, Kaczynski AT, Barr-Anderson DJ, Tate DF. Comparison of traditional versus mobile app self-monitoring of physical activity and dietary intake among overweight adults participating in an mHealth weight loss program. J Am Med Inform Assoc 2013 May 01;20(3):513-518 [FREE Full text] [doi: 10.1136/amiajnl-2012-001510] [Medline: 23429637]

16. Huang Z, Tao H, Meng Q, Jing L. Management of endocrine disease. Effects of telecare intervention on glycemic control in type 2 diabetes: a systematic review and meta-analysis of randomized controlled trials. Eur J Endocrinol 2015 Mar;172(3):R93-101. [doi: 10.1530/EJE-14-0441] [Medline: 25227131]

17. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. J Med Internet Res 2014 Apr 09;16(4):e104 [FREE Full text] [doi: 10.2196/jmir.2968] [Medline: 24718852]

18. Novak D, Uller M, Rousseaux S, Mraz M, Smrz J, Stepankova O, et al. Diabetes management in OLDES project. Annu Int Conf IEEE Eng Med Biol Soc 2009;2009:7228-7231. [doi: 10.1109/IEMBS.2009.5335256] [Medline: 19965284]

19. Schmocker KS, Zwahlen FS, Denecke K. Mobile App for Simplifying Life With Diabetes: Technical Description and Usability Study of GlucoMan. JMIR Diabetes 2018 Feb 26;3(1):e6 [FREE Full text] [doi: 10.2196/diabetes.8160] [Medline: 30291070]

20. Internet v mobilu má 41 % dospělých Čechů. Český statistický úřad. URL: https://www.czso.cz/csu/czso/internet-v-mobilu-ma-41-dospelych-cechu [accessed 2022-01-16]

21. Klasnja P, Kendall L, Pratt W, Blondon K. Long-Term Engagement with Health-Management Technology: a Dynamic Process in Diabetes. AMIA Annu Symp Proc 2015;2015:756-765 [FREE Full text] [Medline: 26958211]

22. Osborn CY, van Ginkel JR, Rodbard D, Heyman M, Marrero DG, Huddleston B, et al. One Drop | Mobile: An Evaluation of Hemoglobin A1c Improvement Linked to App Engagement. JMIR Diabetes 2017 Aug 24;2(2):e21 [FREE Full text] [doi: 10.2196/diabetes.8039] [Medline: 30291059]

23. Tatara N, Arsand E, Skrøvseth SO, Hartvigsen G. Long-term engagement with a mobile self-management system for people with type 2 diabetes. JMIR Mhealth Uhealth 2013 Mar 27;1(1):e1 [FREE Full text] [doi: 10.2196/mhealth.2432] [Medline: 25100649]

24. Hou C, Carter B, Hewitt J, Francisa T, Mayor S. Do Mobile Phone Applications Improve Glycemic Control (HbA1c) in the Self-management of Diabetes? A Systematic Review, Meta-analysis, and GRADE of 14 Randomized Trials. Diabetes Care 2016 Nov;39(11):2089-2095. [doi: 10.2337/dc16-0346] [Medline: 27926892]

25. Quinn CC, Shardell MD, Terrin ML, Barr EA, Ballew SH, Gruber-Baldini AL. Cluster-randomized trial of a mobile phone personalized behavioral intervention for blood glucose control. Diabetes Care 2011 Sep;34(9):1934-1942 [FREE Full text] [doi: 10.2337/dc11-0366] [Medline: 21788632]

26. Dahlhausen F, Zinner M, Bieske L, Ehlers JP, Boehme P, Fehring L. Physicians' Attitudes Toward Prescribable mHealth Apps and Implications for Adoption in Germany: Mixed Methods Study. JMIR Mhealth Uhealth 2021 Nov 23;9(11):e33012 [FREE Full text] [doi: 10.2196/33012] [Medline: 34817385]

27. Ramakrishnan P, Yan K, Balijepalli C, Druyts E. Changing face of healthcare: digital therapeutics in the management of diabetes. Curr Med Res Opin 2021 Dec;37(12):2089-2091. [doi: 10.1080/03007995.2021.1976737] [Medline: 34511002]

28. Debong F, Mayer H, Kober J. Real-World Assessments of mySugr Mobile Health App. Diabetes Technol Ther 2019 Jun;21(S2):S235-S240. [doi: 10.1089/dia.2019.0019] [Medline: 31169427]

29. Holmen H, Torbjørnsen A, Wahl AK, Jenum AK, Småstuen MC, Arsand E, et al. A Mobile Health Intervention for Self-Management and Lifestyle Change for Persons With Type 2 Diabetes, Part 2: One-Year Results From the Norwegian Randomized Controlled Trial RENEWING HEALTH. JMIR Mhealth Uhealth 2014 Dec 11;2(4):e57 [FREE Full text] [doi: 10.2196/mhealth.3882] [Medline: 25499872]

30. Waki K, Fujita H, Uchimura Y, Omae K, Aramaki E, Kato S, et al. DialBetics: A Novel Smartphone-based Self-management Support System for Type 2 Diabetes Patients. J Diabetes Sci Technol 2014 Mar;8(2):209-215 [FREE Full text] [doi: 10.1177/1932296814526495] [Medline: 24876569]

31. Chomutare T, Fernandez-Luque L, Arsand E, Hartvigsen G. Features of mobile diabetes applications: review of the literature and analysis of current applications compared against evidence-based guidelines. J Med Internet Res 2011 Sep 22;13(3):e65 [FREE Full text] [doi: 10.2196/jmir.1874] [Medline: 21979293]

32. Shen Y, Wang F, Zhang X, Zhu X, Sun Q, Fisher E, et al. Effectiveness of Internet-Based Interventions on Glycemic Control in Patients With Type 2 Diabetes: Meta-Analysis of Randomized Controlled Trials. J Med Internet Res 2018 May 07;20(5):e172 [FREE Full text] [doi: 10.2196/jmir.9133] [Medline: 29735475]

33. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. J Med Internet Res 2016 May 16;18(5):e97 [FREE Full text] [doi: 10.2196/jmir.4883] [Medline: 27185295]

34. Böhm AK, Jensen ML, Sørensen MR, Stargardt T. Real-World Evidence of User Engagement With Mobile Health for Diabetes Management: Longitudinal Observational Study. JMIR Mhealth Uhealth 2020 Nov 06;8(11):e22212 [FREE Full text] [doi: 10.2196/22212] [Medline: 32975198]

35. Chen M, Yang J, Zhou J, Hao Y, Zhang J, Youn C. 5G-Smart Diabetes: Toward Personalized Diabetes Diagnosis with Healthcare Big Data Clouds. IEEE Commun. Mag 2018 Apr;56(4):16-23. [doi: 10.1109/mcom.2018.1700788]

36. Subramanian S, Hirsch IB. Personalized Diabetes Management: Moving from Algorithmic to Individualized Therapy. Diabetes Spectr 2014 May;27(2):87-91 [FREE Full text] [doi: 10.2337/diaspect.27.2.87] [Medline: 26246764]

37. Grant RW, Wexler DJ. Personalized medicine in Type 2 diabetes: what does the future hold? Diabetes Manag (Lond) 2012 May;2(3):199-204 [FREE Full text] [doi: 10.2217/dmt.12.15] [Medline: 23814613]

38. Gee PM, Greenwood DA, Paterniti DA, Ward D, Miller LMS. The eHealth Enhanced Chronic Care Model: a theory derivation approach. J Med Internet Res 2015 Apr 01;17(4):e86 [FREE Full text] [doi: 10.2196/jmir.4067] [Medline: 25842005]

39. Castelnuovo G, Pietrabissa G, Manzoni GM, Corti S, Ceccarini M, Borrello M, et al. Chronic care management of globesity: promoting healthier lifestyles in traditional and mHealth based settings. Front Psychol 2015;6:1557 [FREE Full text] [doi: 10.3389/fpsyg.2015.01557] [Medline: 26528215]

40. Tran V, Barnes C, Montori VM, Falissard B, Ravaud P. Taxonomy of the burden of treatment: a multi-country web-based qualitative study of patients with chronic conditions. BMC Med 2015 May 14;13:115 [FREE Full text] [doi: 10.1186/s12916-015-0356-x] [Medline: 25971838]

41. Penckofer S, Quinn L, Byrn M, Ferrans C, Miller M, Strange P. Does glycemic variability impact mood and quality of life? Diabetes Technol Ther 2012 Apr;14(4):303-310 [FREE Full text] [doi: 10.1089/dia.2011.0191] [Medline: 22324383]

42. Owens-Gary MD, Zhang X, Jawanda S, Bullard KM, Allweiss P, Smith BD. The Importance of Addressing Depression and Diabetes Distress in Adults with Type 2 Diabetes. J Gen Intern Med 2019 Feb;34(2):320-324 [FREE Full text] [doi: 10.1007/s11606-018-4705-2] [Medline: 30350030]

43. Faridi Z, Liberti L, Shuval K, Northrup V, Ali A, Katz DL. Evaluating the impact of mobile telephone technology on type 2 diabetic patients' self-management: the NICHE pilot study. J Eval Clin Pract 2008 Jun;14(3):465-469. [doi: 10.1111/j.1365-2753.2007.00881.x] [Medline: 18373577]

44. Trawley S, Baptista S, Browne JL, Pouwer F, Speight J. The Use of Mobile Applications Among Adults with Type 1 and Type 2 Diabetes: Results from the Second MILES-Australia (MILES-2) Study. Diabetes Technol Ther 2017 Dec;19(12):730-738. [doi: 10.1089/dia.2017.0235] [Medline: 29028442]

45. Baptista S, Trawley S, Pouwer F, Oldenburg B, Wadley G, Speight J. What Do Adults with Type 2 Diabetes Want from the "Perfect" App? Results from the Second Diabetes MILES: Australia (MILES-2) Study. Diabetes Technol Ther 2019 Jul;21(7):393-399. [doi: 10.1089/dia.2019.0086] [Medline: 31166804]

46. Katz D, Dalton N, Price B. 2015 Presented at: 8th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2015); February 18-21, 2015; Paris URL: https://researchportal.northumbria.ac.uk/ws/portalfiles/portal/2987132/6854b68da4e55a872a7d6ca405d4099e.pdf

47. Boyle L, Grainger R, Hall RM, Krebs JD. Use of and Beliefs About Mobile Phone Apps for Diabetes Self-Management: Surveys of People in a Hospital Diabetes Clinic and Diabetes Health Professionals in New Zealand. JMIR Mhealth Uhealth 2017 Jun 30;5(6):e85 [FREE Full text] [doi: 10.2196/mhealth.7263] [Medline: 28666975]

48. Pal K, Dack C, Ross J, Michie S, May C, Stevenson F, et al. Digital Health Interventions for Adults With Type 2 Diabetes: Qualitative Study of Patient Perspectives on Diabetes Self-Management Education and Support. J Med Internet Res 2018 Jan 29;20(2):e40 [FREE Full text] [doi: 10.2196/jmir.8439] [Medline: 29463488]

49. Peng W, Yuan S, Holtz BE. Exploring the Challenges and Opportunities of Health Mobile Apps for Individuals with Type 2 Diabetes Living in Rural Communities. Telemed J E Health 2016 Sep;22(9):733-738. [doi: 10.1089/tmj.2015.0180] [Medline: 26982017]

50. Modave F, Bian J, Rosenberg E, Mendoza T, Liang Z, Bhosale R, et al. DiaFit: The Development of a Smart App for Patients with Type 2 Diabetes and Obesity. JMIR Diabetes 2016;1(2):e5 [FREE Full text] [doi: 10.2196/diabetes.6662] [Medline: 29388609]

51. Greenwood DA, Gee PM, Fatkin KJ, Peeples M. A Systematic Review of Reviews Evaluating Technology-Enabled Diabetes Self-Management Education and Support. J Diabetes Sci Technol 2017 Sep;11(5):1015-1027 [FREE Full text] [doi: 10.1177/1932296817713506] [Medline: 28560898]

52. Doupis J, Festas G, Tsilivigos C, Efthymiou V, Kokkinos A. Smartphone-Based Technology in Diabetes Management. Diabetes Ther 2020 Mar;11(3):607-619 [FREE Full text] [doi: 10.1007/s13300-020-00768-3] [Medline: 31983028]

Abbreviations

DM: diabetes mellitus
EU: European Union
mHealth: mobile health

XSL•FO
RenderX

Original Paper

Accessibility and Openness to Diabetes Management Support With Mobile Phones: Survey Study of People With Type 1 Diabetes Using Advanced Diabetes Technologies

Yu Kuei Lin[1], MD; Caroline Richardson[2], MD; Iulia Dobrin[1]; Rodica Pop-Busui[1], MD, PhD; Gretchen Piatt[3], PhD; John Piette[4,5], PhD

[1]Department of Internal Medicine, University of Michigan Medical School, Ann Arbor, MI, United States

[2]Department of Family Medicine, University of Michigan Medical School, Ann Arbor, MI, United States

[3]Department of Learning Health Sciences, University of Michigan Medical School, Ann Arbor, MI, United States

[4]Veterans Affairs Ann Arbor Healthcare System Center for Clinical Management Research, Ann Arbor, MI, United States

[5]Department of Health Behavior and Health Education, University of Michigan School of Public Health, Ann Arbor, MI, United States

Corresponding Author:
Yu Kuei Lin, MD
Department of Internal Medicine
University of Michigan Medical School
1000 Wall Street
Ann Arbor, MI, 48105
United States
Phone: 1 734 232 1573
Email: yuklin@med.umich.edu

Abstract

Background: Little is known about the feasibility of mobile health (mHealth) support among people with type 1 diabetes (T1D) using advanced diabetes technologies including continuous glucose monitoring (CGM) systems and hybrid closed-loop insulin pumps (HCLs).

Objective: This study aims to evaluate patient access and openness to receiving mHealth diabetes support in people with T1D using CGM systems or HCLs.

Methods: We conducted a cross-sectional survey among patients with T1D using CGM systems or HCLs managed in an academic medical center. Participants reported information regarding their mobile device use; cellular call, SMS text message, or internet connectivity; and openness to various channels of mHealth communication (smartphone apps, SMS text messages, and interactive voice response [IVR] calls). Participants' demographic characteristics and CGM data were collected from medical records. The analyses focused on differences in openness to mHealth and mHealth communication channels across groups defined by demographic variables and measures of glycemic control.

Results: Among all participants (N=310; female: n=198, 63.9%; mean age 45, SD 16 years), 98.1% (n=304) reported active cellphone use and 80% (n=248) were receptive to receiving mHealth support to improve glucose control. Among participants receptive to mHealth support, 98% (243/248) were willing to share CGM glucose data for mHealth diabetes self-care assistance. Most (176/248, 71%) were open to receiving messages via apps, 56% (139/248) were open to SMS text messages, and 12.1% (30/248) were open to IVR calls. Older participants were more likely to prefer SMS text messages (*P*=.009) and IVR calls (*P*=.03) than younger participants.

Conclusions: Most people with T1D who use advanced diabetes technologies have access to cell phones and are receptive to receiving mHealth support to improve diabetes control.

KEYWORDS

XSL•FO
RenderX

Introduction

About 1.6 million people in the United States have type 1 diabetes (T1D) [1], and the prevalence continues to increase both in the United States [2] and globally [3]. Managing T1D requires comprehensive skill sets from patients and care providers including proficiency in monitoring and interpreting glucose levels, and administering appropriate doses of insulin based on a range of variables including carbohydrate intake, glucose levels, physical activity, medications, stress, illness, and recent hypoglycemic episodes [4].

Technologies, such as continuous glucose monitoring (CGM) systems and hybrid closed-loop insulin pumps (HCLs), can provide patients with T1D with real-time glucose information and algorithm-based insulin delivery [5]. CGM systems are now considered the standard of care for people with T1D [5], and the number of people using CGM systems has increased rapidly [6]. However, a significant proportion of CGM and HCL users fail to achieve optimal glucose targets [7,8] based on evidence from both clinical trials [9-13] and real-world observational studies [14-16]. Additional support for individuals with T1D beyond these technologies may be critical to optimize diabetes control and minimize complications [17].

More than 85% of the US [18,19] and 48% of the global population [20] uses a smartphone, and nearly half of US smartphone users use their mobile devices to access information and track progress on health-related goals [19]. Health support via mobile devices (ie, mobile health [mHealth]) thus offers a great opportunity to improve access to effective behavioral interventions [21]. The field of mHealth includes a variety of digital tools and communication channels, including smartphone apps, SMS text messages, and interactive voice response (IVR) calls to deliver information and behavior change support [22]. Studies demonstrate that these digital aids can improve patient diabetes knowledge and reduce hyperglycemia [23-25] through digitalized diabetes education, enhanced communications, and incorporations of patient-generated data [23,26]. In 2020, an international collaborative published a consensus on future directions in diabetes mHealth, including diversifying interventions to meet the needs of heterogeneous diabetes populations [21]. Other frameworks for further enhancing technology-enabled diabetes care emphasized the significance of data-driven, two-way feedback loops [27,28] for personalizing and targeting programs that improve T1D self-management.

Given that CGM systems provide data about glucose levels in real time, opportunities exist for the development of T1D mHealth support programs that retrieve data continuously and use that information to deliver timely and personalized patient feedback [27]. However, little is known about mobile phone use among people with T1D using advanced diabetes technologies. In addition, people's receptivity to mHealth programs may vary according to their demographic characteristics and glycemic control, and some patients may not be comfortable sharing CGM data with mHealth platforms. Finally, there is a lack of information on people's relative openness to various communication channels including smartphone apps, SMS text messages, and IVR calls.

To address these gaps in knowledge, we conducted a survey among a large sample of individuals with T1D using CGM systems and receiving diabetes care in an academic medical center. Here we report the findings from that survey including information about participants' access to mobile technology; receptivity to mHealth interventions that require sharing their CGM data; and openness to communication via stand-alone apps, SMS text messaging, or IVR calls.

Methods

Ethics Approval

The survey was conducted between January and April 2021 after receiving approval from the University of Michigan Institutional Review Board (HUM00189672). The sampling frame for the survey was the population of adults with T1D receiving care through outpatient clinics associated with the University of Michigan Health System.

Setting and Recruitment

The University of Michigan Health is a tertiary health center that provides health care to the surrounding communities, with more than 1 million people living in southeastern Michigan, and regularly supports diabetes care for about 3000 adults with T1D. A total of 1024 adults with diagnoses of T1D and ongoing CGM use were identified from the electronic medical record (EMR) system and invited via emails sent through REDCap. Candidates with missing or invalid email addresses were contacted via postal letters and telephone calls. The investigators avoided directly contacting their own patients for recruitment to prevent possible coercion or sampling biases. Survey participants provided written informed consent for linkage of their surveys with demographic data from the EMR and glucose data from their CGM systems. All people determined to be aged ≥18 years, have T1D, and use CGM systems based on EMRs were included in the study and analyses. Participants without 4-week CGM data within the past 3 months were excluded from the analyses involving CGM data.

Survey Measures

The survey assessed participants' durations of diabetes, CGM type and use duration, and insulin pump use information. Cellphone use, including the frequency of the participant carrying the cellphone ("How often do you have your cellphone with you?") and cellular connectivity for calls and SMS text messages ("How often does your cellphone have good reception for text messages or phone calls?"), and internet access ("How often does your cellphone have access to the internet?") at home, at work, and outside of home and work were assessed. Items developed for the study asked about participants' receptivity to mHealth diabetes interventions and openness to different mHealth communication channels. Specifically, we asked "Cellphones could be used for receiving on-site, real-time support as we often carry them around...If you could get additional support at the time of high or low glucose levels to help you with your glucose control, which method(s) would you prefer?" (The response options were apps, SMS text messages, IVR calls, and "do not want diabetes support delivered through cellphone.") Participants could select more

than one communication channel option as their response. Surveys also assessed participants' willingness to share real-time CGM information for glucose control support. Participants were encouraged to complete the survey directly via REDCap. Study team members conducted telephone surveys for participants without immediate access to the internet.

EMRs Review and CGM Data Collection

Participants' age, sex, race, ethnicity, and hemoglobin A_{1c} (HbA_{1c}) levels were abstracted from the EMR. Recent CGM data [29] (ie, within 3 months prior to survey completion) were abstracted from CGM glucose reports uploaded to EMRs or directly from participants with CGM glucose information portals [30,31]. CGM data were collected for 4 weeks for the following measures: percent of time using a CGM system, average glucose level, percent of time spent with glucose levels above 180 (time above range [TAR]) and above 250 mg/dL, and percent of time below 70 (time below range [TBR]) and below 54 (50 for Medtronic CGM system) mg/dL [8].

Statistical Analysis

Using the Cochran formula, we calculated that a sample of 280 respondents was needed to determine the prevalence of people receptive to mHealth diabetes interventions at a 95% confidence level with 5% precision for a pool of 1024 potential respondents. We conducted descriptive analyses of participants' demographics characteristics and CGM glucose data. The Mann-Whitney U test was used to evaluate the difference in age and HbA_{1c} levels between participants and nonrespondents; differences in age, diabetes duration, and CGM glucose information between participants who were versus were not receptive to receiving mHealth interventions; differences in patient characteristics of respondents who were open to receiving mHealth support through various communication channels; and differences in TAR and TBR between female and male participants. Logistic regression analysis was used to evaluate sex differences between participants receptive versus unreceptive to receiving mHealth support and open to various communication channels for receiving mHealth support. For the analyses evaluating the characteristics of respondents open to various communication channels (ie, app vs SMS text message, app vs IVR calls, and SMS text messages vs IVR calls), participants who selected both communication channels were excluded from the analyses. $P<.05$ was considered to be statistically significant.

Results

Participant Characteristics

A total of 310 eligible participants completed the survey (Table 1), and 4-week CGM data within the last 3 months were successfully collected from 277 (89.4%) participants (Figure 1). There was no significant difference in age or HbA_{1c} levels between participants and other contacted candidates who did not complete the survey. A higher proportion of responders were female (n=198, 63.9%) compared to nonrespondents (360/714, 50.4%). No significant differences in TAR and TBR were identified between female and male participants.

Table 1. Participant demographics (N=310).

Characteristics	Participants
Sex, n (%)	
Female	198 (63.9)
Male	112 (36.1)
Age (years), mean (SD)	45 (16)
Age (years), median (IQR)	43 (31-58)
Race, n (%)	
White or Caucasian	289 (93.2)
Black or African American	10 (3.2)
Asian	3 (1.0)
Refused to answer/unknown	1 (0.3)
Other	7 (2.3)
Ethnicity, n (%)	
Non-Hispanic	295 (95.2)
Hispanic	9 (2.9)
Refused to answer/unknown	6 (1.9)
Duration of diabetes (years), median (IQR)	23 (14-32)
Duration of CGM[a] use, n (%)	
0-3 months	9 (2.9)
4-6 months	13 (4.2)
7-12 months	23 (7.4)
1 year to 3 years	131 (42.3)
4-6 years	80 (25.8)
>6 years	54 (17.4)
CGM model, n (%)	
Dexcom G5	4 (1.3)
Dexcom G6	277 (89.4)
Medtronic Guardian Sensor 3	29 (9.4)
Using insulin pump, n (%)	245 (79.0)
With auto-suspension features	164 (52.9)
With closed-loop features	149 (48.1)
Last HbA_{1c}[b] level (%), median (IQR)	7.2 (6.5-7.8)
Time of CGM use (%), median (IQR)	97 (88-99)
CGM average glucose level (mg/dL), median (IQR)	159 (143-178)
TAR[c] on CGM (%), median (IQR)	32 (20-44)
TBR[d] on CGM (%), median (IQR)	1.4 (0.6-3.0)

[a]CGM: continuous glucose monitoring.

[b]HBA_{1c}: hemoglobin A_{1c}.

[c]TAR: time above range.

[d]TBR: time below range.

XSL·FO
RenderX

Figure 1. Patient participation flowchart. CGM: continuous glucose monitoring.
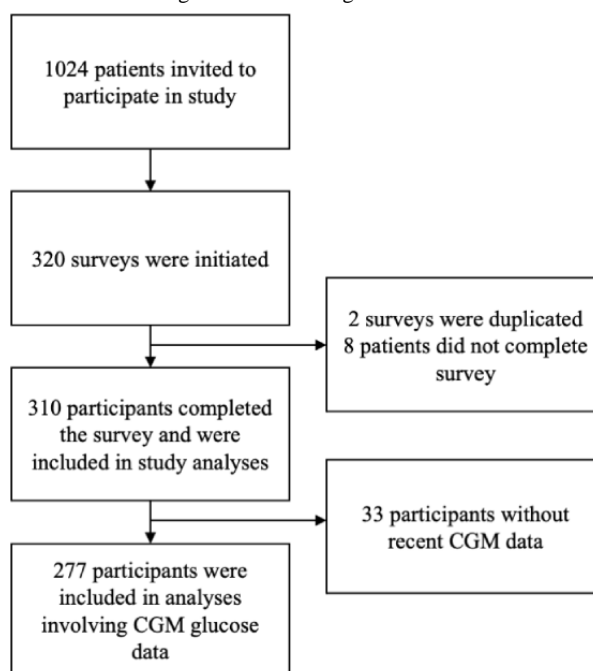
Access to mHealth

Of all 310 participants, 304 (98.1%) reported using cellphones. All these individuals reported using a smartphone, with 68.1% (207/304) using an iPhone and 29.9% (91/304) using an Android phone. About 90.1% (274/304) of participants reported carrying their mobile devices with them all or most of the time and that their mobile devices have connectivity for phone calls, SMS text messages, and the internet all or most of the time (Table 2). Participants were least likely to have their phones with them while at work and were least likely to have internet access when outside of home and work.

Table 2. Accessibility to mobile health support (N=310).

	Having cellphone accompanied, n (%)	Good reception for phone calls or SMS text messages, n (%)	Having access to the internet, n (%)
At home			
All the time	185 (59.7)	187 (60.3)	226 (72.9)
Most of the time	105 (33.9)	109 (35.2)	68 (21.9)
About half of the time	12 (3.9)	9 (2.9)	9 (2.9)
Less than half of the time	4 (1.3)	3 (1.0)	4 (1.3)
Rarely	4 (1.3)	2 (0.6)	3 (1.0)
At work			
All the time	195 (62.9)	170 (54.8)	217 (70.0)
Most of the time	81 (26.1)	116 (37.4)	68 (21.9)
About half of the time	8 (2.6)	16 (5.2)	15 (4.8)
Less than half of the time	9 (2.9)	2 (0.6)	1 (0.3)
Rarely	17 (5.5)	6 (1.9)	9 (2.9)
Outside of home and work			
All the time	225 (72.6)	114 (36.8)	121 (39.0)
Most of the time	73 (23.5)	183 (59.0)	145 (46.8)
About half of the time	8 (2.6)	9 (2.9)	22 (7.1)
Less than half of the time	4 (1.3)	3 (1.0)	15 (4.8)
Rarely	0 (0.0)	1 (0.3)	7 (2.3)

Receptivity to mHealth Support

Of the 310 participants, 248 (80%) were receptive to receiving diabetes self-care support through their phones with the goal of improving their glucose control. There were no significant differences in sex, age, diabetes duration, average glucose level, TAR, TBR, and the percent of time spent with glucose levels above 250 mg/dL and below 54 mg/dL between those who were versus were not receptive to receiving mHealth support. Among participants receptive to mHealth support, 98% (243/248) responded that they would "very much" or "probably" be willing to share real-time glucose level data to receive tailored support for diabetes management.

Openness to Various Communication Channels for Receiving mHealth Support

Among those who were receptive to mHealth support, 71% (176/248) were open to receiving support via apps, 56% (139/248) were open to SMS text messages, and 12.1% (30/248) were open to IVR calls. Participants open to apps but not IVR calls were younger than those open to IVR calls but not apps (Table 3). Similarly, participants open to apps but not SMS text messages were younger than those open to SMS text messages but not apps. No significant differences in diabetes duration, average glucose level, TAR, TBR, and time spent above 250 mg/dL or below 54 mg/dL were observed between those who were open to receiving diabetes support through apps, SMS text messages, or IVR calls. We also observed no sex differences in those open to various communication channels.

Table 3. Patient demographics and glycemic characteristics grouped by openness to mobile health communication channels.

	Apps, median (IQR)	SMS text messages, median (IQR)	IVR[a] calls, median (IQR)	P value[b]		
				Apps vs SMS text messages[c]	Apps vs IVR calls[c]	SMS text messages vs IVR calls[c]
Age (years)	40 (28-54)	44 (32-58)	53 (36-64)	.009	.03	.12
Duration of diabetes (years)	24 (14-32)	23 (12-32)	21 (15-40)	.45	.98	.05
Average glucose level (mg/dL)	158 (143-175)	157 (141-176)	153 (145-182)	.88	.57	.99
TAR[d] (%)	30 (19-42)	31 (18-43)	30 (20-45)	.99	.50	.79
Time with glucose level >250 mg/dL (%)	7 (2-13)	7 (2-13)	5 (2-14)	.98	.95	.69
TBR[e] (%)	1.4 (0.5-3.0)	1.5 (0.7-3.0)	2.4 (0.8-3.8)	.51	.90	.05
Time with glucose level <54 mg/dL (%)	0.2 (0-0.6)	0.2 (0-0.5)	0.2 (0-0.7)	.58	.13	.44

[a]IVR: interactive voice response.

[b]Statistical analysis conducted with the Mann-Whitney U test.

[c]Participants who selected both communication channels were excluded from the analysis.

[d]TAR: time above range.

[e]TBR: time below range.

Discussion

Principal Findings

In this survey of a large sample of people with T1D who used CGM systems and HCLs, nearly all participants used smartphones, and nearly all reported the ability to make phone calls, receive SMS text messages, and connect to the internet most of the time. Participants were receptive to receiving support for diabetes care, including being willing to share CGM data automatically so that mHealth support could be personalized based on their clinical needs. When asked about their openness to various communication channels for receiving mHealth support, the majority were open to apps or SMS text messaging, and only a smaller proportion of individuals indicated openness to receiving IVR calls. Older participants preferred to receive

mHealth support through SMS text messaging or IVR calls over apps.

Comparison to Prior Work and Implications for Future Research

Prior studies have shown that adolescents with T1D are receptive to self-management assistance via mHealth tools [32]. This study adds to this body of evidence on the accessibility and receptivity to using mHealth interventions among adults with T1D who use advanced diabetes technologies to monitor their glycemic control and manage insulin administration. mHealth tools have the capability of providing two-way communication for effective interventions [27]. Advances in these apps have used artificial intelligence (AI) and adaptive messages based on individuals' status [33] to further personalize the support and target individuals' ongoing needs. Given that in this study the majority of CGM and HCL users reported that they were

willing to share real-time glucose information for timely support, incorporations of AI-based prediction of hypoglycemia [34] and adaptive tuning of bolus insulin parameters to prevent hyperglycemia [35] into mHealth could be considered as future research directions.

This study demonstrates that most advanced diabetes technology users are receptive to receiving mHealth support that could enhance their ability and motivation for effective self-care behaviors beyond the simple alarms for hypo- and hyperglycemia currently available via CGM systems and HCLs. Alarm fatigue can lead to turning off the hypo/hyperglycemia alarms or simply ignoring them [36]. Personalized interventions triggered by glucose levels could avoid alarm fatigue using tailored messaging supported by behavioral theories [37] for the generation of practical and culturally sensitive content [38].

We found that the majority of T1D advanced diabetes technology users were open to smartphone apps. However, a significant proportion also favored other communication channels such as SMS text messages and IVR calls, particularly those who were older. This finding underscores the significance of maintaining a diversity of mHealth approaches to promote intervention engagement in heterogeneous diabetes populations [21].

Strengths and Limitations

This study is one of the first to report information related to the feasibility and potential interest in mHealth support among people with T1D using advanced diabetes technologies. Comparisons of characteristics of respondents to nonrespondents identified only a relatively small difference in the sex distribution, and analysis of survey data did not suggest that sex was related to any of the outcomes of interest. Glycemic indexes, including CGM glucose information, confirmed that both patient populations with and without controlled diabetes were receptive to receiving mHealth support.

Several limitations of this study should be considered. Participants were recruited from a population receiving care in a single tertiary academic health center. However, this health care system also has outreach clinics and medical services providing care to >1 million people in surrounding communities. The distribution of participants across racial/ethnicity groups and the proportion reporting use of an insulin pump were similar to the 2016-2018 T1D Exchange national report [6]. With the expanding use of smartphones in the United States [18,19] and increasing implementation of CGM systems [6], the findings are most applicable to tertiary health care centers and may be generalizable to other US T1D populations. Additionally, detailed information about the preferred features of mHealth apps, SMS text messages, and IVR intervention, including the timing and frequency of communication, were not collected. Future research should seek to deepen our understanding of these key dimensions of intervention design.

Conclusions

We found that people with T1D using advanced diabetes technologies have access to mobile technologies and are receptive to receiving mHealth support for improving diabetes control. The majority of people in this population are open to smartphone apps or SMS text messages, and older individuals may favor SMS text messages or IVR calls for mHealth support.

Data Availability

The data sets generated and analyzed during the study are available from the corresponding author on reasonable request.

Authors' Contributions

YKL and JP proposed the study. YKL, CR, RPB, GP, and JP designed the study and study instruments. YKL and ID collected study data. YKL, CR, RPB, GP, and JP conducted the analysis and interpreted the results. All authors contributed to the manuscript and reviewed the manuscript before submission.

Conflicts of Interest

None declared.

References

1.   National Diabetes Statistics Report 2020: estimates of diabetes and its burden in the United States. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf [accessed 2021-09-19]

2.   Rogers M, Kim C, Banerjee T, Lee J. Fluctuations in the incidence of type 1 diabetes in the United States from 2001 to 2015: a longitudinal study. BMC Med 2017 Nov 08;15(1):199 [FREE Full text] [doi: 10.1186/s12916-017-0958-6] [Medline: 29115947]

3.   Mobasseri M, Shirmohammadi M, Amiri T, Vahed N, Hosseini Fard H, Ghojazadeh M. Prevalence and incidence of type 1 diabetes in the world: a systematic review and meta-analysis. Health Promot Perspect 2020;10(2):98-115 [FREE Full text] [doi: 10.34172/hpp.2020.18] [Medline: 32296622]

4.   Cradock S, Cranston IC. Type 1 diabetes education and care: time for a rethink? Diabet Med 2012 Feb;29(2):159-160. [doi: 10.1111/j.1464-5491.2011.03518.x] [Medline: 22060192]

5.   American Diabetes Association. 7. Diabetes technology: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S85-S99. [doi: 10.2337/dc21-S007] [Medline: 33298418]

6.   Foster NC, Beck RW, Miller KM, Clements MA, Rickels MR, DiMeglio LA, et al. State of type 1 diabetes management and outcomes from the T1D exchange in 2016-2018. Diabetes Technol Ther 2019 Feb;21(2):66-72 [FREE Full text] [doi: 10.1089/dia.2018.0384] [Medline: 30657336]

7.   American Diabetes Association. 6. Glycemic targets: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S73-S84. [doi: 10.2337/dc21-S006] [Medline: 33298417]

8.   Battelino T, Danne T, Bergenstal RM, Amiel SA, Beck R, Biester T, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the international consensus on time in range. Diabetes Care 2019 Aug;42(8):1593-1603 [FREE Full text] [doi: 10.2337/dci19-0028] [Medline: 31177185]

9.   Lind M, Polonsky W, Hirsch IB, Heise T, Bolinder J, Dahlqvist S, et al. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: the GOLD randomized clinical trial. JAMA 2017 Jan 24;317(4):379-387. [doi: 10.1001/jama.2016.19976] [Medline: 28118454]

10. Beck RW, Riddlesworth T, Ruedy K, Ahmann A, Bergenstal R, Haller S, DIAMOND Study Group. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: the DIAMOND randomized clinical trial. JAMA 2017 Jan 24;317(4):371-378. [doi: 10.1001/jama.2016.19975] [Medline: 28118453]

11. Brown SA, Kovatchev BP, Raghinaru D, Lum JW, Buckingham BA, Kudva YC, iDCL Trial Research Group. Six-month randomized, multicenter trial of closed-loop control in type 1 diabetes. N Engl J Med 2019 Oct 31;381(18):1707-1717 [FREE Full text] [doi: 10.1056/NEJMoa1907863] [Medline: 31618560]

12. Hásková A, Radovnická L, Petruželková L, Parkin CG, Grunberger G, Horová E, et al. Real-time CGM is superior to flash glucose monitoring for glucose control in type 1 diabetes: the CORRIDA randomized controlled trial. Diabetes Care 2020 Nov;43(11):2744-2750 [FREE Full text] [doi: 10.2337/dc20-0112] [Medline: 32859607]

13. Brown SA, Forlenza GP, Bode BW, Pinsker JE, Levy CJ, Criego AB, Omnipod 5 Research Group. Multicenter trial of a tubeless, on-body automated insulin delivery system with customizable glycemic targets in pediatric and adult participants with type 1 diabetes. Diabetes Care 2021 Jul;44(7):1630-1640 [FREE Full text] [doi: 10.2337/dc21-0172] [Medline: 34099518]

14. Da Silva J, Bosi E, Jendle J, Arrieta A, Castaneda J, Grossman B, et al. Real-world performance of the MiniMed™ 670G system in Europe. Diabetes Obes Metab 2021 Aug;23(8):1942-1949. [doi: 10.1111/dom.14424] [Medline: 33961340]

15. Breton MD, Kovatchev BP. One year real-world use of the control-IQ advanced hybrid closed-loop technology. Diabetes Technol Ther 2021 Sep;23(9):601-608 [FREE Full text] [doi: 10.1089/dia.2021.0097] [Medline: 33784196]

16. DuBose SN, Bauza C, Verdejo A, Beck RW, Bergenstal RM, Sherr J, HYCLO Study Group. Real-world, patient-reported and clinic data from individuals with type 1 diabetes using the MiniMed 670G Hybrid Closed-Loop System. Diabetes Technol Ther 2021 Dec;23(12):791-798. [doi: 10.1089/dia.2021.0176] [Medline: 34524023]

17. Choudhary P, Amiel SA. Hypoglycaemia in type 1 diabetes: technological treatments, their limitations and the place of psychology. Diabetologia 2018 Apr;61(4):761-769 [FREE Full text] [doi: 10.1007/s00125-018-4566-6] [Medline: 29423581]

18. Mobile fact sheet. Pew Research Center. URL: https://www.pewresearch.org/internet/fact-sheet/mobile/ [accessed 2021-09-21]

19. Rising CJ, Jensen RE, Moser RP, Oh A. Characterizing the US population by patterns of mobile health use for health and behavioral tracking: analysis of the National Cancer Institute's Health Information National Trends Survey Data. J Med Internet Res 2020 May 14;22(5):e16299 [FREE Full text] [doi: 10.2196/16299] [Medline: 32406865]

20. How many smartphones are in the world? BankMyCell. URL: https://www.bankmycell.com/blog/how-many-phones-are-in-the-world [accessed 2021-09-08]

21. Fleming GA, Petrie JR, Bergenstal RM, Holl RW, Peters AL, Heinemann L. Diabetes digital app technology: benefits, challenges, and recommendations. A consensus report by the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group. Diabetologia 2020 Feb;63(2):229-241. [doi: 10.1007/s00125-019-05034-1] [Medline: 31802144]

22. Piette JD, List J, Rana GK, Townsend W, Striplin D, Heisler M. Mobile health devices as tools for worldwide cardiovascular risk reduction and disease management. Circulation 2015 Nov 24;132(21):2012-2027 [FREE Full text] [doi: 10.1161/CIRCULATIONAHA.114.008723] [Medline: 26596977]

23. Nkhoma DE, Soko CJ, Bowrin P, Manga YB, Greenfield D, Househ M, et al. Digital interventions self-management education for type 1 and 2 diabetes: a systematic review and meta-analysis. Comput Methods Programs Biomed 2021 Oct;210:106370. [doi: 10.1016/j.cmpb.2021.106370] [Medline: 34492544]

24. Umaefulam V, Premkumar K. Impact of mobile health in diabetic retinopathy awareness and eye care behavior among Indigenous women. Mhealth 2020;6:14. [doi: 10.21037/mhealth.2019.12.01] [Medline: 32270006]

25. Schoenthaler A, Leon M, Butler M, Steinhaeuser K, Wardzinski W. Development and evaluation of a tailored mobile health intervention to improve medication adherence in black patients with uncontrolled hypertension and type 2 diabetes: pilot randomized feasibility trial. JMIR Mhealth Uhealth 2020 Sep 23;8(9):e17135 [FREE Full text] [doi: 10.2196/17135] [Medline: 32965230]

26. Greenwood DA, Gee PM, Fatkin KJ, Peeples M. A systematic review of reviews evaluating technology-enabled diabetes self-management education and support. J Diabetes Sci Technol 2017 Sep;11(5):1015-1027 [FREE Full text] [doi: 10.1177/1932296817713506] [Medline: 28560898]

27. Greenwood DA, Howell F, Scher L, Yousef G, Rinker J, Yehl K, et al. A framework for optimizing technology-enabled diabetes and cardiometabolic care and education: the role of the diabetes care and education specialist. Diabetes Educ 2020 Aug;46(4):315-322. [doi: 10.1177/0145721720935125] [Medline: 32780001]

28. Reidy C, Foster C, Rogers A. A facilitated web-based self-management tool for people with type 1 diabetes using an insulin pump: intervention development using the Behavior Change Wheel and Theoretical Domains Framework. J Med Internet Res 2020 May 01;22(5):e13980 [FREE Full text] [doi: 10.2196/13980] [Medline: 32356776]

29. Riddlesworth TD, Beck RW, Gal RL, Connor CG, Bergenstal RM, Lee S, et al. Optimal sampling duration for continuous glucose monitoring to determine long-term glycemic control. Diabetes Technol Ther 2018 Apr;20(4):314-316. [doi: 10.1089/dia.2017.0455] [Medline: 29565197]

30. Dexcom Clarity. URL: https://clarity.dexcom.com/ [accessed 2021-09-04]

31. Medtronic: CareLink System. URL: https://carelink.medtronic.com/ [accessed 2021-09-04]

32. Dobson R, Whittaker R, Murphy R, Khanolkar M, Miller S, Naylor J, et al. The use of mobile health to deliver self-management support to young people with type 1 diabetes: a cross-sectional survey. JMIR Diabetes 2017 Feb 15;2(1):e4 [FREE Full text] [doi: 10.2196/diabetes.7221] [Medline: 30291057]

33. Piette JD, Krein SL, Striplin D, Marinec N, Kerns RD, Farris KB, et al. Patient-centered pain care using artificial intelligence and mobile health tools: protocol for a randomized study funded by the US Department of Veterans Affairs Health Services Research and Development Program. JMIR Res Protoc 2016 Apr 07;5(2):e53 [FREE Full text] [doi: 10.2196/resprot.4995] [Medline: 27056770]

34. Dave D, DeSalvo DJ, Haridas B, McKay S, Shenoy A, Koh CJ, et al. Feature-based machine learning model for real-time hypoglycemia prediction. J Diabetes Sci Technol 2021 Jul;15(4):842-855 [FREE Full text] [doi: 10.1177/1932296820922622] [Medline: 32476492]

35. Vettoretti M, Cappon G, Facchinetti A, Sparacino G. Advanced diabetes management using artificial intelligence and continuous glucose monitoring sensors. Sensors (Basel) 2020 Jul 10;20(14):3870 [FREE Full text] [doi: 10.3390/s20143870] [Medline: 32664432]

36. Anhalt H. Limitations of continuous glucose monitor usage. Diabetes Technol Ther 2016 Mar;18(3):115-117. [doi: 10.1089/dia.2016.0011] [Medline: 26983025]

37. Nundy S, Dick JJ, Solomon MC, Peek ME. Developing a behavioral model for mobile phone-based diabetes interventions. Patient Educ Couns 2013 Jan;90(1):125-132 [FREE Full text] [doi: 10.1016/j.pec.2012.09.008] [Medline: 23063349]

38. Maar MA, Yeates K, Toth Z, Barron M, Boesch L, Hua-Stewart D, et al. Unpacking the black box: a formative research approach to the development of theory-driven, evidence-based, and culturally safe text messages in mobile health interventions. JMIR Mhealth Uhealth 2016 Jan 22;4(1):e10 [FREE Full text] [doi: 10.2196/mhealth.4994] [Medline: 26800712]

Abbreviations

AI: artificial intelligence
CGM: continuous glucose monitoring
EMR: electronic medical record
HbA$_{1c}$: hemoglobin A$_{1c}$
HCL: hybrid closed-loop insulin pump
IVR: interactive voice response
mHealth: mobile health
T1D: type 1 diabetes
TAR: time above range
TBR: time below range

XSL•FO
RenderX

Original Paper

Evaluating the Implementation of the GREAT4Diabetes WhatsApp Chatbot to Educate People With Type 2 Diabetes During the COVID-19 Pandemic: Convergent Mixed Methods Study

Robert Mash[1], MBChB, PhD; Darcelle Schouw[1], BA (Sports Sc), BA (Hons Biokinetics), MSc (Sports Sc), PhD; Alex Emilio Fischer[2], BSc, MPH, MBA

[1]Faculty of Medicine and Health Sciences, Stellenbosch University, Cape Town, South Africa

[2]Aviro Health, Cape Town, South Africa

Corresponding Author:
Robert Mash, MBChB, PhD
Faculty of Medicine and Health Sciences
Stellenbosch University
Francie van Zijl Rd
Tygerberg
Cape Town, 7505
South Africa
Phone: 27 219389170
Email: rm@sun.ac.za

Abstract

Background: In South Africa, diabetes is a leading cause of morbidity and mortality, which was exacerbated during the COVID-19 pandemic. Most education and counseling activities were stopped during the lockdown, and the GREAT4Diabetes WhatsApp Chatbot was innovated to fill this gap.

Objective: This study aimed to evaluate the implementation of the chatbot in Cape Town, South Africa, between May and October 2021.

Methods: Convergent mixed methods were used to evaluate the implementation outcomes: acceptability, adoption, appropriateness, feasibility, fidelity, cost, coverage, effects, and sustainability. Quantitative data were derived from the chatbot and analyzed using the SPSS. Qualitative data were collected from key informants and analyzed using the framework method assisted by Atlas-ti. The chatbot provided users with 16 voice messages and graphics in English, Afrikaans, or Xhosa. Messages focused on COVID-19 infection and self-management of type 2 diabetes.

Results: The chatbot was adopted by the Metro Health Services to assist people with diabetes who had restricted health care during the lockdown and were at a higher risk of hospitalization and death from COVID-19 infection. The chatbot was disseminated via health care workers in primary care facilities and local nonprofit organizations and via local media and television. Two technical glitches interrupted the dissemination but did not substantially affect user behavior. Minor changes were made to the chatbot to improve its utility. Many patients had access to smartphones and were able to use the chatbot via WhatsApp. Overall, 8158 people connected with the chatbot and 4577 (56.1%) proceeded to listen to the messages, with 12.56% (575/4577) of them listening to all 16 messages, mostly within 32 days. The incremental setup costs were ZAR 255,000 (US $16,876) and operational costs over 6 months were ZAR 462,473 (US $30,607). More than 90% of the users who listened to each message found them useful. Of the 533 who completed the whole program, 351 (71.1%) said they changed their self-management a lot and 87.6% (369/421) were more confident. Most users changed their lifestyles in terms of diet (315/414, 76.1%) and physical activity (222/414, 53.6%). Health care workers also saw benefits to patients and recommended that the service continues. Sustainability of the chatbot will depend on the future policy of the provincial Department of Health toward mobile health and the willingness to contract with Aviro Health. There is the potential to go to scale and include other languages and chronic conditions.

Conclusions: The chatbot shows great potential to complement traditional health care approaches for people with diabetes and assist with more comprehensive patient education. Further research is needed to fully explore the patient's experience of the chatbot and evaluate its effectiveness in our context.

(JMIR Diabetes 2022;7(2):e37882) doi:10.2196/37882

XSL•FO
RenderX

Introduction

Background

Diabetes is the leading cause of death in women in South Africa and the second overall cause of death after tuberculosis [1]. One in four South Africans aged >45 years have diabetes, and in Cape Town, even higher prevalence rates have been reported [2]. There are approximately 100,000 people with diabetes in the Cape Town Metro Health Services (MHS) database [3].

During the COVID-19 pandemic, the de-escalation of facility-based primary care meant that people attended the facilities less often and many received their medication via home delivery [4]. Support groups and group empowerment were mostly stopped, and individual patient education and counseling were much less frequent. At the same time, people with diabetes were among those most at risk of hospitalization and death from COVID-19 infection, especially if they had poorly controlled diabetes [5,6].

Therefore, alternative mechanisms were necessary to improve patient education, self-management, and levels of glycemic control, while maintaining physical distance and de-escalation of services. In South Africa, cell phone coverage is estimated at 82% of the population and extends to all socioeconomic groups [7]. The South African National Department of Health has promoted strategies to improve health through mobile health (mHealth) technology [8]. So far, most initiatives have focused on maternal health and HIV, with very few targeting noncommunicable diseases [9,10].

A review of systematic reviews on the effectiveness of mHealth interventions on diabetes and obesity treatment concluded that mHealth is a useful tool that can reduce the hemoglobin A_{1c} (HbA$_{1c}$; −0.3% to −0.5%) level and weight (−1.0 to −2.4 kg) [11]. A systematic review and meta-analysis of 24 clinical trials also concluded that tailored mobile educational messages can improve HbA$_{1c}$ levels in patients with type 2 diabetes [12].

A few studies have been conducted earlier on WhatsApp messaging and type 2 diabetes. In South Africa, people with diabetes said that WhatsApp was their preferred technology and wanted education to focus on diet, nutrition, and physical activity [13]. Clinical trials in the United States, Brazil, and Saudi Arabia have shown that WhatsApp education programs can be effective in improving knowledge, self-efficacy, adherence, and glycemic control (a reduction of approximately 0.6% in the HbA$_{1c}$ level) [14-16]. WhatsApp education can also be as effective as group education programs [17]. However, little research has investigated WhatsApp messaging for diabetes in low- and middle-income countries.

The Division of Family Medicine and Primary Care at Stellenbosch University, in partnership with the MHS and Aviro Health, designed a project to provide patient education to people with type 2 diabetes in the MHS via audio messages in WhatsApp during the COVID-19 pandemic. During the crisis, this approach to disseminating messages was shown to be successful in other sectors, such as education and religion, where daily church services were sent to poor communities using WhatsApp audio files [18-20].

Objectives

The aim of this study was to evaluate the implementation of the GREAT4Diabetes WhatsApp Chatbot education program in the MHS. This study focused on a range of implementation outcomes: adoption, appropriateness, acceptability, feasibility, fidelity, coverage, cost, effects, and sustainability of the initiative.

Methods

Study Design

A convergent mixed methods study combined quantitative and qualitative data to evaluate the implementation outcomes (Textbox 1). The evaluation focused on the initial implementation of the chatbot in the Northern Tygerberg Substructure (NTSS) over a 6-month period from May to October 2021.

Textbox 1. Description of the implementation outcomes.

Implementation outcome and description

- Acceptability: Why did stakeholders perceive that it was worth doing? What were the factors for and against this?

- Adoption: Why did stakeholders decide to adopt the intervention? What were the key factors they considered in making this decision?

- Appropriateness: Did stakeholders perceive that the intervention was fit for purpose?

- Feasibility: How feasible was it to implement successfully? What were the factors that enabled and hindered implementation?

- Fidelity: How was the intervention modified or customized to make it work? Why was this necessary?

- Coverage: How many people were reached and who were they?

- Cost: What were the incremental setup and operational costs?

- Effects: What was the effect on people's self-management?

- Sustainability: Should this be sustained? What are the future opportunities and threats to the sustainability of the intervention? Can implementation be taken to scale?

Setting

The MHS served the uninsured population of Cape Town who were dependent on the public sector. The population of the NTSS was estimated at 1,081,292 in 2019, and 78% to 90% of the population were uninsured and dependent on the public sector [21]. The leading causes of premature death were interpersonal violence, HIV or AIDS, ischemic heart disease, tuberculosis, stroke, road injuries, diabetes, and lung cancer. Health services in the NTSS were provided by 3 community health centers (open 24 hours) and 11 community day centers (open office hours). These primary care facilities included medical officers, nurse practitioners, and other members of a multidisciplinary team, and each community health center had a family physician (specialist in family medicine). Community-based services were offered via nonprofit organizations under contracts with the MHS. They employed teams of community health workers (CHWs) coordinated by professional nurses and responsible for designated communities (1 CHW for approximately 250 households). The CHWs would visit all the households that they were responsible for on a regular basis. The CHW teams were also connected to a specific primary care facility to form a larger primary health care team comprising facility-based and community-based health workers.

Design of the Intervention

The intervention consisted of 16 three- to four-minute audio messages, which were sometimes supported by a picture (Figure 1). Once a person with diabetes sent the message *Hi* to the designated WhatsApp number, they registered for the program, accepted the standard terms and conditions of Aviro Health and shared key information (age, gender, and language preference). They then automatically received the first audio message. After each message, they had to reply to a question (whether the message was useful) to receive the next message. They could stop receiving messages at any time and were asked to provide a reason for stopping. After the last message, they were asked several questions about self-management of diabetes (Did they change their behavior? What behavior did they change? Did their confidence improve?) and were also able to give free-text feedback.

The content of the audio messages was derived from the Group Empowerment and Training (GREAT) program [22], which was rolled out nationally before the COVID-19 pandemic. The audio messages were recorded in English, Afrikaans, and Xhosa, in a professional recording studio, by members of the GREAT team from Stellenbosch University. Aviro Health was responsible for the WhatsApp Chatbot technology.

Aviro Health set up a content management system and a flow builder that organized the use of this content in a particular sequence and according to specific rules. Aviro Health then sent the messages to a WhatsApp interface provider, in which they entered a queue for distribution and were sent out. A database recorded all the events within the system and what happened with the messages. An extraction mechanism sifted through the raw data to highlight and report on key activities. Once developed, the chatbot was tested using a temporary cell phone number by team members, selected patients with diabetes, and MHS management. The total amount of data required to download all the messages was 94 MB.

Figure 1. Screenshots of the GREAT4Diabetes WhatsApp Chatbot.
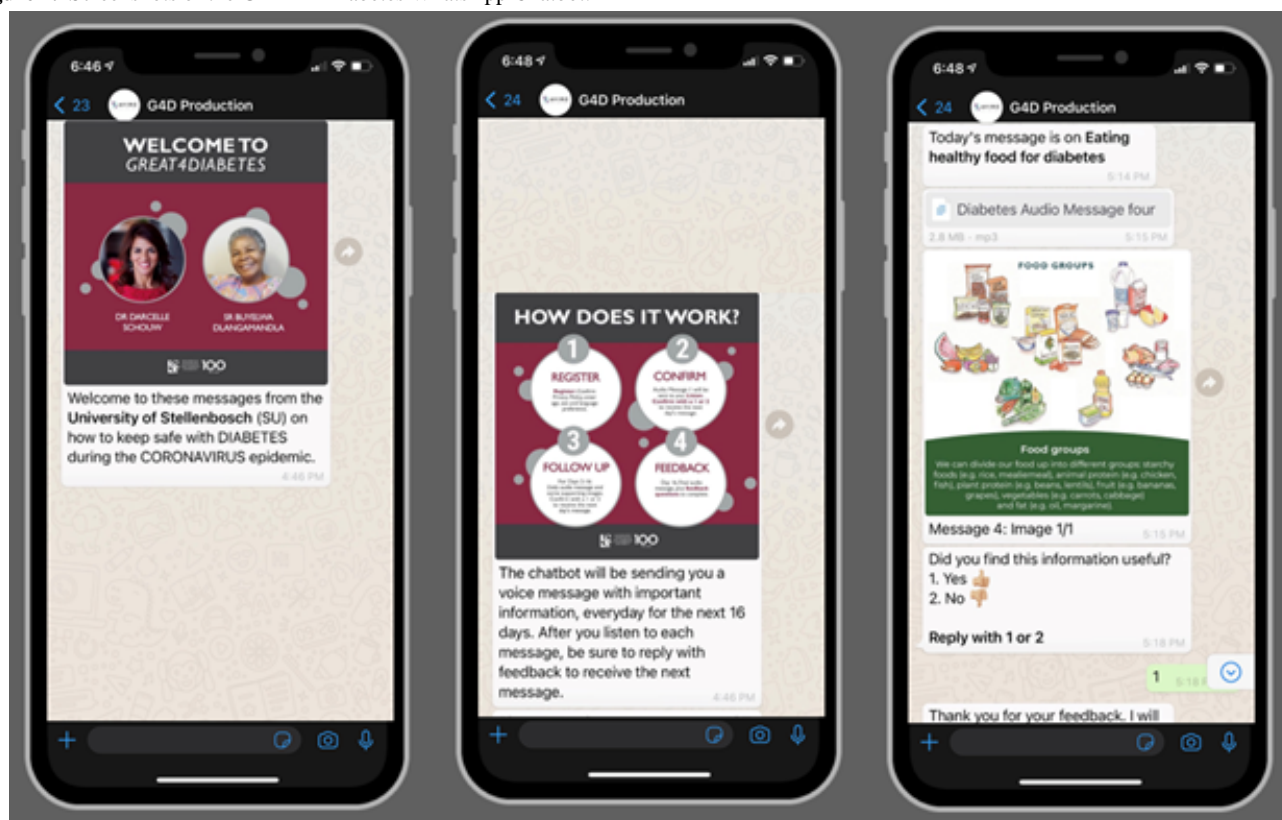
Collection and Analysis of Quantitative Data

The data automatically captured by Aviro Health provided information on *coverage*: the number of people accessing the service and their age, gender, and language preferences. In addition, the number landing on the chatbot, accepting the terms and conditions, listening to each message, and stopping could be determined.

The chatbot also captured data on the reported *effects* of the program. Data were collected on whether participants found the messages useful, as well as on changes in their confidence to self-manage their diabetes. They were specifically asked about changes in behavior with regard to diet, physical activity, adherence to treatment, tobacco smoking, alcohol intake, and foot care.

Stellenbosch University also collected data on the incremental setup and operational *costs* they experienced over the 6-month period.

Data captured by the chatbot were exported into an Excel spreadsheet and then imported into SPSS (version 27; IBM Corp) for analysis. The analysis was mostly descriptive, with categorical data presented as frequencies and percentages and numerical data as means and SDs.

Inferential analysis was conducted to examine any relationships between demographic data and changes in behavior or completion of the program. Categorical variables were compared using the chi-square test, whereas numerical and categorical variables were compared using either the independent samples 2-tailed *t* test or ANOVA, depending on the number of categories.

Collection and Analysis of Qualitative Data

Descriptive exploratory semistructured interviews with key informants were conducted to explore the acceptability, appropriateness, adoption, feasibility, fidelity, and sustainability of the intervention. Key informants were purposively selected, as shown in Table 1, from Stellenbosch University, Aviro Health, MHS management, and health care workers. It was not possible to conduct face-to-face interviews with patients during the COVID-19 pandemic, and their contact details were protected by the Protection of Personal Information Act and could not be shared. Some patients gave qualitative feedback on the chatbot after the last message, and some quotes were selected to support the quantitative findings on the effects of the chatbot.

Interviews were conducted in English by the 2 authors (DS and RM) face to face, via the internet, or telephonically and lasted between 30 and 60 minutes. All interviews were recorded. An interview guide was used to ensure that all the implementation outcomes were explored. In some cases, a small group interview was conducted when people were available at the same time.

Audiotapes were transcribed verbatim and checked for errors or omissions. Transcripts were analyzed inductively to identify themes related to the implementation outcomes. Atlas.ti software was used to assist with the analysis. The first author, DS, performed most of the analyses, whereas the second author confirmed the coding index and interpretation of data. The researchers used the framework method to analyze the data [23]:

1. Familiarization: reading the transcripts and identifying key issues that need to be coded

2. Coding index: creating an index of codes and organizing them in categories
3. Coding: coding all data according to the coding index
4. Charting: gathering all data on the same code or category together in a chart
5. Interpretation: interpreting each chart for the key themes, range of ideas and experiences within a theme, and any relationships among themes

The different data sources and perspectives were triangulated in the analysis, which contributed to its credibility and trustworthiness. In terms of reflexivity and confirmability, DS

is a biokineticist by background and employed as a researcher at Stellenbosch University. She recorded both the English and Afrikaans versions of the messages in the chatbot and acted as the project coordinator. She had prior experience in qualitative interviewing. RM is a family physician and an established researcher at Stellenbosch University with experience in qualitative research. He had previously led the GREAT for Diabetes project on which the voice messages were based. Both researchers were involved in the implementation and evaluation of the project. Guidelines for reporting of mHealth interventions were also followed [24].

Table 1. Characteristics of key informants (N=23).

Categories	Participants	Interviews, n (%)
MHS[a] managers	Chief director and director of NTSS[b]	2 (9)
Primary care facilities	A total of 2 family physicians, 2 medical officers, 2 professional nurses, 1 facility manager, and 1 health educator	8 (35)
Nonprofit organization 1	In all, 1 program manager, 1 professional nurse, and 2 CHWs[c]	4 (17)
Nonprofit organization 2	In all, 1 program manager, 1 professional nurse, 2 CHWs, and 1 dietician	5 (22)
Aviro Health	Chief executive officer, production manager, and implementation manager	3 (13)
Stellenbosch University	Project coordinator	1 (4)

[a]MHS: Metro Health Services.

[b]NTSS: Northern Tygerberg Substructure.

[c]CHW: community health worker.

Ethics Approval

The study was approved by the Health Research Ethics Committee at Stellenbosch University (reference 21/03/006-COVID-19), and permission was obtained from MHS and Aviro Health.

Results

This section integrates the findings derived from both quantitative and qualitative data and presents them according to the implementation outcomes.

Acceptability, Adoption, and Appropriateness

The motivation to adopt the GREAT4Diabetes WhatsApp Chatbot was to improve patient education and levels of glycemic control, while maintaining physical distance and de-escalation of services during the COVID-19 pandemic:

> *COVID prompted us to think differently in many areas. And I think the whole telemedicine, using technology to reach your target beneficiary, has become important...value of self-management in the client, assisted self-management or supported self-management. And I viewed this is the way to support your uneducated and educated clients in managing their disease.* [MHS manager]

De-escalation of services was vital to free up the capacity to handle the surge in patients with COVID-19 infection and allow facilities to maintain adequate social distancing. At the same time, it was dangerous for people with diabetes to congregate at health centers and travel via public transport. During the

COVID-19 pandemic, services at primary health care facilities were reorganized, which meant that people attended the facilities less often, support groups were stopped, and individual patient education and counseling were infrequent. People with diabetes were among those at the highest risk of hospitalization and death from COVID-19 infection, especially if they had poorly controlled diabetes. The chatbot could therefore provide self-management support to people with diabetes, while keeping them safe and avoiding congestion at primary care facilities. Therefore, the MHS management accepted and adopted this motivation.

The MHS had an existing relationship with Aviro Health and Chatbot technology through another COVID-19–related initiative called the Pocket Clinic, which was designed to help patients request home delivery of medication and update their address on the system. This paved the way for the adoption of the chatbot:

> *It's the ability to piggyback a prevention and promotion message onto an existing electronic platform and target people who would benefit the most from it.* [MHS manager]

Likewise, Aviro Health had prior experience of developing WhatsApp-based products to interact with and educate patients, which made it easy for them to adopt the idea for a chatbot. Aviro Health was particularly keen to include diabetes, as it had previously mostly focused on infectious diseases. The proposed chatbot was simpler in design than other products, as it implemented existing content instead of using the traditional in-house analysis and design process to respond urgently to the crisis. The content was derived from the Living GREAT with

Diabetes program, which was viewed as an appropriate group empowerment approach for the same target audience.

Feasibility and Fidelity

Recruitment of Users and Technical Challenges

Users were initially recruited from the NTSS. Pamphlets and posters were made available to the health centers and nonprofit organizations. Patients were introduced to the chatbot by family physicians, medical officers, professional nurses, and health promoters in the facilities, as well as by professional nurses, CHWs, and dieticians in the community. Initially, the uptake was low, and a roadshow was organized throughout the substructure to introduce the chatbot and explain how it worked.

This roadshow was necessary to raise awareness among and motivate health care workers who were already overburdened with the challenges of reorganizing primary health care and responding to the COVID-19 pandemic. Health care workers might see promoting the chatbot as an additional task they were asked to do:

> *Staff morale was also low at some points in Covid, so to get people motivated to do an additional task is a problem. Because we're trying to...we had an integrated service. So in your room you're meant to be able to see to all the primary illness, you're meant to be doing HIV testing in your room, you're meant to be doing other screening in your room, so now you've got an additional thing to do which becomes a problem.* [Family physician]

CHWs received face-to-face training on how to use the chatbot and share it with patients during home visits. It was important to demonstrate the chatbot and engage them in the value it could add during the pandemic, especially to those with poorly controlled diabetes:

> *And yes, also in my experience, I found that it wasn't going to work, just to come in, share the programme with them and ask them to do it. I had to get their buy-I had to motivate the community health workers to get their buy-in and also to focus on them and to see how they're doing with and collaborating with them asking their input, how would it work best?* [Stellenbosch University]

However, several medical officers and professional nurses experienced the chatbot as a great initiative that could be used as part of their normal consultations and reported saving time following its introduction. The chatbot was a valuable tool to complement the education of patients and could be quickly explained to the patient. In addition, illiterate patients, who might struggle with written information, could easily listen to messages:

> *So I sort of incorporated into, into my consultations here. When I was working at the, at the sort of outpatient department. I was speaking to most of, all my diabetics, in fact, I've been sort of advocating, because normally you would educate patients, give them advice on the medications or diet and so on, but*

> *I feel it's quite helpful, because then you don't have to speak so much.* [Medical officer]

In facilities that were short staffed and used several different locums, it was difficult to continuously orientate new clinicians to the chatbot. However, other health care workers, such as health promotion officers, could also successfully inform patients about the service:

> *I said with the locum staff now every time there's a different locum working now you got to explain it to them. So somehow the process then falls flat.* [Family physician]

Following this, the number of users started to increase but also coincided with the first technical problem. Over a 3-week period, 183 users received their first message repeatedly. As each message started in a similar manner, it was assumed that users did not realize the messages were different. Eventually, the technical problem was recognized and corrected when management at the MHS confirmed it. Despite the technical glitch, users who received duplicates during this period did not show any significant difference in drop-off compared with users who received the correct flow. All users who experienced these issues were identified and sent a message notifying them of the error and inviting them to continue using the service. Health care workers, however, lost confidence in promoting the service when they were aware of the technical problem. Aviro Health sent messages to users via WhatsApp to recommence their journey. In addition, Stellenbosch University informed the health workers when the chatbot was functioning again and asked them to inform patients:

> *So she did ask me what's happening, the messages had stopped. So I said to her that I will get back to her. I will get feedback from the office.* [CHW]

In an attempt to drive more users to the chatbot, Stellenbosch University then issued a press release to inform the media about the service and communicate directly to the public. The initial pilot was intended for only 500 completed journeys at NTSS, but a series of local radio interviews culminated in a news story on national television. This strategy was successful in increasing the number of users, and the news story attracted more than 6000 users in a day. However, this volume stressed the chatbot, which was designed to host only a few dozen journeys a day. This stress blocked the dissemination of more than 1000 messages to users, as messages were queued up in the system and eventually dropped as there were too many messages at once. Aviro Health was able to quickly redesign the back end to accommodate much higher volumes than anticipated, retime, and batch messages, thus allowing them through the system:

> *Yes it was a TV news station on SABC or whatever, and then we landed our second glitch. So we had the numbers up. What Aviro did not let us know was that they only had, they did not have capacity for that amount of people. What we had communicated with them prior was to say that before every interview, before every radio interview, before every television interview, we would inform them, which we did.* [Stellenbosch University]

Recruitment was also facilitated by word of mouth from patients, health care workers, and even MHS managers who told friends and relatives about the chatbot:

> *I've got a sister-in-law who's diabetic and who developed Covid and she used it as well...well actually I'm just remembering my brother-in-law who stays in Gauteng also used it.* [MHS manager]

In some facilities, health promoters played voice messages to patients as part of individual or group education sessions held in the facility. Similarly, in the community, patients were introduced to the chatbot during support or adherence group meetings:

> *Because of Covid and the reason that we can't get people into the Day Hospital. All of our rooms...consulting rooms are all occupied. So we have a little space in the garden where there's an under-roof where we go and sit at times but it's not conducive because if one come in, everybody wants to come in.* [Health promoter]

Patients' Readiness to Use Technology

Most health workers and patients found the process easy and self-explanatory and were able to follow the instructions to save the number on their phones and send a message on WhatsApp to receive the first voice message.

> *I think that people are ready for this type of technology especially from the facilities. Everything is moving towards technology. Everything is moving...the only thing that I really think would be a threat is where people don't have access to internet.* [Medical officer]

Patients who did not understand how to use the chatbot received assistance from the CHWs or family members. For example, some older people thought they had to dial the number instead of sending a message on WhatsApp or struggled with saving the number as a contact on their phone:

> *I just had to sit next to them and link them up one by one. When they were here with their phones, I had to sit next to them* [Health promoter]

It was noted that older people more often made use of analog phones, which could not use WhatsApp, whereas most of the younger people had smartphones. When patients did not have a smartphone, some CHWs used their own phones and made repeat visits for them to listen to voice messages. Others requested assistance from family members with a smartphone. However, these solutions were not always feasible. Health workers at the primary health care facilities and nonprofit organizations in the community also held group sessions where they shared messages as part of chronic disease education:

> *A lot of the older people, they didn't have smart phones like they would have a phone but it wouldn't be a smart phone. It would be just like a normal analogue phone and data was an issue for some of the patients. That was the only two factors. For the people that had a smart phone that were cell phone illiterate, they usually had a family member or earlier*

> *on you know that could help them with it.* [Medical officer]

Data issues were not a major challenge to accessing the chatbot, as most people had already made use of WhatsApp calls and had data for this purpose. For those who struggled to afford data, there were other options. All facilities were equipped with free open-access Wi-Fi, and the City of Cape Town had installed additional routers in the NTSS, which meant that anybody in close proximity could access the chatbot. Patients who had gone for consultation and were introduced to the service at the facilities could retrieve the first voice message while waiting for their medication. They could also access the facility on days when they did not have appointments and make use of the free Wi-Fi. Alternative options include accessing data through free Wi-Fi at shops and malls in the local community:

> *No it's not so much that they don't have data. Because they won't have a piece of bread in the house but data they will have on their phone. Those who have got smart phones you understand.* [CHW]

Modification of the Chatbot

The content of the messages was not changed during the study; however, modifications were made to the interface to improve the flow and retention of users. Explanatory text was simplified, particularly the initial consent and acceptance of terms and conditions. The text at the landing and consent stages was replaced by infographics that explained how to use the chatbot. In addition, an infographic introduced photographs of the 2 presenters to make a more personal connection with the voices:

> *Based on user feedback and analysis of drop-offs through the flow, Aviro modified the content (simplified that wording, reduced the consent, added more emoticons, and made slight changes to the flow) to make it easier for those with diabetes to navigate and understand the experience.* [Aviro Health]

Coverage

Between March 2021 and October 2021, a total of 8158 people landed on the chatbot. However, of 8158 people, only 4716 (57.83%) responded to the terms and conditions, and their distribution per month is shown in Figure 2. Overall, 77.29% (3645/4716) of these people connected during July 2021, which coincided with the most intense period of media exposure, including television.

Of 8158 who considered the terms and conditions, 4577 (97.1%) agreed to them but 139 (2.9%) did not. Overall, 81.01% (3708/4577) provided demographic information and the mean age of the participants was 51.0 (SD 12.4) years.

Out of the 4577 participants who provided demographic details, 2066 (55.7%) were women, 1632 (44%) were men, and 10 (0.3%) were identified as other. Most preferred English (2281/4577, 61.5%), but 34.9% (1293/4577) chose Afrikaans and 3.58% (134/4577) chose Xhosa.

Of the 4577 participants, 263 (5.7%) requested to stop the chatbot, and 164 (62.4%) of them did so within the first 24 hours. Of those who stopped, 78.3% (206/263) gave feedback and 11.7% (24/263) said it was not useful, 46.1% (95/263) said

it was because of data issues, and 42.2% (87/263) did not give a specific reason. Table 2 presents the proportion of participants who started receiving each message. Only 12.56% (575/4577) of those who received message 1 also received the final message 16. Although the television interviews drew the largest number of new users, only 4.53% (280/6173) of these users completed the program, whereas 12% (53/441) of the users from radio and 16.47% (28/170) of the users recruited by health care workers completed the program.

Table 3 shows the time taken to complete the entire program. Of 510 participants, only 122 (23.9%) participants completed within the expected 16 days, although most of them completed within 32 days (n=362, 71%).

Patients also reported forwarding the messages to others, which increased the coverage:

> *Thank you for the information, very helpful. I did forward your messages to my friends and families who are diabetic.* [Female, 49 years]

Figure 2. Percentage of people landing on the chatbot per month in 2021 (N=4716).
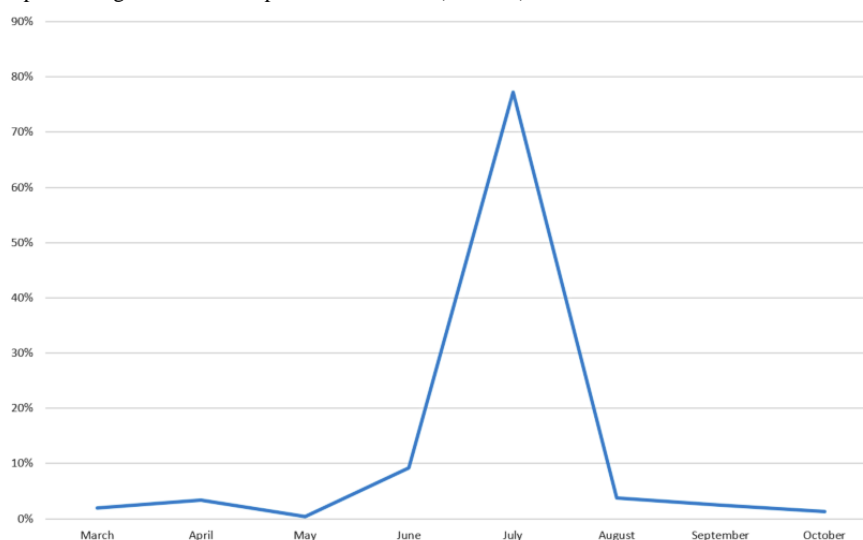
Table 2. Proportion of participants receiving each message (N=4577).

Message number and topic	Participants, n (%)
Message 1: Avoiding COVID-19 infection	4577 (100)
Message 2: Reducing COVID-19 infection	3293 (71.93)
Message 3: What is diabetes?	2534 (55.42)
Message 4: Eating healthy food types	2173 (47.48)
Message 5: Portion sizes	1910 (41.74)
Message 6: Cooking and meals	1650 (36)
Message 7: Drinks	1470 (32.12)
Message 8: Aerobic activity	1210 (26.39)
Message 9: Resistance	998 (21.83)
Message 10: Medication	896 (19.56)
Message 11: Low blood sugar	837 (18.34)
Message 12: High blood sugar	798 (17.42)
Message 13: Mental health	752 (16.43)
Message 14: Control and complications	697 (15.17)
Message 15: Feet	652 (14.23)
Message 16: Visiting the clinic	575 (12.61)

Table 3. Time taken to complete the program (N=510).

Within number of days	Participants, n (%)
16	122 (23.9)
32	240 (47.1)
48	69 (13.5)
64	56 (11)
80	14 (2.7)
96	3 (0.6)
112	5 (1)
128	1 (0)

Costs

Table 4 lists the incremental setup and operational costs involved in the chatbot. Over the 6-month period, it cost ZAR 255,000 (US $16,876) for setup and ZAR 462,473 (US $30,607) in implementation and operational costs. The operational cost for each person who accessed the chatbot was, therefore, US $6.69. This amount would decrease if the number of users increased, as operational costs were not related to the number of users. The monthly operational cost was US $5101.

Table 4. Incremental setup and operational costs for 6 months.

Type of costs	Costs (ZAR)	Costs (US $)[a]
Setup		
Design and development of Chatbot	245,000	16,214
Recording studio	10,000	662
Total	255,000	16,876
Operational		
Project coordinator (over 6 months)	150,000	9927
Chatbot operations	291,000	19,259
Promotional materials, design, and printing	21,473	1421
Total	462,473	30,607

[a]1$=ZAR15.11 on March 10, 2022.

Effects

Table 5 shows the proportion of participants who listened to each message, provided feedback, and found it useful. More than 90% of those who listened to the messages found them to be useful. The least useful message was the first one on the COVID-19 infection (3093/3293, 93.92%), and the most useful was mental health and stress (691/697, 99.1%).

Overall, 494 participants gave feedback on changes in their behavior at the end of the program; of these, 351 (71.1%) reported that they changed *a lot*, whereas 123 (24.9%) reported that they changed *a little*, and 20 (4%) reported no change:

> *I did find the messages very inspiring and to put it in action is very important for my health.* [Female, 70 years]

> *All the sessions was applicable to me, I gain more information at large on how to look and care about myself. I was negative about my diabetes, after going through with you all these sessions, I am positive about it and would like you to continue the excellent work, thanks a lot. Regards.* [Male, 52 years]

In addition, of the 421 participants, 369 (87.6%) reported that they were much more confident in self-care for their diabetes:

> *You help me a lot about a knowledge and confidence thanks a lot.* [Male, 39 years]

Table 6 presents the behaviors that people reported as changing because of the program. The most common changes were in diet and physical activity. A substantial proportion also improved their adherence to medication, foot care, and stress management. Only a small proportion changed their alcohol use or tobacco smoking, although the proportion of smokers or using alcohol was unknown:

> *Yes thank you very much, now I understand my diabetes condition a lot and already feeling much better I use to have rash and itchy, now it's gone, I changed the way I eat.* [Male, 54 years]

> *Wish there was more on exercise.* [Female, 49 years]

> *I can say I've learnt a lot about diabetes and can educate my community more about how to manage and live healthy lifestyle with diabetes.* [Female, 49 years]

There was no significant association between age, gender, or language preference and the probability of changing behavior. Those who completed all 16 messages were likely to be slightly older (mean 52.0 vs 50.1 years; mean difference 1.18, 95% CI 0.043-2.32; P=.04). There was no association between gender or language preference and those who completed the program.

Table 5. Proportion of participants who found each message useful.

Message number and topic	Participants, N	Participants who found it useful, n (%)
Message 1: Avoiding the COVID-19 infection	3293	3093 (93.9)
Message 2: Reducing the COVID-19 infection	2534	2382 (94)
Message 3: What is diabetes?	2173	2099 (96.6)
Message 4: Eating healthy food types	1910	1835 (96.6)
Message 5: Portion sizes	1650	1660 (97.1)
Message 6: Cooking and meals	1470	1397 (95)
Message 7: Drinks	1210	1144 (94.5)
Message 8: Aerobic activity	998	948 (95)
Message 9: Resistance	896	877 (97.9)
Message 10: Medication	—a	—
Message 11: Low blood sugar	798	775 (97.1)
Message 12: High blood sugar	752	731 (97.2)
Message 13: Mental health	697	691 (99.1)
Message 14: Control and complications	652	635 (97.4)
Message 15: Feet	575	565 (98.3)
Message 16: Visiting the clinic	533	524 (98.3)

[a]Data not available.

Table 6. Changes in specific behavioral issues in self-care for diabetes (N=414).

Behavioral change	Yes, n (%)
I changed my diet	315 (76.1)
I changed physical activity	222 (53.6)
I improved adherence to medication	182 (44)
I changed my foot care	178 (43)
I changed my stress management	186 (44.9)
I changed my smoking	34 (8.2)
I changed my alcohol intake	46 (11.1)
I changed something else	27 (6.5)

Sustainability

All respondents agreed that the chatbot service should continue and made many suggestions to improve or extend the service and its integration into the MHS:

> Don't stop what you're doing, don't stop. Digital health is the future, but digital health is a complimentary service to what you are doing. We are not getting to the people prof. We're not getting to people with diseases like diabetes. It's going to be the leading killer. You know heart disease, these are controllable but there's like controllable at a personal level. [Aviro Health]

> I think that this program should definitely be sustained. I think we've seen that there is an appetite for it just simply by the number of users who landed...it's not just about people who complete a program but people who show interest by just on-boarding. And we've seen spikes in those numbers. Particularly when there were roadshows. [Aviro Health]

Health care workers and managers suggested that additional services be developed for other chronic diseases, such as hypertension, heart failure, asthma, and chronic obstructive pulmonary disease. The chatbot could complement consultations and make them more efficient while providing more comprehensive information than would be possible in a short

consultation. A menu of WhatsApp-based patient education programs for chronic conditions could be provided:

> *It can happen for different chronic diseases it could really help in consultations to cut it a little bit shorter, it's quite important and I do think it would be helpful to roll it out or try it for different chronic diseases.* [Medical officer]

The staff who implemented the chatbot recommended that it be introduced to all auxiliary workers, clinicians, and health care workers treating patients with diabetes and incorporated into all consultations and home visits. The chatbot should be promoted as part of service delivery through the usual management structures:

> *From the facility perspective, I think having to get all the health workers involved and not just speak to the Doctors, but like I say the CNPs and the CDCs as well, so we are a CHC but there are CDCs in our areas, so having to maybe speak to the CNPs and everyone that is involved with treating diabetic patients.* [Medical officer]

> *I think it should be from our department or all the other sub-structures needs to be informed...we need to be trained on this chat group and it should be a natural thing in the Day Hospital where everybody has their number...all our clinicians have their little flyer and it also explain to the person that maybe missed me when I was talking.* [Health educator]

In addition, respondents suggested that it should be integrated with the Pocket Clinic as one package of WhatsApp-based services for people. This would consolidate services via WhatsApp and build people's awareness and confidence in such a system. It was also suggested that the chatbot could be promoted via the parcel of medications that stable patients received:

> *I know the pocket clinic is working quite well and I think if it is integrated it might work better because I really think like stand-alone things like that don't work. So once its integrated into a system it might actually work better.* [Family physician]

> *But also with the medication, it is theoretically possible to say everybody that's getting diabetic medication through the CDU system, should automatically with their parcel, get a thing saying "please WhatsApp the following number if you're interested in getting more information."* [MHS management]

Ideally, data from the chatbot service should also be integrated with district health information (eg, single patient viewer) so that health care workers could see who has accessed the material. There might also be an option to suggest the chatbot to patients who had poorly controlled diabetes.

The chatbot could be scaled up if a no-cost health data option was made available to users through cellular networks, similar to the no-cost data packages offered to students during the COVID-19 pandemic and lockdown. This would eliminate financial barriers and enable access to all potential users. In addition, a website could be developed in which users could access messages without any subscription or downloading costs.

Introducing other languages into the chatbot would also allow for it to be scaled up nationally, outside the Western Cape. Some minority and migrant groups within Western Cape might also benefit from other languages.

Finally, the technology needs to ensure that it can go to scale and avoid technical problems experienced during the study period. Communication and monitoring of errors between the WhatsApp service provider and Aviro Health must be improved. Aviro Health also suggested that a feedback or help option could be added to the platform so that end users could directly provide feedback. Going to scale might also improve the service, as Aviro Health commented that the WhatsApp service provider regarded this as a small-scale and relatively unimportant initiative:

> *Mostly around the technical infrastructure. It is...yeah, in terms of their technical infrastructure there are times where there might be errors. So we send out a message from our system. And like I said, they're the middleman, so it kind of goes through their console, before it goes to users. And sometimes we didn't receive error messages or error logs and that is due to kind of how their tech stack is set up.* [Aviro Health]

Discussion

Principal Findings

The chatbot was adopted as a useful innovation in response to the COVID-19 pandemic and was rapidly developed and implemented. It was feasible to implement via health services and media and for people with type 2 diabetes to use in our context. Minor changes were made to the chatbot to improve usability and solve technical glitches. Coverage was sufficient for 8158 participants to land on the chatbot, 4577 to consent, and 575 to complete all 16 messages over a 6-month period. Incremental costs were US $16,876 for setup, and operational costs were US $30,607. Patients reported substantial changes in their confidence in self-managing diabetes and behavior change. All stakeholders supported the continuation of the chatbot, although health services must make a final policy decision in the future. There is potential to include other languages and conditions.

Discussion of Key Findings

The key findings will be discussed in relation to "the framework (abbreviated NASSS) for studying the Non-adoption and Abandonment of technologies by individuals and the challenges to Scale-up, Spread and Sustainability of such technologies in health and care organizations" [25]. The NASSS framework has 7 components: condition, technology, value proposition, adopters, organization or organizations, wider system, and embedding and adaptation over time. These components have been identified through the synthesis of multiple theories of technological implementation and the realization that many innovations do not succeed for a variety of complex reasons.

The focus of the intervention on diabetes was affirmed by respondents as a key strategy during the COVID-19 pandemic. We were not able to determine any improvement in glycemic control among users, but previous studies have suggested a modest but clinically significant improvement in HbA_{1c} levels [14-16]. Similarly, the number of hospitalizations and deaths averted from COVID-19 infections is unknown. Feedback from patients suggested changes in lifestyle modifications, medication adherence, and confidence in self-management, which would be consistent with improved glycemic control. Ideally, a clinical trial should be conducted to confirm that the intervention is effective in improving control over type 2 diabetes.

Overall, the technology appeared to be a good fit with the target audience, who mostly had smartphones, were familiar with WhatsApp, and could afford data. Several strategies were mentioned for people who did not meet these criteria. Cell phone penetration is known to be high in low-socioeconomic communities in South Africa, and WhatsApp has been identified as the preferred mode of communication for people with diabetes [7,13]. Although several other educational apps for diabetes are available on the market, they may target patients in the private sector with more resources and a different lifestyle than those using the public sector. They may also assume a higher data use. Therefore, the chatbot may be more appropriate for communities dependent on the public sector. To resolve problems more quickly, a help desk function would be useful to allow users to report errors and get assistance. If the chatbot is scaled, it will require more robust systems and regular monitoring to work at a sufficient level of stability to be acceptable outside of a pilot setting.

In terms of the value proposition, the value to health services was the possibility of reduced morbidity and mortality from both diabetes and COVID-19 infection while decongesting primary care facilities and freeing up the capacity to respond to the pandemic. The costs per patient were at par with a monthly prescription for diabetes medication. The per capita cost would also decrease with scale-up and increased reach. The impact of the chatbot will also depend on the coverage and going to scale. Reach was amplified by the use of media, particularly television, but this recruitment strategy is not sustainable. Reach via health care workers was on a much smaller scale, and scale-up would require the use of the chatbot to be embedded routinely into clinical encounters.

Value to the technology company was less certain. The mission of Aviro Health "is to help health care workers focus on more complicated cases by providing technology-enabled services that automate workflows, improve access to quality medical information, and provide digitally-enabled counselling services" [26]. The future commitment of Aviro Health is interdependent on the policy and priorities of the Department of Health and whether they are willing to contract in the longer term. Aviro Health are also keen to change the WhatsApp service provider to prevent technological problems and enable scalability. This would require redesigning the product using new software and additional development costs.

The value to patients was clear in terms of the potential to support a comprehensive understanding of their condition and self-management. Such comprehensive patient education is often lacking in primary care services [27,28]. The large drop-off in potential users that land on a new digital product and actually use it is common in this environment. Each message was found to be useful by those who listened to it. However, only a small proportion of patients completed all 16 messages, and retaining users' attention over a prolonged period is a challenge for such interventions. This also raises the question as to whether the number of messages should be reduced. Further evaluation of the service by users might answer some of these questions.

The cost of data was minimal, even in poor communities, as 100 MB would cost between US $0.66 and US $0.99 for the entire program. The time taken to listen to the messages did not appear to be an issue, and users could stretch the program for more than 16 days. The reach was limited to the Xhosa-speaking population, although it is likely that many first-language Xhosa speakers chose to listen in English. However, overall, the value proposition appeared to be favorable for all stakeholders.

The chatbot was easily adopted by most users who were already familiar with WhatsApp and smartphones. Older people require assistance in understanding the process. Health care workers overcame their initial resistance to adopting a new task, as they realized that the chatbot could save them time and add value for the patient. However, the promotion of the chatbot needs to be embedded into clinical practice, be part of the orientation of new health care workers, and be introduced to everyone who interacts with patients (eg, pharmacy assistants, pharmacists, and dieticians). The ongoing adoption of the chatbot may also depend on the ownership of the initiative by MHS managers from the facility to district level.

During the pandemic, the MHS showed an ability to innovate and adapt rapidly to the situation, as exemplified by their support for the chatbot. Going forward, however, the organization must make critical decisions regarding the use of digital solutions for primary health care. Almost all facets of primary health care need improved electronic information systems, from the need for electronic medical records to mHealth systems for CHWs. Technological and informational decision-making is complex and difficult, and the place of WhatsApp-based services is not yet clear. There is a need for a coherent and integrated digital architecture and policy rather than an eclectic mix of digital innovations and projects, each trying to solve a problem in isolation. There is also a tension between a desire to innovate in-house, to own the technology and control the product, and a need to move quickly with the help of external companies that already have expertise in the area but on whom you become dependent. The future of the chatbot in its current form is threatened by inertia in such complex decision-making, which may not reach a conclusion quickly enough and might decide against the current model. However, respondents were positive about the potential future contribution of WhatsApp-based services.

The COVID-19 pandemic has highlighted the importance and value of digital health solutions. Examples include telehealth, web-based consultations, remote monitoring, and WhatsApp messaging [29]. Funders such as the Bill and Melinda Gates Foundation have recently emphasized their interest in funding

digital health solutions for primary health care, and the climate for such innovations is favorable [30]. There are medicolegal concerns with clinicians using WhatsApp to share patients' medical details and with the collection of personal information by third parties [31]. Medical ethics and professionalism must adapt their principles to guide professionals in the digital age. However, the chatbot did not raise any such concerns.

Limitations of the Methods

Quantitative data were limited to what was routinely collected by the chatbot, which was not primarily designed to collect research data. For example, we had no data on where patients were located, their clinical history, glycemic control, or risk factors. Although we hoped to interview patients and obtain their qualitative feedback, this was not possible. First, the COVID-19 pandemic made it impossible to conduct face-to-face interviews. Second, the recent Protection of Personal Information Act in South Africa and standard Aviro Health terms and conditions did not allow for the sharing of confidential patient contact details with the researchers. Qualitative data were obtained by interviewing other key stakeholders. Qualitative researchers were involved in implementing the chatbot and evaluating the implementation. On the one hand, this meant that researchers had in-depth insights into the issues raised by interviewees; on the other hand, they were committed to the project's success and could have been inclined to a more positive interpretation of the data. The blurring of roles between implementation and implementation evaluation is common in embedded research and implementation science [32].

Recommendations

This evaluation supports the value of the chatbot and the need to sustain it. Although the intervention itself is relatively simple, the complexity of decision-making around digital health solutions in the health services and financially constrained health sectors may prevent any immediate long-term commitment. Should the health services commit to the chatbot in the future, there is potential to add more languages and chronic conditions and evaluate it further. The Diabetes Alliance strongly recommends the use of such services in South Africa [33]. Such chatbots could have the potential to scale up nationally and even within the region. Future research can evaluate users' experience and feedback on the content and the effectiveness of the education by measuring clinical outcomes such as HbA_{1c}.

Conclusions

The chatbot was seen as an acceptable initiative by the MHS and quickly adopted during the COVID-19 pandemic to assist people with diabetes. The initiative appeared to be appropriate and useful to patients, with reported improvements in confidence and self-management. The chatbot was feasible to implement despite some technical glitches, and most patients had access to smartphones and sufficient data and were able to navigate the system. There was fidelity to the original design, although the text was simplified and more infographics were added to support the usability and retention of users. Coverage by health care workers was slow and amplified dramatically by the use of radio and television media. Costs were relatively modest and would improve with economies of scale. Respondents thought the chatbot should be sustained and saw the potential for adding languages and other conditions. Sustainability, however, is generally dependent on organizational decision-making around policy, costs, and design of digital health solutions. Further research should explore patients' perspectives and effectiveness of the chatbot.

Authors' Contributions

All authors drafted, reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

References

1. Key findings: P0309.3 - Mortality and causes of death in South Africa: Findings from death notification, 2015. Statistics South Africa. 2018. URL: http://www.statssa.gov.za/?page_id=1856&PPN=P0309.3&SCH=6987 [accessed 2019-03-26]
2. Amod A. SEMDSA 2017 guidelines for the management of type 2 diabetes mellitus. J Endocrinol Metabol Diabetes South Afr 2017;22(Supplement 1):S1-196 [FREE Full text] [doi: 10.13140/RG.2.2.29645.90083]
3. Boake MW. Diabetes in the cape town metropole – a secondary analysis of the diabetes cascade database 2015 - 2020. Stellenbosch University. 2021. URL: https://scholar.sun.ac.za:443/handle/10019.1/123808 [accessed 2022-02-20]
4. Mash R, Goliath C, Perez G. Re-organising primary health care to respond to the Coronavirus epidemic in Cape Town, South Africa. Afr J Prim Health Care Fam Med 2020 Dec 05;12(1):e1-e4 [FREE Full text] [doi: 10.4102/phcfm.v12i1.2607] [Medline: 33181873]

5. Western Cape Department of Health in collaboration with the National Institute for Communicable Diseases, South Africa. Risk factors for coronavirus disease 2019 (COVID-19) death in a population cohort study from the Western Cape Province, South Africa. Clin Infect Dis 2021 Oct 05;73(7):e2005-e2015 [FREE Full text] [doi: 10.1093/cid/ciaa1198] [Medline: 32860699]

6. Mash RJ, Presence-Vollenhoven M, Adeniji A, Christoffels R, Doubell K, Eksteen L, et al. Evaluation of patient characteristics, management and outcomes for COVID-19 at district hospitals in the Western Cape, South Africa: descriptive observational study. BMJ Open 2021 Jan 26;11(1):e047016 [FREE Full text] [doi: 10.1136/bmjopen-2020-047016] [Medline: 33500292]

7. Sector Forecasting – State of the ICT sector in South Africa. Independent Communications Authority of South Africa. 2021. URL: https://www.icasa.org.za/pages/sector-forecasting [accessed 2022-02-20]

8. mHealth strategy (2015-2019). National Department of Health, South Africa. 2015. URL: https://www.hst.org.za/publications/NonHST%20Publications/mHealth%20Strategy%202015.pdf [accessed 2022-03-10]

9. Venter W, Coleman J, Chan VL, Shubber Z, Phatsoane M, Gorgens M, et al. Improving linkage to HIV care through mobile phone apps: randomized controlled trial. JMIR Mhealth Uhealth 2018 Jul 17;6(7):e155 [FREE Full text] [doi: 10.2196/mhealth.8376] [Medline: 30021706]

10. Seebregts C, Dane P, Parsons AN, Fogwill T, Rogers D, Bekker M, et al. Designing for scale: optimising the health information system architecture for mobile maternal health messaging in South Africa (MomConnect). BMJ Glob Health 2018 Apr 24;3(Suppl 2):e000563 [FREE Full text] [doi: 10.1136/bmjgh-2017-000563] [Medline: 29713506]

11. Wang Y, Min J, Khuri J, Xue H, Xie B, Kaminsky LA, et al. Effectiveness of mobile health interventions on diabetes and obesity treatment and management: systematic review of systematic reviews. JMIR Mhealth Uhealth 2020 Apr 28;8(4):e15400 [FREE Full text] [doi: 10.2196/15400] [Medline: 32343253]

12. Sahin C, Courtney KL, Naylor PJ, E Rhodes R. Tailored mobile text messaging interventions targeting type 2 diabetes self-management: a systematic review and a meta-analysis. Digit Health 2019 Apr 22;5:2055207619845279 [FREE Full text] [doi: 10.1177/2055207619845279] [Medline: 31041110]

13. Fischer A, Chadyiwa M, Tshuma N, Nkosi V. Acceptability of mobile health interventions to increase diabetic risk factor awareness among the commuter population in Johannesburg: descriptive cross-sectional study. JMIR Diabetes 2019 Oct 20;4(3):e12600 [FREE Full text] [doi: 10.2196/12600] [Medline: 31586363]

14. Sartori AC, Rodrigues Lucena TF, Lopes CT, Picinin Bernuci M, Yamaguchi MU. Educational intervention using WhatsApp on medication adherence in hypertension and diabetes patients: a randomized clinical trial. Telemed J E Health 2020 Dec;26(12):1526-1532. [doi: 10.1089/tmj.2019.0305] [Medline: 32155382]

15. Omar MA, Hasan S, Palaian S, Mahameed S. The impact of a self-management educational program coordinated through WhatsApp on diabetes control. Pharm Pract (Granada) 2020;18(2):1841 [FREE Full text] [doi: 10.18549/PharmPract.2020.2.1841] [Medline: 32477434]

16. Alanzi T, Bah S, Alzahrani S, Alshammari S, Almunsef F. Evaluation of a mobile social networking application for improving diabetes type 2 knowledge: an intervention study using WhatsApp. J Comp Eff Res 2018 Sep;7(9):891-899. [doi: 10.2217/cer-2018-0028] [Medline: 29943647]

17. Al-Hamdan R, Avery A, Al-Disi D, Sabico S, Al-Daghri NM, McCullough F. Efficacy of lifestyle intervention program for Arab women with prediabetes using social media as an alternative platform of delivery. J Diabetes Investig 2021 Oct;12(10):1872-1880 [FREE Full text] [doi: 10.1111/jdi.13531] [Medline: 33638248]

18. Cetinkaya L. The impact of WhatsApp use on success in education process. Int Rev Res Open Distance Learn 2017 Nov 29;18(7):59-74. [doi: 10.19173/irrodl.v18i7.3279]

19. Gon S, Rawekar A. Effectivity of e-Learning through WhatsApp as a teaching learning tool. J Med Sci 2017 May 22;4(1):19. [doi: 10.18311/mvpjms/0/v0/i0/8454]

20. Faith leaders use technology to combat COVID-19 in developing countries. World Vision. 2020 Apr 23. URL: https://www.wvi.org/newsroom/coronavirus-health-crisis/faith-leaders-use-technology-combat-covid-19-developing [accessed 2022-03-10]

21. Cape Metro District Health Plan 2018/19 - 2020/21. Metro Health Services. 2018. URL: https://tinyurl.com/ydukwmty [accessed 2022-05-20]

22. Mash RJ, Rhode H, Zwarenstein M, Rollnick S, Lombard C, Steyn K, et al. Effectiveness of a group diabetes education programme in under-served communities in South Africa: a pragmatic cluster randomized controlled trial. Diabet Med 2014 Aug;31(8):987-993 [FREE Full text] [doi: 10.1111/dme.12475] [Medline: 24766179]

23. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess R, editors. Analyzing Qualitative Data. London, UK: Routledge; 1994:173-194.

24. Agarwal S, LeFevre AE, Lee J, L'Engle K, Mehl G, Sinha C, WHO mHealth Technical Evidence Review Group. Guidelines for reporting of health interventions using mobile phones: mobile health (mHealth) evidence reporting and assessment (mERA) checklist. BMJ 2016 Mar 17;352:i1174. [doi: 10.1136/bmj.i1174] [Medline: 26988021]

25. Greenhalgh T, Abimbola S. The NASSS framework - a synthesis of multiple theories of technology implementation. Stud Health Technol Inform 2019 Jul 30;263:193-204. [doi: 10.3233/SHTI190123] [Medline: 31411163]

26. Your self-care partner. Aviro Health. 2022. URL: https://www.avirohealth.com/ [accessed 2022-02-20]

XSL•FO

RenderX

27.   Parker WA, Steyn NP, Levitt NS, Lombard CJ. They think they know but do they? Misalignment of perceptions of lifestyle
        modification knowledge among health professionals. Public Health Nutr 2011 Aug;14(8):1429-1438. [doi:
        10.1017/S1368980009993272] [Medline: 20105391]
28.   Malan Z, Mash B, Everett-Murphy K. A situational analysis of training for behaviour change counselling for primary care
        providers, South Africa. Afr J Prim Health Care Fam Med 2015 Mar 18;7(1):731 [FREE Full text] [doi:
        10.4102/phcfm.v7i1.731] [Medline: 26245589]
29.   David NJ, Brey Z, Ismail M. Telemedicine in the Western Cape department of health during the first peak of the COVID-19
        pandemic: leveraging data to save lives by activating a telemedicine response. Afr J Prim Health Care Fam Med 2021 May
        20;13(1):e1-e4 [FREE Full text] [doi: 10.4102/phcfm.v13i1.2954] [Medline: 34082548]
30.   Introduction to the Global Delivery Program's (GDP) Primary Health Care Strategy. Bill and Melinda Gates Foundation.
        2022. URL: https://www.gatesfoundation.org/our-work/programs/global-development/global-delivery-programs [accessed
        2022-03-10]
31.   Ethical Guidelines on Social Media. Health Professions Council of South Africa. 2019. URL: https://www.hpcsa.co.za/
        Uploads/Professional_Practice/Conduct%20%26%20Ethics/Ethical2%20Guidelines%20on%20Social%20Media.pdf
        [accessed 2022-02-20]
32.   Cheetham M, Wiseman A, Khazaeli B, Gibson E, Gray P, Van der Graaf P, et al. Embedded research: a promising way to
        create evidence-informed impact in public health? J Public Health (Oxf) 2018 Mar 01;40(suppl_1):i64-i70. [doi:
        10.1093/pubmed/fdx125] [Medline: 29538721]
33.   Inaugural South African Diabetes Summit 2021. Diabetes Alliance. 2021. URL: https://www.diabetesalliance.org.za/
        diabetes-summit/ [accessed 2022-01-13]

Abbreviations

CHW: community health worker
GREAT: Group Empowerment and Training
HbA$_{1c}$: hemoglobin A$_{1c}$
mHealth: mobile health
MHS: Metro Health Services
NASSS: Non-adoption and Abandonment of technologies by individuals and the challenges to Scale-up, Spread
and Sustainability
NTSS: Northern Tygerberg Substructure

XSL•FO
RenderX

Acceptance and Effect of Continuous Glucose Monitoring on Discharge From Hospital in Patients With Type 2 Diabetes: Open-label, Prospective, Controlled Study

Barbara Depczynski[1], MBBS, PhD; Ann Poynten[1], MBBS, PhD

Prince of Wales Hospital, Randwick, Australia

Corresponding Author:
Barbara Depczynski, MBBS, PhD
Prince of Wales Hospital
Barker St
Randwick, NSW 2031
Australia
Phone: 61 293824600
Fax: 61 2938246012
Email: barbaradepczynski@gmail.com

Abstract

Background: Continuous glucose monitors (CGM) can provide detailed information on glucose excursions. There is little information on safe transitioning from hospital back to the community for patients who have had diabetes therapies adjusted in hospital and it is unclear whether newer technologies may facilitate this process.

Objective: Our aim was to determine whether offering CGM on discharge would be acceptable and if CGM initiated on hospital discharge in people with type 2 diabetes (T2DM) would reduce hospital re-presentations at 1 month.

Methods: This was an open-label study. Adult inpatients with T2DM, who were to be discharged home and required postdischarge glycemic stabilization, were offered usual care consisting of clinic review at 2 weeks and at 3 months. In addition to usual care, participants in the intervention arm were provided with a Libre flash glucose monitoring system (Abbott Australia). An initial run-in phase for the first 20 participants was planned, where all consenting participants were enrolled in an active arm. Subsequently, all participants were to be randomized to the active arm or usual care control group.

Results: Of 237 patients screened during their hospital admission, 34 had comorbidities affecting cognition that prevented informed consent and affected their ability to learn to use the CGM device. In addition, 21 were not able to be approached as the material was only in English. Of 101 potential participants who fulfilled eligibility criteria, 19 provided consent and were enrolled. Of the 82 patients who declined to participate, 31 advised that the learning of a new task toward discharge was overwhelming or too stressful and 26 were not interested, with no other details. Due to poor recruitment, the study was terminated without entering the randomization phase to determine whether CGM could reduce readmission rate.

Conclusions: These results suggest successful and equitable implementation of telemedicine programs requires that any human factors such as language, cognition, and possible disengagement be addressed. Recovery from acute illness may not be the ideal time for introduction of newer technologies or may require more novel implementation frameworks.

Introduction

The COVID-19 pandemic has accelerated the incorporation of telemedicine including remote monitoring into patient care, including the outpatient setting [1]. There are many potential benefits associated with remote patient monitoring in a large range of chronic conditions [2]. Studies assessing the effect of telemedicine on hospital readmission rates have yielded mixed results. A capitated telehealth coaching service did not reduce hospital readmissions; however, there was a reduction in acute hospital bed days [3]. In patients with heart failure, a systematic review found that a reduction in hospitalizations was accompanied by an increase in nonemergency outpatient visits [4]. Glycemic therapy frequently requires revision during

hospital stay [5]. There is little information on safe transitioning from hospital back to the community for patients who have had diabetes therapies adjusted in hospital. It is unclear whether telemedicine may facilitate this process. Unplanned hospital readmissions are higher among those with diabetes [6]. A risk factor for hospital readmission for hypoglycemia is a preceding recent hospital admission [7], suggesting that failure to adequately titrate therapy postdischarge is a contributor to readmission. Processes to facilitate better continuity of care for those with diabetes may reduce unplanned readmissions [6].

Continuous glucose monitors (CGMs) are minimally invasive, recording interstitial glucose levels every 5-15 minutes [8]. Since CGMs provide a more comprehensive overall glucose profile, both the person with diabetes and the clinician, either face-to-face or remotely, have more detailed information to personalize glycemic management plans [9]. CGMs are standard of care for most people with type 1 diabetes [10]. The role of CGMs in type 2 diabetes (T2DM) is less clear, with variable impacts on glycemic control [11-13].

The aim of our study was to determine whether the use of continuous subcutaneous glucose monitoring in patients with T2DM being discharged from hospital would reduce unplanned hospital re-presentations at 1 month as compared to a control group using capillary blood glucose meters. The secondary aim was to determine whether continuous glucose monitoring would be acceptable in this cohort.

Methods

Participants

The study was conducted at Prince of Wales Hospital, a tertiary referral teaching hospital in an urban area of Australia. There are approximately 50,000 admissions annually. Although servicing a broader area, the hospital is located in the Randwick local government area, where 18% of residents are aged ≥60 years and 29% of the residents are from countries where English is not their first language. Inpatient care of diabetes is primarily the responsibility of the admitting team. Consultations to the diabetes service are made on an ad hoc basis by formal referral from the admitting team. Potential participants were identified from consultations to the diabetes ward service, and so could be recruited from any medical or surgical wards. Inclusion criteria were adult inpatients with T2DM as primary or secondary diagnosis, who were to be discharged home and required postdischarge glycemic stabilization. Exclusion criteria were patients with other forms of diabetes, or who were unable to provide consent. Potential participants were approached between October 1, 2019, and March 20, 2020.

Study Design

This was an open-label, prospective, controlled study. Potential participants were identified by the endocrinologist or fellow providing ward consultation service and recruitment was undertaken by a clinician not involved in the care of the potential participant. An initial run-in phase for the first 20 participants was planned, where all consenting participants were enrolled in an active arm. The run-in period enabled the establishment of streamlined referral pathways and familiarization with technology platforms. Subsequently, all participants were to be randomized to the active arm or usual care control group.

Intervention

Usual care consisted of clinic review at 2 weeks (with a credentialled diabetes nurse educator who had provided the participant with education when they were an inpatient) and at 3-4 months (with an endocrinologist or trainee who had provided the inpatient diabetes consultation if new to the outpatient service, or if known to the service, then with their usual endocrinologist). In addition to usual care, participants in the intervention arm were provided with Libre flash glucose monitoring system (Abbott Australia). Education on the use of the glucose monitoring system was provided by a credentialled diabetes educator. A disposable sensor was applied to the back of the upper arm on the day of discharge. No capillary calibration is required. Participants were provided with a handheld reader and encouraged to pass the reader over the sensor at least 3 times per day. Glucose results are available in real time to the participant and glucose data can be downloaded and reviewed with the participant at the 2-week visit. The manufacturer did not supply the device and was not involved with the study in any way.

Ethics Approval

Ethics approval was granted by the South Eastern Sydney Local Health District Human Ethics committee (18/263 HREC/19/POWH/102).

Data Analysis

The primary outcome was to determine whether the addition of subcutaneous continuous glucose monitoring to usual care during glycemic therapy stabilization after hospital admission can reduce the number of unplanned hospital re-presentations in the first month following discharge. The secondary outcome was assessment of the acceptability of continuous glucose monitoring after hospital discharge.

We planned to recruit 440 patients. Early unplanned hospital re-presentation for patients with type 2 diabetes are up to 20% [14]. In medical service patients with glycated hemoglobin (HbA$_{1c}$) of 8% or higher, intensification of glycemic management during admission was associated with reduced 30-day readmission (adjusted odds ratio 0.33, 95% CI 0.12-0.88) [14]. We planned to study intervention cases and controls with 1 control per intervention case. Our unpublished data for our hospital indicated that the readmission rate among controls is 20% at 1 month. If the readmission rate for experimental subjects is 10%, we will need to study 199 experimental subjects and 199 control subjects to be able to reject the null hypothesis that the failure rates for experimental and control subjects are equal with probability 0.8. The type I error probability associated with this test of this null hypothesis is 0.05. We estimated a dropout rate of 10%. Logistic regression models will be constructed for primary outcome of unplanned hospital re-presentations within 30 days of discharge with CGM provision in addition to usual care versus usual care alone as the independent variable and admission type (medical vs surgical admission) and age as covariables. To assess the secondary objective of acceptability of the CGM, the response at 2 weeks

postdischarge to a 4-point Likert question ("How satisfied are you with the medical devices available for you to monitor your glucose levels?") between the intervention and usual care groups will be compared. Data were collected prospectively.

Results

A total of 237 patients were screened for eligibility from October 1, 2019, prior to study suspension on March 20, 2020, due to poor recruitment and restrictions on non–COVID-19 research. Overall, 136 patients were not eligible (other forms of diabetes=32, limited ability to provide informed consent due to cognitive comorbidities=34 or because the study material was only provided in English=21, antihyperglycemic agent titration was not required on discharge=14, goals of care changed to palliation=8, out of area and unable to attend for review=9, other care destination after discharge=18). Of the 101 potential participants who were approached over 5 months, 19 were recruited and completed the study. Participant characteristics are given in Table 1. Of 19 participants, 2 were readmitted within 1 month of their participation. HbA_{1c} improved (or was stable when to target) in 17 of 18 participants who had a 3-month HbA_{1c} result available. Of the 19 participants, 16 were very satisfied and 3 fairly satisfied with the medical devices available to monitor glucose levels at 2 weeks postdischarge. Of the 82 patients who declined to participate, 31 advised that the learning of a new task toward discharge was overwhelming or too stressful, 26 were not interested, 15 did not wish to attend for follow-up, 6 were approached but were discharged after trial closure, and 3 elected to self-fund CGM.

Table 1. Characteristics of 19 study participants.

Variable	Values
Age (years), median (range)	68.5 (32-75)
Sex, n (%)	
Male	14 (74)
Female	5 (26)
Length of stay (days), median (range)	8 (2-36)
Glycated hemoglobin at enrolment (%), median (range)	10.9 (6.5-14.8)
Glycated hemoglobin at 3 months (%), median (range)	8.0 (5-10.8)[a]
Admission type, n (%)	
Endocrinology	6 (32)
Other medical specialties	7 (37)
Surgical specialties	6 (32)
New diagnosis of diabetes, n (%)	4 (21)
Requiring insulin on discharge, n (%)	19 (100)

[a]Result from 18 patients.

Discussion

Principal Findings

Only 19 of 101 potential participants were recruited to the study. Of the 19 participants in the intervention arm, only 2 (10%) had an unplanned hospital re-presentation in the first month after discharge, versus a published rate of 17% [14]. Participants were satisfied with the CGM. Although telehealth has the potential for enhanced clinical care [15], our negative study demonstrates the difficulties in implementing new technologies in a cohort of older adults with chronic illness after acute hospitalization. Our study supports previous work that suggests human factors may impede the uptake of newer technologies [16]. Our study highlights patient concerns and barriers that will need to be addressed if telemedicine is to be provided equitably. This includes addressing cognitive and mental health barriers. The provision of culturally, socially, and educationally appropriate technical material in a range of languages may be required. Acute illness and transitioning home is a stressful time for a person and their support network, and so may not be a suitable time to introduce new diabetes self-management tasks. This is in addition to limited access to technology and telemedicine "unreadiness" being high among older adults [17].

The underpowered sample size and early termination were significant limitations to our study, and we were not able to address our primary or secondary aims. A further limitation is that we were unable to ascertain whether our low recruitment rate, particularly for those not wishing to attend a follow-up clinic visit, may reflect reticence due to recovery from acute illness or chronic disease burnout. It is unclear whether our intervention would have been more acceptable if offered at a different time point in the provision of diabetes care [18]. Age may be another factor; a recent study has shown a low participation rate of approximately 10% for a remote, technology-based intervention for adults with an average age of 60 years with chronic disease [19].

Conclusion

Diabetes therapy frequently requires adjustment on discharge from hospital. Newer technologies such as CGM provide a more comprehensive glucose profile that can be incorporated into

XSL•FO
RenderX

remote patient monitoring. Where used, satisfaction with such newer technologies to facilitate telemedicine for diabetes management is high. The limited recruitment to our study suggests hospital discharge may not be the optimal time to introduce complex new technologies to patients. In embracing the promise of telemedicine including remote monitoring, further research on addressing human factors, to ensure equity, is required.

Conflicts of Interest

None declared.

References

1. Hollander JE, Carr BG. Virtually Perfect? Telemedicine for Covid-19. N Engl J Med 2020 Apr 30;382(18):1679-1681. [doi: 10.1056/NEJMp2003539] [Medline: 32160451]

2. Celler B, Varnfield M, Nepal S, Sparks R, Li J, Jayasena R. Impact of At-Home Telemonitoring on Health Services Expenditure and Hospital Admissions in Patients With Chronic Conditions: Before and After Control Intervention Analysis. JMIR Med Inform 2017 Sep 08;5(3):e29 [FREE Full text] [doi: 10.2196/medinform.7308] [Medline: 28887294]

3. Martin C, Hinkley N, Stockman K, Campbell D. Capitated Telehealth Coaching Hospital Readmission Service in Australia: Pragmatic Controlled Evaluation. J Med Internet Res 2020 Dec 01;22(12):e18046 [FREE Full text] [doi: 10.2196/18046] [Medline: 33258781]

4. Auener SL, Remers TEP, van Dulmen SA, Westert GP, Kool RB, Jeurissen PPT. The Effect of Noninvasive Telemonitoring for Chronic Heart Failure on Health Care Utilization: Systematic Review. J Med Internet Res 2021 Sep 29;23(9):e26744 [FREE Full text] [doi: 10.2196/26744] [Medline: 34586072]

5. American Diabetes Association. 15. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S211-S220. [doi: 10.2337/dc21-S015] [Medline: 33298426]

6. Soh JGS, Wong WP, Mukhopadhyay A, Quek SC, Tai BC. Predictors of 30-day unplanned hospital readmission among adult patients with diabetes mellitus: a systematic review with meta-analysis. BMJ Open Diabetes Res Care 2020 Aug 11;8(1):e001227 [FREE Full text] [doi: 10.1136/bmjdrc-2020-001227] [Medline: 32784248]

7. Emons MF, Bae JP, Hoogwerf BJ, Kindermann SL, Taylor RJ, Nathanson BH. Risk factors for 30-day readmission following hypoglycemia-related emergency room and inpatient admissions. BMJ Open Diabetes Res Care 2016 Apr 04;4(1):e000160 [FREE Full text] [doi: 10.1136/bmjdrc-2015-000160] [Medline: 27110366]

8. Joseph JI. Review of the Long-Term Implantable Senseonics Continuous Glucose Monitoring System and Other Continuous Glucose Monitoring Systems. J Diabetes Sci Technol 2021 Jan 29;15(1):167-173 [FREE Full text] [doi: 10.1177/1932296820911919] [Medline: 32345047]

9. Edelman S, Argento N, Pettus J, Hirsch I. Clinical Implications of Real-time and Intermittently Scanned Continuous Glucose Monitoring. Diabetes Care 2018 Nov;41(11):2265-2274. [doi: 10.2337/dc18-1150] [Medline: 30348844]

10. Holt R, DeVries J, Hess-Fischl A, Hirsch IB, Kirkman MS, Klupa T, et al. The Management of Type 1 Diabetes in Adults. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2021 Nov;44(11):2589-2625. [doi: 10.2337/dci21-0043] [Medline: 34593612]

11. Beck RW, Riddlesworth TD. Continuous Glucose Monitoring Versus Usual Care in Patients With Type 2 Diabetes Receiving Multiple Daily Insulin Injections. Ann Intern Med 2018 Apr 03;168(7):526-527. [doi: 10.7326/L17-0706] [Medline: 29610905]

12. Hermanns N, Ehrmann D, Schipfer M, Kröger J, Haak T, Kulzer B. The impact of a structured education and treatment programme (FLASH) for people with diabetes using a flash sensor-based glucose monitoring system: Results of a randomized controlled trial. Diabetes Res Clin Pract 2019 Apr;150:111-121 [FREE Full text] [doi: 10.1016/j.diabres.2019.03.003] [Medline: 30844467]

13. Furler J, O'Neal D, Speight J, Blackberry I, Manski-Nankervis J, Thuraisingam S, et al. Use of professional-mode flash glucose monitoring, at 3-month intervals, in adults with type 2 diabetes in general practice (GP-OSMOTIC): a pragmatic, open-label, 12-month, randomised controlled trial. Lancet Diabetes Endocrinol 2020 Jan;8(1):17-26. [doi: 10.1016/S2213-8587(19)30385-7] [Medline: 31862147]

14. Wei NJ, Wexler DJ, Nathan DM, Grant RW. Intensification of diabetes medication and risk for 30-day readmission. Diabet Med 2013 Feb 21;30(2):e56-e62 [FREE Full text] [doi: 10.1111/dme.12061] [Medline: 23126686]

15. Tuckson RV, Edmunds M, Hodgkins ML. Telehealth. N Engl J Med 2017 Oct 19;377(16):1585-1592. [doi: 10.1056/NEJMsr1503323] [Medline: 29045204]

16. Kerr D, Sabharwal A. Principles for virtual health care to deliver real equity in diabetes. Lancet Diabetes Endocrinol 2021 Aug;9(8):480-482. [doi: 10.1016/S2213-8587(21)00176-5] [Medline: 34217405]

17. Lam K, Lu AD, Shi Y, Covinsky KE. Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic. JAMA Intern Med 2020 Oct 01;180(10):1389-1391 [FREE Full text] [doi: 10.1001/jamainternmed.2020.2671] [Medline: 32744593]

18.   Flink M, Brandberg C, Ekstedt M. Why patients decline participation in an intervention to reduce re-hospitalization through patient activation: whom are we missing? Trials 2019 Jan 25;20(1):82 [FREE Full text] [doi: 10.1186/s13063-019-3187-9] [Medline: 30683140]

19.   Li A, Del Olmo MG, Fong M, Sim K, Lymer SJ, Cunich M, et al. Effect of a smartphone application (Perx) on medication adherence and clinical outcomes: a 12-month randomised controlled trial. BMJ Open 2021 Aug 09;11(8):e047041 [FREE Full text] [doi: 10.1136/bmjopen-2020-047041] [Medline: 34373299]

Abbreviations

CGM: continuous glucose monitor
HbA$_{1c}$: glycated hemoglobin
T2DM: type 2 diabetes

XSL·FO
RenderX

Original Paper

Content Quality of YouTube Videos About Gestational Diabetes: Systematic Evaluation

Eleanor M Birch[1], MD, MPH; Karolina Leziak[1], BA; Jenise Jackson[1], MPH; Emma Dahl[1]; Charlotte M Niznik[1], APN, CDCES; Lynn M Yee[1], MD, MPH

Division of Maternal-Fetal Medicine, Department of Obstetrics & Gynecology, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States

Corresponding Author:
Lynn M Yee, MD, MPH
Division of Maternal-Fetal Medicine
Department of Obstetrics & Gynecology
Feinberg School of Medicine, Northwestern University
250 E. Superior Street, #5-2145
Chicago, IL, 60611
United States
Phone: 1 312 472 4685
Fax: 1 312 472 0511
Email: lynn.yee@northwestern.edu

Abstract

Background: People with gestational diabetes have enhanced learning requirements during pregnancy, and management of their disease often requires the translation of health information into new health behavior changes. Seeking information from the internet to augment learning from health professionals is becoming more common during pregnancy. YouTube is a popular free and accessible web-based resource, which may be particularly useful for individuals with low health literacy or other barriers to receiving high-quality health care; however, the quality and content of YouTube videos varies, and little is known about those covering gestational diabetes.

Objective: We aimed to systematically evaluate the quality, content, and reliability of YouTube videos about gestational diabetes.

Methods: A systematic search of YouTube videos was conducted over the course of 1 week in April 2020 using the following keywords: "gestational diabetes," "gestational diabetes management," "gestational diabetes treatment," and "pregnancy and diabetes." The search results were displayed by relevance, replicating a default YouTube search attempt. The first 60 results from each keyword were reviewed (n=240). Exclusion criteria were videos unrelated to gestational diabetes, videos not in English, and those for which the full video was not available at the time of review. For each unique video, a gestational diabetes content score was used to rate video comprehensiveness and accuracy, and the DISCERN instrument, a validated metric to assess consumer health information, was used to evaluate the reliability of information presented. Videos were further categorized by quality: videos with DISCERN scores lower than 3 (out of 5) or a content score less than 4 (out of 7) were categorized as low quality, and all others were designated high quality. We performed descriptive analysis and compared video characteristics by source and quality rating.

Results: For 115 unique videos, the mean content score (out of 7) was 3.5 (SD 2.0) , and the mean DISCERN score (out of 5) was 2.7 (SD 0.7), representing low to moderate information comprehensiveness and reliability respectively. Video sources were categorized as personal vlog (12/115, 10.4%), web-based education (37/115, 32.2%), medical (52/115, 45.2%), business or company (13/115, 11.3%), and media clip (1/115, 0.9%). DISCERN and content scores trended higher among medical and web-based education videos. The majority of videos (n=88) were categorized as low quality, while 27 videos were categorized as high quality. Video duration was longer for high-quality videos ($P<.001$); high- and low-quality videos otherwise had similar views and viewer interaction numbers.

Conclusions: Although high-quality videos about gestational diabetes exist, reliability, accuracy, and comprehensiveness were low overall, and higher quality was not associated with increased viewer interaction. It is important to acknowledge the limitations of this platform and to assist patients in accessing high quality content and differentiating the quality of information sources.

Introduction

Gestational diabetes is one of the most common complications of pregnancy. Untreated or undertreated gestational diabetes is associated with perinatal and maternal complications, including preeclampsia, macrosomia, neonatal hypoglycemia, and maternal risk of developing type 2 diabetes [1]. Because management of gestational diabetes may include a combination of nutritional therapy, physical activity, blood glucose monitoring, or medication, affected individuals require health behavior changes beyond those required during routine pregnancy care in order to have best outcomes [2-4]. These increased requirements are particularly noteworthy because individuals with gestational diabetes are more likely to belong to racial, ethnic, and socioeconomic groups that face barriers to access to high-quality care [1,5,6]. Because an individual's access to and application of informative resources about gestational diabetes testing, treatment, and self-management may determine their risk of adverse pregnancy outcomes, improving access to high-quality health information and support for health behavior change is crucial [6-10].

The internet is a widely available, increasingly accessed resource for health information, and it is a common source of information for pregnancy-related health concerns [11,12]. Multiple studies [13-17] have found high prevalences of internet and other digital media use among pregnant patients in the United States—estimated to be greater than 70% among patients of different ages, races or ethnicities, and socioeconomic groups. Web-based information-seeking has been reported for many pregnancy-related topics including fetal development, pregnancy complications, prenatal care, medication safety, nutrition, and gestational weight gain [15,17-19]. The rapidity of information access and availability of supplemental explanation are reported advantages of seeking information from the internet [17]. YouTube is a particularly important source of health information, both because of its popularity as one of the most used web-based platforms, and because its information is unregulated [20-25]. Evaluations on a variety of topics, including infertility treatment, medication safety during pregnancy, and diabetes outside of pregnancy have reported variability in the value of YouTube as a health information source and some found that videos provided incomplete or misleading information, while others have reported advantages, including the availability of personal experience–based information [26-28]. However, little is known about the content and quality of information from YouTube on gestational diabetes.

Given the emerging role of web-based platforms—including YouTube—as health information resources, and the importance of optimizing health care information and interventions for individuals with gestational diabetes, it is important to learn more about the content and quality of resources about gestational diabetes that are available on YouTube. Restrictions on access

to care [8], limited health literacy [18], and lack of availability of culturally appropriate interventions [8,29,30] are well-known barriers in the provision of prenatal care for gestational diabetes, and understanding resources—such as videos available on YouTube—that may help combat those barriers is vital. Thus, our objective was to examine the quality and content of videos about gestational diabetes in order to ultimately develop opportunities for better, more accessible health care delivery.

Methods

Search Strategy

We systematically reviewed YouTube content on gestational diabetes on April 30, 2020. Search terms were identified in consultation with 2 perinatal diabetes care specialists (CN and LY), and Google Trends was used to identify top searches associated with gestational diabetes. The search was then conducted on a cache-cleared web browser using incognito mode with the following terms: "gestational diabetes," "gestational diabetes management," "gestational diabetes treatment," and "pregnancy and diabetes." The search was conducted via public access—a registered account was not used.

Search results were displayed by relevance, which is the default search setting. The first 60 results—representing the first 3 pages of results—from each keyword search were reviewed and analyzed. The sample size and sort strategy were selected based on research indicating that the majority of internet searchers view only 1 page of results, and 83% of searchers view no more than 3 pages [31]. Duplicate videos, videos unrelated to gestational diabetes, videos in a language other than English, and clips for which the full video was unavailable were excluded.

Data Extraction

Descriptive characteristics of each video were collected, including video length, number of comments, channel number of subscribers, number of views, number of likes, and number of dislikes. Collection of this information was completed by 1 reviewer (EB), over the course of 1 week (from April 26, 2020 to May 2, 2020) to minimize variability in number of views and other characteristics collected. Source characteristics were also gathered from each video. These included the video source and whether the video was a *character video*, which was defined as a video in which a specific, identifiable person was presenting. Video source was determined based on the affiliation of each video's author when available (eg, identified as an employee of a hospital system or pharmaceutical company), or the channel description and theme (eg, medical school test preparation videos or personal vlog in which the author presents primarily personal experiences).

Content and Quality Assessment

Criteria to judge video content were formulated from American College of Obstetricians and Gynecologists recommendations

for management of gestational diabetes, and in consultation with perinatal diabetes care specialists (CN and LY). Video comprehensiveness and accuracy of information provided about (1) screening or testing guidelines; (2) treatment for gestational diabetes self-management; (3) nutrition information; (4) information about the purpose of gestational diabetes treatment and benefits; (5) blood glucose level monitoring guidelines; (6) gestational diabetes effects on long-term maternal health; and (7) gestational diabetes effects on the fetus. These topics were selected because they represent key foundational knowledge regarding gestational diabetes that is essential for participants to understand their condition, participate in self-monitoring and management, and engage in health care to prevent adverse perinatal outcomes. To evaluate videos, we used a content score—1 point for each content area addressed accurately in the video (ie, the video included relevant information in that topic area, though depth of explanation varied); thus, a maximum score of 7 was possible if a video covered the comprehensive range of topics about gestational diabetes accurately. Similar assessments have been performed in prior evaluations of YouTube videos as a health information source [32-36].

The DISCERN instrument [37] was used to assess the quality and reliability of the videos as information sources. The DISCERN instrument consists of 16 questions assessing the (1) reliability, (2) quality, and (3) overall rating of web-based publications. DISCERN criteria are written as questions and are rated on a scale from 1 (not satisfied) to 5 (fully satisfied). The DISCERN tool has been validated for use in a variety of settings, and it has been used in similar studies that have evaluated YouTube videos as a source of health information [34,35,38-42].

A combination of both scoring techniques was used to divide videos into high- and low-quality categories. Videos with a mean DISCERN score less than 3 or a content score less than 4 were defined as low quality; otherwise, videos were defined as high quality. These quality cutoffs were chosen because they correspond to a DISCERN rating representing potentially important shortcomings or an inclusion of fewer than half of the expert-developed content topics, respectively, both of which affect the overall quality of the video as a reliable comprehensive source of information.

After determining evaluation criteria, 2 videos were assessed collaboratively by 3 reviewers (EB, JJ, ED) to establish consensus on the application of these criteria and scoring. Subsequently, these 3 reviewers independently evaluated the same 15 randomly selected videos for content and reliability. The remaining videos were then divided evenly among the reviewers, and each was evaluated using the established standardized criteria. Data for each video were collected and stored using REDCap (Vanderbilt University) software.

Statistical Analysis

Statistical analyses were performed using Excel software (version 2020; Microsoft Inc). Interrater agreement was analyzed using intraclass correlation coefficients and single-factor analysis of variance. Descriptive statistics were used to evaluate study data. Frequencies were used to describe categorical

variables; normally distributed continuous variables were presented as means, and nonnormally distributed variables as medians. The Kruskal-Wallis test for intergroup comparison, Spearman rank correlation, and Wilcoxon rank-sum test were used for analysis involving nonnormally distributed continuous variables. A P value<.05 was considered significant.

Ethics Statement

This study was deemed exempt from review by the Northwestern University institutional review board because it does not involve human participants.

Results

The mean scoring disparity for the 15 videos was 0.27 (for DISCERN), and correlation was 88% (intraclass correlation 0.81), indicating a high level of interrater agreement. Of the 240 videos initially identified, 109 were duplicates, 3 were in a language other than English (Urdu, Nepali, Bengali), 2 with full videos unavailable at the time of data recording, and 11 had a primary topic that was not gestational diabetes. After applying exclusion criteria, 115 videos remained for analysis (Figure 1; Multimedia Appendix 1). Video characteristics (Table 1) varied widely, for example, the number of comments ranged from 0 to 651, and the number of channel subscribers ranged from 0 to 2 million. Out of 115 videos, 64 videos were categorized as character videos.

DISCERN scores (Table 2) ranged from 1.4 to 5, but were, on average, low (mean 2.70, SD 0.73). Content scores were similarly low; on average, videos contained accurate information on 3.5 out of the 7 topics (SD 2.01). The majority of videos (77/115, 67%) contained information about some type of gestational diabetes treatment, including medical nutritional therapy, physical activity, insulin, or oral medications. However, fewer videos contained information about nutritional guidelines for patients with gestational diabetes or about blood glucose monitoring (Figure 2). Of all video characteristics, only duration was significantly positively associated with both DISCERN score ($P<.001$) and topic score ($P<.001$).

The sources of videos included medical institutions or hospitals (52/115, 45.2%), web-based education (37/115, 32.2%), personal vlog (12/115, 10.4%), business or company (13/115, 11.3%), and media (1/115, 0.9%). The single video in the media category had the second highest number of views, comments, and subscribers; the highest number of dislikes; and was in the top 10 videos by number of likes; however, because the media category had only 1 video, it was not included in comparisons of characteristics by source. Among other sources (Table 3), personal vlogs were longer ($P<.001$), with more comments ($P<.001$), likes ($P=.001$), and dislikes ($P=.01$); there was no significant difference in views ($P=.22$) or subscribers ($P=.60$). The mean DISCERN score was highest for web-based education videos (mean 2.91, SD 0.79), followed by that for videos from medical institutions or hospital (mean 2.69, SD 0.64). Web-based education was the source with the highest average topic score (mean 4.3, SD 1.93).

Of 115 videos reviewed, 27 videos were designated as high quality, and 88 videos were designated as low quality. The

low-quality group included 12 videos that were rated as low only because they included fewer than 4 topics; their DISCERN scores ranged from 3.0 to 3.6. Therefore, the scoring system did not result in a large number of videos with reliable in-depth information about a small number of topics, but instead, a small number of videos with moderate reliability and low topic comprehensiveness, being found in the low-quality categorization. Longer video duration was associated with higher quality ($P<.001$), but the numbers of views, comments, likes, dislikes, and subscribers were not associated with quality (Table 4). Among high-quality videos, 24 out of 27 were from web-based education or medical sources, 2 were personal vlogs, and 1 was from a business or company.

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) flow diagram. GDM: gestational diabetes mellitus.
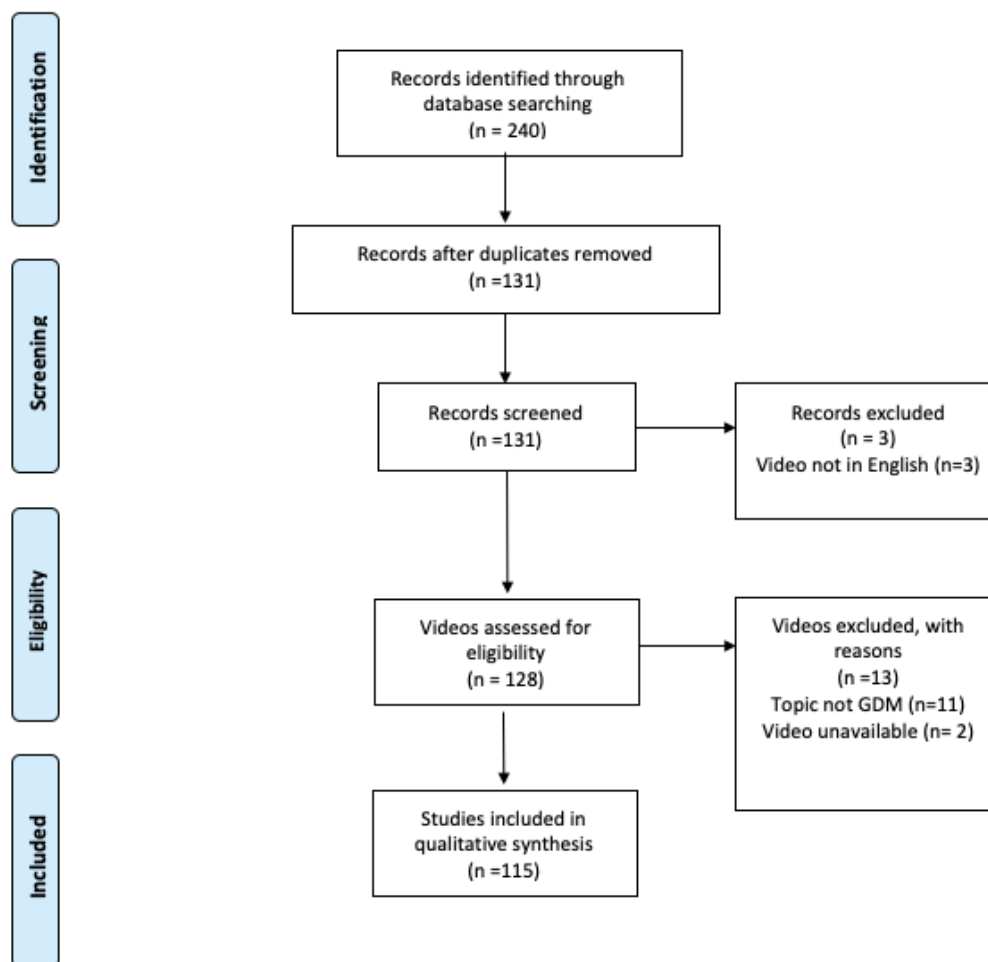
Table 1. Characteristics of the videos (n=115).

Video characteristic	Median (IQR)	Minimum to maximum
Duration (seconds)	234 (114-598)	34-3722
Views	4045 (808-23,809)	57-548,409
Comments	1 (0-8)	0-651
Likes	21 (3-112)	0-5700
Dislikes	1 (0-7)	0-1600
Channel subscribers	10,300 (750-60,000)	0-2,700,000

Table 2. Reliability and content score of YouTube videos about gestational diabetes by source.

Source	DISCERN		Content	
	Score, mean (SD)	P value	Score, mean (SD)	P value
Total	2.70 (0.73)	.05	3.51 (2.01)	.05
Medical institution or hospital (n=52)	2.69 (0.64)	—[a]	3.27 (1.77)	—
Web-based education (n=37)	2.91 (0.79)	—	4.30 (1.93)	—
Personal vlog (n=12)	2.54 (0.56)	—	3.08 (2.18)	—
Business or company (n=13)	2.38 (0.80)	—	2.92 (2.20)	—
Media clip (n=1)	1.40 (—)	—	0 (—)	—

[a]No data or not applicable.

Figure 2. YouTube video content inclusion by topic area.
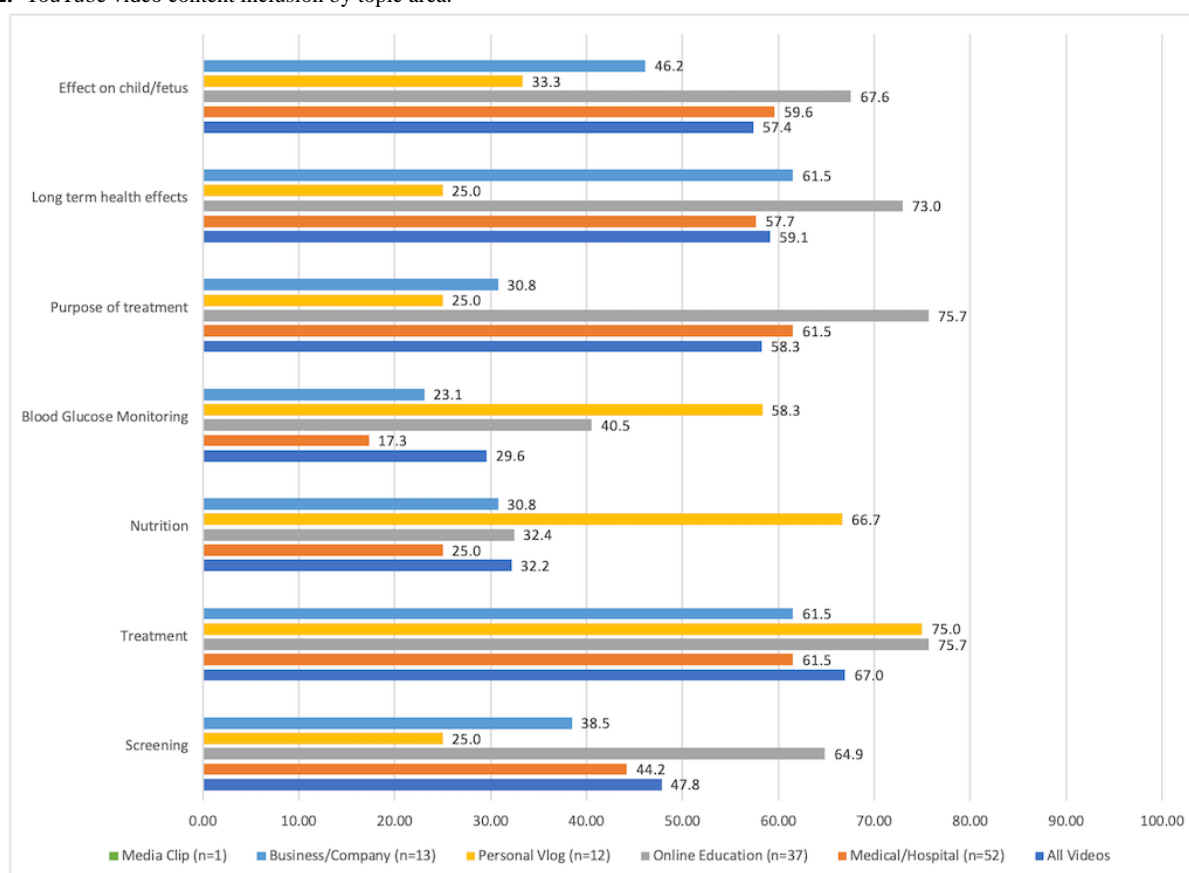
Table 3. Characteristics of YouTube videos about gestational diabetes by source.

Source	Characteristic, median (IQR)					
	Duration	Views	Comments	Likes	Dislikes	Subscribers
Medical (n=52)	192 (112-270)	2943 (612-14,576)	0 (0-3)	10 (2-45)	0 (0-4)	14,150 (2232-58,175)
Web-based education (n=37)	337 (164-975)	4045 (820-25,896)	2 (0-10)	19 (4-157)	1 (0-10)	6250 (268-79,900)
Personal vlog (n=12)	677 (438-974)	10,206 (5186-54902)	27 (4-143)	254 (48-699)	10 (2-29)	18,950 (1835-77,475)
Business or company (n=13)	113 (70-309)	1388 (702-23,902)	0 (0-4)	6 (2-47)	2 (0-6)	6090 (156-40,700)
Media clip (n=1)	58 (—[a])	409,285 (—)	389 (—)	834 (—)	1600 (—)	2,100,000 (—)

Table 4. Characteristics of YouTube videos about gestational diabetes by quality.

Characteristic	Low quality (n=88), median (IQR)	High quality (n=27)), median (IQR)	*P* value
Views	3851.5 (762.5-23,439.2)	4523 (1253- 24,533)	.63
Comments	1 (0-8.8)	0 (0-4)	.40
Likes	21 (2.3-114.3)	19 (4-84)	.90
Dislikes	1 (0-7.8)	2 (0-4)	.86
Duration	203.5 (98-374)	760 (263-1320)	<.001
Subscribers	13,950 (695-62,925)	6430 (819-38,300)	.90

Discussion

Principal Findings

In this study, we identified no relationship between video quality and indicators of video popularity. These findings indicate that the information available to pregnant individuals with gestational diabetes is highly variable in quality, and may not deliver accurate or comprehensive information to users.

Comparison With Prior Work

YouTube has been evaluated as a source of health information on a variety of topics, including emerging infectious diseases and pregnancy [43,44], medication use in pregnancy [27], and diabetes outside of pregnancy [34], as well as colorectal cancer [36], ankylosing spondylitis [39], and rheumatoid arthritis [40]. The average DISCERN score in this study is concordant with that found in many previous studies of YouTube videos [34,35,38-40,43]. Scores in previous studies have typically fallen in the low to moderate reliability range, indicating potentially important shortcomings. Although studies evaluating other health conditions used various topic-specific comprehensiveness scales, they found similar levels of topic coverage, accuracy, and comprehensiveness to those found by us [36,40,41]. We found that this level of topic inclusion represents notably incomplete coverage of the health condition. The majority of videos we evaluated covered only 3 to 4 key topics about gestational diabetes accurately, and only 1 topic—gestational diabetes management—was included by more than 50% of videos. The overall low comprehensiveness of individual videos evaluated has implications for their utility as health information resource. In further research, it could be helpful to investigate YouTube user viewing patterns to ascertain whether these shortcomings can be overcome through careful combination of videos and topics covered.

Interestingly, in our study, one of the lowest rated videos overall by both DISCERN criteria and topic coverage had some of the highest views, likes, comments, and channel subscribers. This video was a media clip related to a television personality; therefore, the high numbers of views, likes, comments, and subscribers are likely because viewers accessed the clip for entertainment rather than for information about gestational diabetes. However, this highlights an important aspect of finding health information on YouTube—the search algorithm may not take the quality of the video into account for any specific search term, and quality varies significantly between videos. As we found and as has been seen previously, there are rare videos

available with both good reliability and comprehensive topic coverage; however, it is difficult to ensure that these videos are accessed, as they are not necessarily the most viewed, liked, or highly ranked videos available [38,45,46].

Clinical and Research Implications

Pregnant patients increasingly seek health education via web-based sources, including YouTube, and web-based media can be helpful adjuncts to clinical care [15,17,25,47-49]. Trust in information found on the internet is often reported to be high, and many people who sought information on the internet did not discuss it with their providers [15,17]. Therefore, it is important for providers to be aware of the overall use and limitations of YouTube as a resource when counselling patients with gestational diabetes, and it may be useful for clinicians to query and understand the resources patients are using to augment their clinical care.

However, it is also important to note that YouTube has the potential to address the specific needs of individuals with gestational diabetes. Health information and supportive social networks—which are both easily accessed via the internet—have been found to influence the challenges experienced by people with gestational diabetes [49-51]. In addition, patients' health literacy levels and access to information are known to affect glycemic control and gestational diabetes–related outcomes [52-55]; interventions for pregnant individuals at an appropriately targeted health literacy level are particularly essential to address health inequities present in gestational diabetes care and outcomes [8,56]. Video-based information has frequently been used to combat care barriers related to health literacy [57-59]. Despite the limitations found in this study, YouTube videos remain a low-cost, easily accessible resource, and further interventions should investigate ways to address these limitations in order to harness YouTube's potential as a patient education tool. Clinicians also have the opportunity to assist patients who are using YouTube as resource by recommending specific videos, discussing ways to identify reliable resources, or even creating high-quality content. Health care providers involved in gestational diabetes care are likely to have both the knowledge base and the resources available to create accurate comprehensive videos with information that is helpful for patients with gestational diabetes.

Limitations

To the best of our knowledge, this study is the first to assess the reliability, content, and quality of YouTube videos about gestational diabetes, but it has several limitations. First, while

the sample size was chosen to encompass the majority of videos likely to be encountered by individuals searching for information about gestational diabetes, we cannot ensure that all videos that a user may find were included, given the dynamic nature of video uploading. Search history or location may also affect ranking and accessibility of videos in ways that were not demonstrated in this paper. Second, we could not evaluate the target audience for each video, because most videos do not indicate their audience and default search setting will not necessarily preclude people from accessing videos aimed at different groups. As such, our assessment of quality and reliability may not reflect all videos with which pregnant individuals engage. Additionally, our search was limited to English-language videos, and future work is necessary to corroborate our findings with those for videos in other languages.

We also noted little gender, racial, or ethnic diversity among YouTube presenters in videos about gestational diabetes.

Especially because social media sites, and YouTube specifically, may be sought as a more personal or personal-experience based resource, this lack of diverse representation is a noteworthy limitation. Based on the representation found in the videos evaluated, many patients may not see themselves or their experiences reflected fully.

Conclusions

Despite the relatively low quality and comprehensiveness found among YouTube videos for individuals with gestational diabetes, YouTube is an easily accessible and increasingly important source of health information. Providers caring for individuals with gestational diabetes should remain aware of the limitations of this resource, especially when discussing information sources with patients. Further study may be helpful in elucidating ways to harness the potential strengths of YouTube for providing high-quality accessible health information.

Conflicts of Interest

None declared.

Multimedia Appendix 1
List of videos (n=115) included in study.
[XLSX File (Microsoft Excel File), 18 KB - diabetes_v7i2e30156_app1.xlsx]

References

1. Committee on Practice BO. ACOG practice bulletin no. 190: gestational diabetes mellitus. Obstet Gynecol 2018 Feb;131(2):e49-e64. [doi: 10.1097/AOG.0000000000002501] [Medline: 29370047]
2. Bennett WL, Liu S, Yeh H, Nicholson WK, Gunderson EP, Lewis CE, et al. Changes in weight and health behaviors after pregnancies complicated by gestational diabetes mellitus: the CARDIA study. Obesity (Silver Spring) 2013 Jun;21(6):1269-1275 [FREE Full text] [doi: 10.1002/oby.20133] [Medline: 23666593]
3. Shepherd E, Gomersall J, Tieu J, Han S, Crowther C, Middleton P. Combined diet and exercise interventions for preventing gestational diabetes mellitus. Cochrane Database Syst Rev 2017 Nov 13;11:CD010443 [FREE Full text] [doi: 10.1002/14651858.CD010443.pub3] [Medline: 29129039]
4. Crowther CA, Hiller JE, Moss JR, McPhee AJ, Jeffries WS, Robinson JS, Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) Trial Group. Effect of treatment of gestational diabetes mellitus on pregnancy outcomes. N Engl J Med 2005 Jun 16;352(24):2477-2486. [doi: 10.1056/NEJMoa042973] [Medline: 15951574]
5. Novick G. Women's experience of prenatal care: an integrative review. J Midwifery Womens Health 2009;54(3):226-237 [FREE Full text] [doi: 10.1016/j.jmwh.2009.02.003] [Medline: 19410215]
6. Yee L, McGuire J, Taylor S, Niznik C, Simon M. "I was tired of all the sticking and poking": identifying barriers to diabetes self-care among low-income pregnant women. J Health Care Poor Underserved 2015 Aug;26(3):926-940. [doi: 10.1353/hpu.2015.0073] [Medline: 26320923]
7. Lu MC, Kotelchuck M, Hogan VK, Johnson K, Reyes C. Innovative strategies to reduce disparities in the quality of prenatal care in underresourced settings. Med Care Res Rev 2010 Oct 30;67(5 Suppl):198S-230S. [doi: 10.1177/1077558710374324] [Medline: 20675351]
8. Carolan M, Gill GK, Steele C. Women's experiences of factors that facilitate or inhibit gestational diabetes self-management. BMC Pregnancy Childbirth 2012 Sep 18;12(1):99 [FREE Full text] [doi: 10.1186/1471-2393-12-99] [Medline: 22988897]
9. Yee L, McGuire J, Taylor S, Niznik C, Simon M. Factors promoting diabetes self-care among low-income, minority pregnant women. J Perinatol 2016 Jan;36(1):13-18. [doi: 10.1038/jp.2015.134] [Medline: 26513455]

10. Shub A, Huning EY, Campbell KJ, McCarthy EA. Pregnant women's knowledge of weight, weight gain, complications of obesity and weight management strategies in pregnancy. BMC Res Notes 2013 Jul 18;6:278 [FREE Full text] [doi: 10.1186/1756-0500-6-278] [Medline: 23866845]

11. Perrin A, Kumar M. About three-in-ten US adults say they are "almost constantly" online. Pew Research Center. URL: https://www.pewresearch.org/fact-tank/2019/07/25/americans-going-online-almost-constantly/ [accessed 2020-12-04]

12. Health topics. Pew Research Center. 2011. URL: https://www.pewresearch.org/internet/2011/02/01/health-topics-4/ [accessed 2020-12-02]

13. Lupton D. The use and value of digital media for information about pregnancy and early motherhood: a focus group study. BMC Pregnancy Childbirth 2016 Jul 19;16(1):171 [FREE Full text] [doi: 10.1186/s12884-016-0971-3] [Medline: 27435182]

14. Peragallo Urrutia R, Berger A, Ivins A, Beckham A, Thorp JJ, Nicholson W. Internet use and access among pregnant women via computer and mobile phone: implications for delivery of perinatal care. JMIR Mhealth Uhealth 2015 Mar 30;3(1):e25 [FREE Full text] [doi: 10.2196/mhealth.3347] [Medline: 25835744]

15. Narasimhulu DM, Karakash S, Weedon J, Minkoff H. Patterns of internet use by pregnant women, and reliability of pregnancy-related searches. Matern Child Health J 2016 Dec;20(12):2502-2509. [doi: 10.1007/s10995-016-2075-0] [Medline: 27456311]

16. Declercq ER, Sakala C, Corry MP, Applebaum S, Herrlich A. Major survey findings of listening to mothers (SM) III: pregnancy and birth: report of the third national U.S. survey of women's childbearing experiences. J Perinat Educ 2014;23(1):9-16 [FREE Full text] [doi: 10.1891/1058-1243.23.1.9] [Medline: 24453463]

17. Sayakhot P, Carolan-Olah M. Internet use by pregnant women seeking pregnancy-related information: a systematic review. BMC Pregnancy Childbirth 2016 Mar 28;16:65 [FREE Full text] [doi: 10.1186/s12884-016-0856-5] [Medline: 27021727]

18. Chilukuri N, West M, Henderson J, Lawson S, Ehsanipoor R, Costigan K, et al. Information and communication technology use among low-income pregnant and postpartum women by race and ethnicity: a cross-sectional study. J Med Internet Res 2015 Jul 03;17(7):e163 [FREE Full text] [doi: 10.2196/jmir.3916] [Medline: 26142162]

19. Willcox J, Campbell K, McCarthy E, Lappas M, Ball K, Crawford D, et al. Gestational weight gain information: seeking and sources among pregnant women. BMC Pregnancy Childbirth 2015 Aug 07;15:164 [FREE Full text] [doi: 10.1186/s12884-015-0600-6] [Medline: 26249832]

20. van Kessel P. 10 facts about Americans and YouTube. Pew Research Center. 2019 Dec 10. URL: https://www.pewresearch.org/fact-tank/2019/12/04/10-facts-about-americans-and-youtube/ [accessed 2020-12-04]

21. Smith A, Toor S, Van Kessel P. Many turn to YouTube for children's content, news, how-to lessons. Pew Research Center. 2018 Nov 7. URL: https://www.pewresearch.org/internet/2018/11/07/many-turn-to-youtube-for-childrens-content-news-how-to-lessons/ [accessed 2020-12-05]

22. Flanders CE, Pragg L, Dobinson C, Logie C. Young sexual minority women's use of the internet and other digital technologies for sexual health information seeking. Can J Hum Sex 2017 Apr;26(1):17-25. [doi: 10.3138/cjhs.261-A2]

23. Park D, Goering E. The health-related uses and gratifications of youtube: motive, cognitive involvement, online activity, and sense of empowerment. J Consum Health Internet 2016 May 09;20(1-2):52-70. [doi: 10.1080/15398285.2016.1167580]

24. Vance K, Howe W, Dellavalle RP. Social internet sites as a source of public health information. Dermatol Clin 2009 Apr;27(2):133-6, vi. [doi: 10.1016/j.det.2008.11.010] [Medline: 19254656]

25. The top 500 sites on the web. Alexa. 2021. URL: https://www.alexa.com/topsites [accessed 2021-12-05] [WebCite Cache ID 6xbJjPSrN]

26. Kelly-Hedrick M, Grunberg PH, Brochu F, Zelkowitz P. "It's totally okay to be sad, but never lose hope": content analysis of infertility-related videos on YouTube in relation to viewer preferences. J Med Internet Res 2018 May 23;20(5):e10199 [FREE Full text] [doi: 10.2196/10199] [Medline: 29792296]

27. Hansen C, Interrante JD, Ailes EC, Frey MT, Broussard CS, Godoshian VJ, et al. Assessment of YouTube videos as a source of information on medication use in pregnancy. Pharmacoepidemiol Drug Saf 2016 Jan 05;25(1):35-44 [FREE Full text] [doi: 10.1002/pds.3911] [Medline: 26541372]

28. Gimenez-Perez G, Robert-Vila N, Tomé-Guerreiro M, Castells I, Mauricio D. Are YouTube videos useful for patient self-education in type 2 diabetes? Health Informatics J 2020 Mar 29;26(1):45-55 [FREE Full text] [doi: 10.1177/1460458218813632] [Medline: 30488752]

29. Thai C, Gaysynsky A, Falisi A, Chou W, Blake K. Trust in health information sources and channels, then and now: evidence from the health information national trends survey (2005–2013). In: Hale TM, Chou WYS, Cotten SR, Khilnani A, editors. eHealth: Current Evidence, Promises, Perils and Future Directions (Studies in Media and Communications, Vol. 15). Bingley: Emerald Publishing Limited; 2018:43-67.

30. Richardson A, Allen JA, Xiao H, Vallone D. Effects of race/ethnicity and socioeconomic status on health information-seeking, confidence, and trust. J Health Care Poor Underserved 2012 Nov;23(4):1477-1493. [doi: 10.1353/hpu.2012.0181] [Medline: 23698662]

31. Jansen BJ, Spink A. How are we searching the World Wide Web? A comparison of nine search engine transaction logs. Inf Process Manag 2006 Jan;42(1):248-263. [doi: 10.1016/j.ipm.2004.10.007]

32. Kecojevic A, Basch C, Basch C, Kernan W. Pre-exposure prophylaxis YouTube videos: content evaluation. JMIR Public Health Surveill 2018 Feb 16;4(1):e19 [FREE Full text] [doi: 10.2196/publichealth.7733] [Medline: 29467119]

33. Erdem MN, Karaca S. Evaluating the accuracy and quality of the information in kyphosis videos shared on YouTube. Spine (Phila Pa 1976) 2018 Nov 15;43(22):E1334-E1339. [doi: 10.1097/BRS.0000000000002691] [Medline: 29664816]

34. Leong AY, Sanghera R, Jhajj J, Desai N, Jammu BS, Makowsky MJ. Is YouTube useful as a source of health information for adults with type 2 diabetes? a South Asian perspective. Can J Diabetes 2018 Aug;42(4):395-403.e4. [doi: 10.1016/j.jcjd.2017.10.056] [Medline: 29282200]

35. Radonjic A, Fat Hing NN, Harlock J, Naji F. YouTube as a source of patient information for abdominal aortic aneurysms. J Vasc Surg 2020 Feb;71(2):637-644 [FREE Full text] [doi: 10.1016/j.jvs.2019.08.230] [Medline: 31611104]

36. Sahin A, Sahin A, Schwenter F, Sebajang H. YouTube videos as a source of information on colorectal cancer: what do our patients learn? J Cancer Educ 2019 Dec;34(6):1160-1166 [FREE Full text] [doi: 10.1007/s13187-018-1422-9] [Medline: 30242615]

37. Charnock D, Shepperd S, Needham G, Gann R. DISCERN: an instrument for judging the quality of written consumer health information on treatment choices. J Epidemiol Community Health 1999 Feb 01;53(2):105-111 [FREE Full text] [doi: 10.1136/jech.53.2.105] [Medline: 10396471]

38. Aydin MA, Akyol H. Quality of information available on YouTube videos pertaining to thyroid cancer. J Cancer Educ 2020 Jun 5;35(3):599-605. [doi: 10.1007/s13187-019-01502-9] [Medline: 30838529]

39. Kocyigit BF, Nacitarhan V, Koca TT, Berk E. YouTube as a source of patient information for ankylosing spondylitis exercises. Clin Rheumatol 2019 Jun 15;38(6):1747-1751. [doi: 10.1007/s10067-018-04413-0] [Medline: 30645752]

40. Singh AG, Singh S, Singh PP. YouTube for information on rheumatoid arthritis--a wakeup call? J Rheumatol 2012 May;39(5):899-903. [doi: 10.3899/jrheum.111114] [Medline: 22467934]

41. Rittberg R, Dissanayake T, Katz SJ. A qualitative analysis of methotrexate self-injection education videos on YouTube. Clin Rheumatol 2016 May 6;35(5):1329-1333. [doi: 10.1007/s10067-015-2910-5] [Medline: 25739847]

42. Charnock D, Shepperd S. Learning to DISCERN online: applying an appraisal tool to health websites in a workshop setting. Health Educ Res 2004 Aug;19(4):440-446. [doi: 10.1093/her/cyg046] [Medline: 15155597]

43. Yuksel B, Cakmak K. Healthcare information on YouTube: pregnancy and COVID-19. Int J Gynaecol Obstet 2020 Aug;150(2):189-193. [doi: 10.1002/ijgo.13246] [Medline: 32471005]

44. Basch CH, Fung IC, Hammond RN, Blankenship EB, Tse ZTH, Fu K, et al. Zika virus on YouTube: an analysis of english-language video content by source. J Prev Med Public Health 2017 Mar;50(2):133-140 [FREE Full text] [doi: 10.3961/jpmph.16.107] [Medline: 28372356]

45. Madathil KC, Rivera-Rodriguez AJ, Greenstein JS, Gramopadhye AK. Healthcare information on YouTube: a systematic review. Health Informatics J 2015 Sep;21(3):173-194 [FREE Full text] [doi: 10.1177/1460458213512220] [Medline: 24670899]

46. Ho M, Stothers L, Lazare D, Tsang B, Macnab A. Evaluation of educational content of YouTube videos relating to neurogenic bladder and intermittent catheterization. Can Urol Assoc J 2015 Oct 13;9(9-10):320-354 [FREE Full text] [doi: 10.5489/cuaj.2955] [Medline: 26644803]

47. Lagan BM, Sinclair M, Kernohan WG. Internet use in pregnancy informs women's decision making: a web-based survey. Birth 2010 Jun;37(2):106-115. [doi: 10.1111/j.1523-536X.2010.00390.x] [Medline: 20557533]

48. Bert F, Gualano MR, Brusaferro S, De Vito E, de Waure C, La Torre G, et al. Pregnancy e-health: a multicenter Italian cross-sectional study on Internet use and decision-making among pregnant women. J Epidemiol Community Health 2013 Dec 01;67(12):1013-1018. [doi: 10.1136/jech-2013-202584] [Medline: 24072743]

49. Sayakhot P, Carolan-Olah M. Sources of information on gestational diabetes mellitus, satisfaction with diagnostic process and information provision. BMC Pregnancy Childbirth 2016 Sep 29;16(1):287 [FREE Full text] [doi: 10.1186/s12884-016-1067-9] [Medline: 27679990]

50. Dayyani I, Terkildsen Maindal H, Rowlands G, Lou S. A qualitative study about the experiences of ethnic minority pregnant women with gestational diabetes. Scand J Caring Sci 2019 Sep 17;33(3):621-631. [doi: 10.1111/scs.12655] [Medline: 30653703]

51. Martis R, Brown J, McAra-Couper J, Crowther CA. Enablers and barriers for women with gestational diabetes mellitus to achieve optimal glycaemic control - a qualitative study using the theoretical domains framework. BMC Pregnancy Childbirth 2018 Apr 11;18(1):91 [FREE Full text] [doi: 10.1186/s12884-018-1710-8] [Medline: 29642898]

52. Pirdehghan A, Eslahchi M, Esna-Ashari F, Borzouei S. Health literacy and diabetes control in pregnant women. J Family Med Prim Care 2020 Feb;9(2):1048-1052 [FREE Full text] [doi: 10.4103/jfmpc.jfmpc_891_19] [Medline: 32318465]

53. Gharachourlo M, Mahmoodi Z, Akbari Kamrani M, Tehranizadeh M, Kabir K. The effect of a health literacy approach to counselling on the lifestyle of women with gestational diabetes: A clinical trial. F1000Res 2018;7:282 [FREE Full text] [doi: 10.12688/f1000research.13838.1] [Medline: 29560264]

54. Nielsen KK, Kapur A, Damm P, de Courten M, Bygbjerg IC. From screening to postpartum follow-up - the determinants and barriers for gestational diabetes mellitus (GDM) services, a systematic review. BMC Pregnancy Childbirth 2014 Jan 22;14(1):41 [FREE Full text] [doi: 10.1186/1471-2393-14-41] [Medline: 24450389]

55. Martinez NG, Niznik CM, Yee LM. Optimizing postpartum care for the patient with gestational diabetes mellitus. Am J Obstet Gynecol 2017 Sep;217(3):314-321 [FREE Full text] [doi: 10.1016/j.ajog.2017.04.033] [Medline: 28455081]

56.   Yee L, Niznik C, Simon M. Examining the role of health literacy in optimizing the care of pregnant women with diabetes. Am J Perinatol 2016 Nov 20;33(13):1242-1249. [doi: 10.1055/s-0036-1584540] [Medline: 27322666]

57.   Yeung DL, Alvarez KS, Quinones ME, Clark CA, Oliver GH, Alvarez CA, et al. J Am Pharm Assoc (2003) 2017 Jan;57(1):30-37 [FREE Full text] [doi: 10.1016/j.japh.2016.08.012] [Medline: 27816544]

58.   Ross L, Ashford AD, Bleechington SJ, Dark T, Erwin DO. Applicability of a video intervention to increase informed decision making for prostate-specific antigen testing. J Natl Med Assoc 2010 Mar;102(3):228-236 [FREE Full text] [doi: 10.1016/s0027-9684(15)30529-0] [Medline: 20355352]

59.   Sheele J, Bhangu J, Wilson A, Mandac E. Patient preference for medical information in the emergency department: post-test survey of a random allocation intervention. J Emerg Nurs 2019 Sep;45(5):517-522.e6. [doi: 10.1016/j.jen.2019.05.009] [Medline: 31445628]

XSL•FO
RenderX

<u>Original Paper</u>

Evaluation of Self-care Activities and Quality of Life in Patients With Type 2 Diabetes Treated With Metformin Using the 2D Matrix Code of Outer Drug Packages as Patient Identifier: the DePRO Proof-of-Concept Observational Study

Christian Mueller[1], PhD; Isabel Schauerte[2], PhD; Stephan Martin[3], MD; Valeska Irrgang[1], MD

[1]Bayer Vital GmbH, Leverkusen, Germany

[2]Institut Dr. Schauerte, Munich, Germany

[3]Westdeutsches Diabetes- und Gesundheitszentrum, Düsseldorf, Germany

Corresponding Author:
Christian Mueller, PhD
Bayer Vital GmbH
Building K 56, 1D321
Leverkusen, 51368
Germany
Phone: 49 175 3005134
Fax: 49 214 86486926
Email: christian.mueller4@bayer.com

Abstract

Background: The use of digital technology to assess patients remotely can reduce clinical study costs. In the European Union, the 2D matrix code on prescription drug packaging serves as a unique identifier of a given package of medication, and thus, also of the patient receiving that medication. Scanning of the 2D matrix code may therefore allow remote patient authentication in clinical studies.

Objective: The aim of the DePRO study was to assess the feasibility of a fully digital data-capture workflow, the authentication of participants via drug packaging 2D matrix codes, in patients with type 2 diabetes mellitus (T2DM) who use metformin. The primary objective was to describe the self-care activities of these patients. Secondary objectives were to evaluate (1) the self-reported health status of these patients, (2) the association of self-care activities with demographics and disease characteristics, and (3) the usability of the my ePRO app.

Methods: DePRO was an observational, multicenter, cross-sectional, digital, and patient-driven study conducted in Germany from June to December 2020. Adult patients prescribed metformin were invited to participate via their pharmacist or a medication tracker app. Participants downloaded the my ePRO app onto their own mobile device, scanned the 2D matrix code on their metformin package for registration and authentication, and provided informed consent via an electronic form. They were then able to complete a study-specific questionnaire on demographics and clinical characteristics, the German version of the Summary of Diabetes Self-Care Activities measure (SDSCA-G), the Diabetes Treatment Satisfaction Questionnaire (DTSQ), and the EQ-5D-5L. The patients conducted the study without support from a health care professional. Statistical analyses were exploratory and descriptive.

Results: In total, 3219 patients were invited to participate. The proportion of patients giving consent was greater among those invited by pharmacists (19/217, 8.8%) than among those invited via the medication tracker app (13/3002, 0.4%). Of the 29 patients eligible for analysis, 28 (97%) completed all study questionnaires. Most of the patients (23/29, 79%) were aged <60 years, and 59% (17/29) were male. The patients spent a mean total of 3.5 (SD 1.3) days out of 7 days on self-care activities (SDSCA-G). Most patients (24/29, 83%) were satisfied to extremely satisfied with their current treatment (DTSQ). Events of perceived hyperglycemia or hypoglycemia were reported by 20 of 29 (69%) patients. The best possible health status (EQ-5D-5L) was reported by 18 of 28 (64%) patients. Age was positively correlated with time spent on general and specific diet (Spearman coefficient 0.390 and 0.434, respectively).

XSL•FO

RenderX

Conclusions: The DePRO study demonstrates the feasibility of fully digital authentication (via 2D matrix codes on drug packaging) and data capture in patients with T2DM. Personal invitations yielded higher recruitment rates than remote invitations via the medication tracker app. A high questionnaire completion rate was realized, based on completion by 28 out of 29 patients.

Trial Registration: ClinicalTrials.gov NCT04383041; https://clinicaltrials.gov/ct2/show/NCT04383041

International Registered Report Identifier (IRRID):   RR2-10.2196/21727

Introduction

In clinical studies, the need for participants to visit a study clinic for on-site assessments is an important driver of cost [1]. The use of digital technology for remote assessment of study participants can remove the need for site visits, as exemplified by several recent clinical studies without study sites [2-4].

In the European Union, all prescription drugs (with specific exceptions such as radionuclide generators and precursors) are required to bear a 2D matrix code on their packaging [5]. The 2D matrix code is a unique identifier of a given package of medication; once the medication is given to a patient, the code also serves as a unique identifier of the patient as the user of that medication. Scanning of the 2D matrix code therefore has the potential to allow remote patient authentication across a range of indications.

We designed the DePRO study to assess the feasibility of a fully digital data-capture workflow with the authentication of eligible patients via the 2D matrix codes on drug packaging [6]. The target population was patients with type 2 diabetes mellitus (T2DM) who had been prescribed metformin (the recommended initial treatment for T2DM [7]). For patients with T2DM, clinical recommendations suggest a key role for self-care in maintaining health and quality of life [8,9]. Therefore, the primary objective of the DePRO study was to describe the self-care activities of patients with T2DM who use metformin. Secondary objectives were to evaluate (1) the self-reported health status of these patients, (2) the association of self-care activities with demographics and disease characteristics, and (3) the usability of the my ePRO app (acceptance of participation and completion of study questionnaires).

Methods

Study Design

The study design has been published previously [6] and is briefly summarized here.

DePRO was an observational, multicenter, cross-sectional, digital, and patient-driven study conducted in Germany from June 2020 to December 2020 (ClinicalTrials.gov NCT04383041). The study was conducted using the my ePRO app, a patient-reported outcome (PRO) data capture tool that can gather additional data based on individual study requirements (codeveloped by Institut Dr. Schauerte and Bayer

and hosted by Institut Dr. Schauerte). The my ePRO app is not a self-care management tool supporting patients in their treatment of T2DM.

Adult patients who had been prescribed metformin-containing medications were eligible to participate. Eligible patients were invited via their pharmacist (who personally handed out a download link for the my ePRO app on a postcard alongside the patient's metformin-containing medication and explained the study workflow to the patients—downloading the my ePRO app, scanning the 2D matrix code, consenting, answering the questionnaires, and then getting reimbursed) or via the MyTherapy medication tracker app (SmartPatient). The latter route was added as a revision to the original published study design [6] following difficulties recruiting sufficient pharmacies because of restrictions related to the COVID-19 pandemic (we originally planned to recruit 12 diabetes-focused pharmacies, but of the 35 pharmacies contacted, only 4 participated in the study). All patients who were registered on the medication tracker app and were taking metformin-containing medications in Germany were invited twice (on December 2 and 7, 2020) via an in-app message to participate in the DePRO study. All patients who were taking metformin received the invitation (which was automatically deployed) in their daily to-do list and voluntarily downloaded the my ePRO app to participate in the DePRO study. The recruitment finished on December 9, 2020. The medication tracker app provided a download link for the my ePRO app.

In each case, participating patients downloaded the my ePRO app onto their own mobile device (smartphone or tablet). They then scanned the unique 2D matrix code on their metformin-containing medication package for registration and authentication. The 2D matrix code includes an identifier of the drug package, which is unique, and the pharma central number of the drug. The sponsors of the study were only aware of which 2D matrix codes were used and could verify eligibility of the patients via the pharma central number. By using the my ePRO app, no additional personal data were requested for participation, ensuring the anonymity and privacy of all participants. After providing informed consent via an electronic form, they were able to complete a study-specific questionnaire on patient characteristics and 3 validated questionnaires: the German version of the Summary of Diabetes Self-Care Activities measure (SDSCA-G) [10]; the Diabetes Treatment Satisfaction Questionnaire (DTSQ; possible score range of 0-36, with higher scores reflecting greater satisfaction) [11]; and the EQ-5D-5L

[12]. After completing the questionnaires, each patient received compensation (a voucher worth €15 [US $15.82]) for the time spent providing data. The patients conducted the entire study without any support from their pharmacist or health care professional.

Data were transferred to the study database upon completion of each questionnaire and as soon as the patient's device was connected to the internet. Reports of hyperglycemia and hypoglycemia were identified by the contract research organization (Institut Dr. Schauerte) and forwarded as potential adverse events to the relevant market authorization holders.

Statistical Analysis

Statistical analyses were exploratory, descriptive, and performed using SAS statistical software (version 9.4 or higher; SAS Institute Inc). Spearman rank correlation coefficients were used as measures of association, with $P<.05$ considered significant. We estimated that a sample size of 300 patients would be required to obtain a 95% CI of the mean level of self-care with a precision of 3 points [6].

Ethics Approval

The study protocol has been approved by the Ethics Committee of the Medical Association Nordrhein (approval number 2020084).

Results

Patients

A total of 3219 patients were invited to participate in the study, either by their pharmacist (n=217) or via the medication tracker app (n=3002; Figure 1). Of the 217 patients invited by their pharmacist, 108 did not agree to participate, most commonly because they had no interest (n=54), no time (n=22), or no smartphone (n=21). The proportion of patients who gave consent was greater among those invited by their pharmacist (19/217, 8.8%) than among those invited via the medication tracker app (13/3002, 0.4%). However, 3 patients were excluded due to the withdrawal of informed consent or because they did not complete at least one questionnaire. Thus, 29 patients were eligible for analysis. Of the 29 patients, 28 (97%) completed all study questionnaires; 16 (55%) patients answered all of the questions, 12 (41%) answered ≥80% to <100% of the questions, and 1 (3%) answered <80% of the questions.

Patient characteristics are summarized in Table 1. In total, 59% (17/29) of the patients were male and 79% (23/29) were aged <60 years. A substantial proportion (9/29, 31%) did not report their family income (this was also observed during user-experience testing of the my ePRO app). According to their zip codes, the majority of the patients (17/29, 59%) lived in western Germany, reflecting the location of the participating pharmacies. Concomitant medication use was reported by 12/29 (41%) patients; the most commonly reported concomitant medications were those acting on the cardiovascular system (9/29, 31%).

Most of the patients (27/29, 93%) reported having visited an ophthalmologist, but few reported eye-related comorbidities: 1 patient reported that their ophthalmologist had seen changes in their retina/fundus caused by diabetes, and another patient had received laser eye surgery or intraocular medication injections. Responses to other questions regarding comorbidities are summarized in Multimedia Appendix 1.

Figure 1. Flow chart of study participation. An individual patient could give multiple reasons for not agreeing to participate.
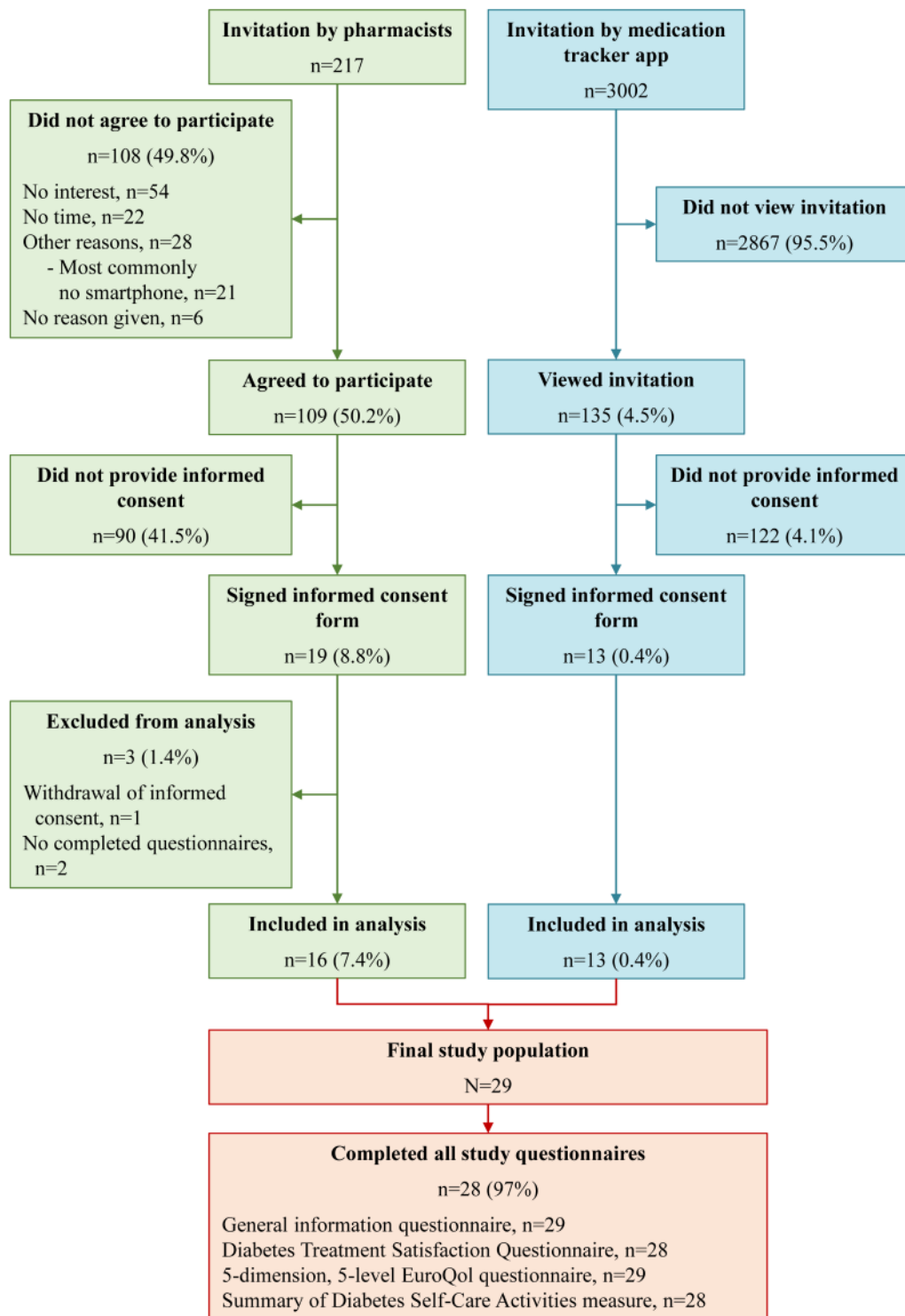
Table 1. Patient characteristics.

Characteristic	Patients, n (%)
Total study population	29 (100)
Gender	
Female	12 (41)
Male	17 (59)
Age (years)	
<40	10 (34)
40-59	13 (45)
≥60	6 (21)
BMI (kg/m^2)	
<25	3 (10)
25 to <30	12 (41)
30 to <35	7 (24)
≥35	7 (24)
Education level	
Not reported	1 (3)
No certificate	3 (10)
General secondary school	3 (10)
Vocational education	13 (45)
Intermediate secondary school	2 (7)
High school	1 (3)
College or university	6 (21)
Family income (€gross/month; US$ gross/month)	
Not reported	9 (31)
2000 to <3000 (2108 to <3162)	10 (34)
3000 to <5000 (3162 to <5270)	8 (28)
≥5000 (≥5270)	2 (7)
Geographic region in Germany	
North	3 (10)
East	4 (14)
South	5 (17)
West	17 (59)
Time since diagnosis of type 2 diabetes mellitus (years)	
Not reported	2 (7)
<1	5 (17)
1-5	10 (34)
6-10	8 (28)
≥11	4 (14)
Latest glycated hemoglobin value (%)	
Missing	2 (7)
<6.0	11 (38)
6.0-6.5	3 (10)
6.6-7.0	4 (14)

XSL•FO
RenderX

Characteristic	Patients, n (%)
7.1-7.5	4 (14)
7.6-8.0	0
8.1-8.5	3 (10)
8.6-9.0	1 (3)
>9.0	1 (3)
Concomitant medications	
0	17 (59)
1	5 (17)
2	4 (14)
3	1 (3)
4	1 (3)
6	1 (3)

Self-care Activities, Quality of Life, and Treatment Satisfaction

According to the SDSCA-G, the patients spent a mean total of 3.5 (SD 1.3) days out of 7 days on self-care activities. The greatest mean number of days was spent on general diet (4.7, SD 1.9 days), followed by specific diet (3.9, SD 2.9 days), exercise (3.8, SD 2.1 days), and blood-glucose testing (3.4, SD 2.6 days). Data were missing for 1 patient in each sub-score. A total of 8/29 (28%) patients reported that they smoked.

The participants had a median EQ-5D-5L index score of 1.00 (IQR 0.73-1.00; n=28). The best possible health status was reported by 18/28 (64%) patients. The median EuroQol visual analog scale score was 79.0 (IQR 49.6-99.0; n=29). The majority of the patients reported no problems with mobility, self-care, usual activity, or anxiety and depression, whereas more than half (15/29, 52%) reported problems with pain and discomfort (Table 2).

The median DTSQ score was 24.5 (IQR 12.0-30.0; n=28). Most patients (24/29, 83%) were satisfied to extremely satisfied with their current treatment (Multimedia Appendix 2).

Overall, 20/29 (69%) patients reported events of perceived hyperglycemia or hypoglycemia. High scores (≥4) for perceived hyperglycemia and hypoglycemia were reported by few patients (4/29, 14% and 2/29, 7%, respectively).

Age was positively correlated with time spent on general diet (Spearman coefficient 0.390; P=.04) and specific diet (Spearman coefficient 0.434; P=.02), but not with the total SDSCA-G score or other SDSCA-G subscores (n=28).

Table 2. Responses to the 5-dimension, 5-level EuroQol questionnaire.

	Mobility, n (%)	Self-care, n (%)	Usual activity, n (%)	Pain and discomfort, n (%)	Anxiety and depression, n (%)
Total	29 (100)	29 (100)	29 (100)	29 (100)	29 (100)
Missing data	1 (3)	1 (3)	1 (3)	1 (3)	1 (3)
Extreme problems	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Severe problems	0 (0)	0 (0)	0 (0)	2 (7)	0 (0)
Moderate problems	2 (7)	0 (0)	1 (3)	4 (14)	4 (14)
Slight problems	1 (3)	2 (7)	4 (14)	9 (31)	5 (17)
No problems	25 (86)	26 (90)	23 (79)	13 (45)	19 (66)

Discussion

Principal Findings

The innovative approach taken in the DePRO study was to implement a fully digital data-capture workflow, bypassing the involvement of health care professionals in the assessment of PROs and more importantly in the authentication of eligible patients. Overall, the results demonstrate the feasibility of this approach; participating patients were able to follow the study workflow to completion. We observed a higher rate of enrollment among patients invited by pharmacists than among those invited via the medication tracker app. Although enrollment in the DePRO study was low overall (32/3219, 1%), the proportion of participating patients completing all study questionnaires was high (28/29, 97%). The high rate of completion may be due to the iterative development of the app, which included user-experience testing in patients with T2DM before launching the app.

The patients spent a mean total of 3.5 (SD 1.3) days on self-care activities, and most (24/29, 83%) were satisfied to extremely satisfied with their current treatment. The majority of the patients reported the best health status in the EQ-5D-5L. Positive

correlations were found between age and time spent on diet, but the small sample size limits the interpretation of these findings.

Comparison With Prior Work

The low participation rate among patients invited remotely via the medication tracker app in the DePRO study (13/3002, 0.4%) was broadly similar to that observed in the Apple Heart Study (419,297 patients recruited from among more than 30 million device users, ~1.4%) [2]. The higher rate of enrollment among patients invited by their pharmacist compared to patients invited remotely is consistent with a recent meta-analysis, which found higher conversion rates for offline versus online recruitment strategies (risk ratio 0.8, 95% CI 0.67-0.96; P=.02) [13].

Our results suggest that personal contact with a trusted health care professional was an important factor for enrollment in the DePRO study. This personal contact may have helped to overcome potential barriers such as patients' lack of familiarity with the my ePRO app and concerns regarding data protection. Other possible reasons for the low response rate among patients invited remotely could include the COVID-19 pandemic, the timing of the invitations (December is likely to have been a busy month for many patients), or the media switch—from offline to online or between different systems (from the medication tracker app to the my ePRO app). Altering the invitation design and wording and sending multiple reminders may increase the rate of remote enrollment in future studies, as shown in the mHealth Screening to Prevent Strokes trial [14]. For both invitation routes, the design of the electronic informed consent form may also influence enrollment; we found that a substantial proportion of patients who viewed the remote invitation or agreed to participate when invited by their pharmacist did not provide informed consent.

Many of the patients were using concomitant cardiovascular medications and had visited an ophthalmologist, as expected for a population with T2DM [15-17]. The DePRO study population was relatively young—79% of the study population was aged <60 years; in contrast, only 19.5% of the 324,708 patients with T2DM in a recent German claims database analysis were aged <60 years [15]. Again, the small sample size of the DePRO study limits the interpretation of this finding; larger studies are needed to determine if a fully digital workflow results in a selection bias toward patients who are young technophiles.

The PROs were generally consistent with previous reports. For example, the mean time spent on self-care activities was similar to that reported by 315 patients with T2DM (3.5, SD 1.4 days) in a validation study of the SDSCA-G [10]. In a large survey in Germany (N=1291), patients with T2DM reported greater

problems with pain and discomfort than with other EQ-5D-5L dimensions [18], similar to the pattern observed in our study. We found a high rate of treatment satisfaction; this was also shown in a study of 602 patients receiving metformin in Italy where the mean DTSQ scores reflected satisfaction with the treatment overall [19].

Limitations

The limitations of the DePRO study design have been described in detail previously [6]. Briefly, they include its reliance on PROs, the identification of patients via a 2D matrix code on drug packaging rather than a validated diagnosis by a health care professional, possible selection bias toward patients who are young technophiles, the lack of verification of medication intake, the single-arm design, the focus on users of metformin rather than all patients with T2DM, geographic bias toward western Germany, and anonymized data (making source-data verification impossible).

The small sample size is an additional limitation, which can be explained by a lack of interest in studies and a fear of infection with COVID-19 by staying too long in a pharmacy. Additionally, further meaningful correlations between self-care activities and demographics could not be established due to the limited sample size. We were unable to recruit sufficient pharmacies because of the COVID-19 pandemic, and recruitment via a medication tracker app yielded a low response rate. Nevertheless, the study demonstrates the feasibility of recruiting patients via both pharmacist- and app-based approaches. The app-based approach was implemented rapidly in response to changing circumstances and offers a promising starting point for further development. The optimal recruitment strategy may differ across indications and age groups.

Conclusions

The DePRO study demonstrates the feasibility of a fully digital authentication and data-capture workflow in a population of patients with T2DM, with a high rate of completion of questionnaires by participants. It also shows that 2D matrix codes on outer packages of medications can serve as a direct channel to patients. This approach enables researchers to collect PROs without the involvement of health care professionals. Further research is needed to optimize recruitment via the medication tracker app, pair data-capturing activities with valuable services for patients, and establish whether such remote recruitment can provide a suitable alternative to personal invitations, particularly in the context of German legislation that will allow patients to voluntarily make the data in their electronic health records available to researchers starting in 2023 [20].

Authors' Contributions

CM was responsible for the design, initiation, and conduct of the study. IS contributed to the protocol, study design and implementation, data management, and statistical analysis. SM contributed to the protocol and study design. VI contributed to the protocol, study design, and discussion of the results. All authors revised the article critically for important intellectual content, and all authors approved the final version.

Conflicts of Interest

CM and VI are employees of Bayer Vital GmbH (Leverkusen, Germany). IS is the chief operating officer of Institut Dr. Schauerte, the contract research organization that was commissioned to conduct the DePRO study on behalf of Bayer. SM has received support from Bayer Vital GmbH.

Multimedia Appendix 1
Responses to the comorbidity questionnaire.
[DOCX File , 33 KB - diabetes_v7i2e31832_app1.docx]

Multimedia Appendix 2
Patient's rating of treatment satisfaction, convenience, and flexibility.
[DOCX File , 32 KB - diabetes_v7i2e31832_app2.docx]

References

1. Moore TJ, Heyward J, Anderson G, Alexander GC. Variation in the estimated costs of pivotal clinical benefit trials supporting the US approval of new therapeutic agents, 2015-2017: a cross-sectional study. BMJ Open 2020 Jun 11;10(6):e038863 [FREE Full text] [doi: 10.1136/bmjopen-2020-038863] [Medline: 32532786]

2. Perez MV, Mahaffey KW, Hedlin H, Rumsfeld JS, Garcia A, Ferris T, Apple Heart Study Investigators. Large-scale assessment of a smartwatch to identify atrial fibrillation. N Engl J Med 2019 Nov 14;381(20):1909-1917 [FREE Full text] [doi: 10.1056/NEJMoa1901183] [Medline: 31722151]

3. Steinhubl SR, Waalen J, Edwards AM, Ariniello LM, Mehta RR, Ebner GS, et al. Effect of a home-based wearable continuous ECG monitoring patch on detection of undiagnosed atrial fibrillation: the mSToPS randomized clinical trial. JAMA 2018 Jul 10;320(2):146-155 [FREE Full text] [doi: 10.1001/jama.2018.8102] [Medline: 29998336]

4. Yao X, Attia ZI, Behnken EM, Walvatne K, Giblon RE, Liu S, et al. Batch enrollment for an artificial intelligence-guided intervention to lower neurologic events in patients with undiagnosed atrial fibrillation: rationale and design of a digital clinical trial. Am Heart J 2021 Sep;239:73-79. [doi: 10.1016/j.ahj.2021.05.006] [Medline: 34033803]

5. Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use. The European Commission. 2016. URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf [accessed 2022-05-05]

6. Mueller C, Schauerte I, Martin S. Evaluation of self-care activities and quality of life in patients with type 2 diabetes mellitus treated with metformin using the 2D matrix code of outer drug packages as patient identifier: protocol for the DePRO proof-of-concept observational study. JMIR Res Protoc 2021 Jan 11;10(1):e21727 [FREE Full text] [doi: 10.2196/21727] [Medline: 33427685]

7. Bloomgarden ZT, Handelsman Y. Approaches to treatment 2: comparison of American Association of Clinical Endocrinologists (AACE) and American Diabetes Association (ADA) type 2 diabetes treatment guidelines. J Diabetes 2016 Jan;8(1):4-6. [doi: 10.1111/1753-0407.12345] [Medline: 26431291]

8. American Diabetes Association. Standards of medical care in diabetes-2016 abridged for primary care providers. Clin Diabetes 2016 Jan;34(1):3-21 [FREE Full text] [doi: 10.2337/diaclin.34.1.3] [Medline: 26807004]

9. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the American Diabetes Association, the American Association of

Diabetes Educators, and the Academy of Nutrition and Dietetics. J Acad Nutr Diet 2015 Aug;115(8):1323-1334. [doi: 10.1016/j.jand.2015.05.012] [Medline: 26054423]

10. Kamradt M, Bozorgmehr K, Krisam J, Freund T, Kiel M, Qreini M, et al. Assessing self-management in patients with diabetes mellitus type 2 in Germany: validation of a German version of the Summary of Diabetes Self-Care Activities measure (SDSCA-G). Health Qual Life Outcomes 2014 Dec 18;12:185 [FREE Full text] [doi: 10.1186/s12955-014-0185-1] [Medline: 25519204]

11. Bradley C, Lewis KS. Measures of psychological well-being and treatment satisfaction developed from the responses of people with tablet-treated diabetes. Diabet Med 1990 Jun;7(5):445-451. [doi: 10.1111/j.1464-5491.1990.tb01421.x] [Medline: 2142043]

12. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res 2011 Dec;20(10):1727-1736 [FREE Full text] [doi: 10.1007/s11136-011-9903-x] [Medline: 21479777]

13. Brøgger-Mikkelsen M, Ali Z, Zibert JR, Andersen AD, Thomsen SF. Online patient recruitment in clinical trials: systematic review and meta-analysis. J Med Internet Res 2020 Nov 04;22(11):e22179 [FREE Full text] [doi: 10.2196/22179] [Medline: 33146627]

14. Baca-Motes K, Edwards AM, Waalen J, Edmonds S, Mehta RR, Ariniello L, et al. Digital recruitment and enrollment in a remote nationwide trial of screening for undiagnosed atrial fibrillation: lessons from the randomized, controlled mSToPS trial. Contemp Clin Trials Commun 2019 Jun;14:100318 [FREE Full text] [doi: 10.1016/j.conctc.2019.100318] [Medline: 30656241]

15. Gabler M, Geier S, Mayerhoff L, Rathmann W. Cardiovascular disease prevalence in type 2 diabetes - an analysis of a large German statutory health insurance database. BMC Public Health 2021 Feb 09;21(1):328 [FREE Full text] [doi: 10.1186/s12889-021-10381-z] [Medline: 33563256]

16. Bramlage P, Lanzinger S, van Mark G, Hess E, Fahrner S, Heyer CHJ, et al. Patient and disease characteristics of type-2 diabetes patients with or without chronic kidney disease: an analysis of the German DPV and DIVE databases. Cardiovasc Diabetol 2019 Mar 16;18(1):33 [FREE Full text] [doi: 10.1186/s12933-019-0837-x] [Medline: 30878037]

17. Schunk M, Stark R, Reitmeir P, Meisinger C, Holle R. Towards patient-oriented diabetes care: results from two KORA surveys in southern Germany. J Diabetes Res 2015;2015:368570 [FREE Full text] [doi: 10.1155/2015/368570] [Medline: 25859544]

18. Ose D, Miksch A, Urban E, Natanzon I, Szecsenyi J, Kunz CU, et al. Health related quality of life and comorbidity. A descriptive analysis comparing EQ-5D dimensions of patients in the German disease management program for type 2 diabetes and patients in routine care. BMC Health Serv Res 2011 Aug 02;11:179 [FREE Full text] [doi: 10.1186/1472-6963-11-179] [Medline: 21810241]

19. Derosa G, Romano D, Bianchi L, D'Angelo A, Maffioli P. Metformin powder formulation compared to metformin tablets on glycemic control and on treatment satisfaction in subjects with type 2 diabetes mellitus. J Clin Pharmacol 2015 Apr;55(4):409-414. [doi: 10.1002/jcph.415] [Medline: 25328091]

20. Entwurf eines Gesetzes zum Schutz elektronischer Patientendaten in der Telematikinfrastruktur (Patientendaten-Schutz-Gesetz – PDSG) 2020. Deutscher Bundestag. 2020 Apr 27. URL: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/P/PDSG-Bundestag_Drs-18793.pdf [accessed 2021-06-16]

Abbreviations

DTSQ: Diabetes Treatment Satisfaction Questionnaire
PRO: patient-reported outcome
SDSCA-G: German version of the Summary of Diabetes Self-Care Activities measure
T2DM: type 2 diabetes mellitus

XSL•FO
RenderX

Original Paper

Community Health Worker-Led mHealth-Enabled Diabetes Self-management Education and Support Intervention in Rural Latino Adults: Single-Arm Feasibility Trial

Shiyu Li[1], MSc; Zenong Yin[2], PhD; Janna Lesser[3], RN, PhD; Chengdong Li[4], PhD; Byeong Yeob Choi[5], PhD; Deborah Parra-Medina[6], MPH, PhD; Belinda Flores[7], BSc, RN; Brittany Dennis[1], MSc; Jing Wang[4], RN, MPH, PhD

[1]Center on Smart and Connected Health Technologies, School of Nursing, University of Texas Health Science Center at San Antonio, San Antonio, TX, United States

[2]Department of Public Health, The University of Texas at San Antonio, San Antonio, TX, United States

[3]School of Nursing, University of Texas Health Science Center at San Antonio, San Antonio, TX, United States

[4]College of Nursing, Florida State University, Tallahassee, FL, United States

[5]Department of Population Health Sciences, University of Texas Health Science Center at San Antonio, San Antonio, TX, United States

[6]Latino Research Institute, The University of Texas at Austin, Austin, TX, United States

[7]South Coastal Area Health Education Center, Corpus Christi, TX, United States

Corresponding Author:
Jing Wang, RN, MPH, PhD
College of Nursing
Florida State University
98 Varsity Way, Suite 472B
Tallahassee, FL, 32306
United States
Phone: 1 8506446844
Email: jingwang@nursing.fsu.edu

Abstract

Background: Latinos living in rural South Texas have a higher prevalence of diabetes, but their access to diabetes self-management education and support (DSMES) is limited.

Objective: We aimed to test the feasibility of a community health worker-led, mobile health (mHealth)-based DSMES intervention to reduce disparities in accessing DSMES in underserved rural Latino residents in South Texas.

Methods: This 12-week, single-arm, pre-post trial was delivered by trained community health workers to 15 adults with type 2 diabetes. The intervention consisted of digital diabetes education, self-monitoring, a cloud-based connected platform, and community health worker support. Feasibility was evaluated as retention, actual intervention use, program satisfaction, and barriers to implementation. We also explored the intervention's effect on weight loss and hemoglobin A_{1c} (HbA$_{1c}$).

Results: All 15 participants were Latino (mean age 61.87 years, SD 10.67; 9/15 female, 60%). The retention rate at posttest was 14 of 15 (93%). On average, the participants completed 37 of 42 (88%) digital diabetes education lessons with 8 participants completing all lessons. Participants spent 81/91 days (89%) step tracking, 71/91 days (78%) food logging, 43/91 days (47%) blood glucose self-monitoring, and 74/91 days (81%) weight self-monitoring. The level of program satisfaction was high. On average, participants lost 3.5 (SD 3.2) kg of body weight (*P*=.001), while HbA$_{1c}$ level remained unchanged from baseline (6.91%, SD 1.28%) to posttest (7.04%, SD 1.66%; *P*=.668).

Conclusions: A community health worker-led mHealth-based intervention was feasible and acceptable to improve access to DSMES services for Latino adults living in rural communities. Future randomized controlled trials are needed to test intervention efficacy on weight loss and glycemic control.

XSL•FO
RenderX

Introduction

Diabetes is a complex and costly disease that requires persons with diabetes to make daily self-care decisions to prevent the onset of complications [1]. Diabetes self-management education and support (DSMES) is the ongoing process of offering knowledge, skills, and support for diabetes self-care. Improving access to DSMES could empower persons with diabetes to self-manage diabetes and improve their health [2]. This is particularly important for residents of South Texas, who have a higher prevalence of diabetes than the rest of Texas (11.6% vs 9.3%) or the United States overall (8.9%) [3].

South Texas has 38 counties, of which 25 are rural. Diabetes care disparities exist in rural South Texas for a variety of reasons. Rural persons with diabetes frequently lack adequate transportation and must travel long distances to clinics, impeding diabetes care and potentially impacting glycemic control [4,5]. Meanwhile, rural residents are poorer, making active participation in routine care more difficult [4,6]; empirical evidence suggests that rural patients are more likely to defer care due to limited financial resources than their urban counterparts [7]. Furthermore, Texas has a significant physician shortage in rural areas which has been exacerbated by the COVID-19 pandemic [8]. Rural residents rely heavily on federally funded health care programs, resulting in much lower reimbursement payments for rural physicians and hospitals than their urban counterparts and a diminished desire to work in rural areas [4]. Additionally, rural residents' low levels of education and literacy may hinder their capacity to comprehend diabetes self-management knowledge and skills [6]. An aging population may also exacerbate these barriers in rural Texas; many elderly residents have decreased cognitive function and suffer from diabetes comorbidities [9,10].

More than 80% of the South Texas population is Latino. Latinos face additional cultural barriers when it comes to diabetes care [11]. The lack of cultural competence among health care providers has been extensively documented as a barrier for Latinos during clinical encounters, potentially contributing to lower patient satisfaction and disengagement from care [11,12]. A lack of linguistic proficiency has been linked to inadequate diabetes care for Latinos in several studies [13]. For example, Lopez-Quintero et al [12] found that non–Spanish speaking providers are less likely than Spanish-speaking physicians to provide physical activity and diet recommendations to their Latino patients. Furthermore, switching to a healthy diet from their traditional Latino cuisine is difficult for Latinos with type 2 diabetes [14]. Rice, beans, and tortillas, which are high in refined carbohydrates, are staples of traditional Latino food [15]. A qualitative study done by Hu et al [14] reported that one of the most significant hurdles to healthy diet adherence is overcoming cravings for traditional foods. Diet adherence is also impeded by the importance of family support in Latino culture, particularly for women, who have been reported to experience family conflicts about dietary issues, such as keeping their husband and children happy while adhering to diet restrictions [11,14,15].

Improving access to DSMES for rural Latino population requires applying a multidimensional research lens. The National Institute on Minority Health and Health Disparities framework conceptualizes multiple domains of health determinants that affect minority health [16]. According to the framework, to address access barriers for the rural Latino population, equity-oriented strategies are necessary that may include addressing individual beliefs and attitudes pertaining to diabetes education–seeking behavior (behavioral-individual), familial norms about diet and exercise (behavioral-interpersonal), Latino culture–specific norms that hinder diabetes self-management (sociocultural environment-community), limited language proficiency and literacy level (sociocultural environment-individual), uninsured status (health care system-individual), limited access to DSMES services (health care system-community), and state and federal policies pertaining to local communities (behavioral-societal and health care system-societal) [16].

Community health worker-led DSMES is a culturally-appropriate and cost-effective approach for improving access to DSMES services among rural and minority populations [17]. Community health workers are community members trained to provide culturally appropriate health education. As trusted community members sharing similar cultural and linguistic backgrounds with persons with diabetes, community health workers can provide individual-level emotional support and instrumental support [18]. They also have a unique ability to close health disparities by assessing multilevel needs of persons with diabetes and connecting them to community resources [19]. Interventions delivered by community health workers increase their sociocultural acceptability [20]. DSMES interventions integrating community health workers have shown success in improving diabetes self-management and health in rural minority populations [21,22]. However, community health workers face obstacles when working in rural communities, such as transportation, limited resources, and limited supervision and support, which affect their work productivity and service quality [23,24]. Thus, providing sufficient support to community health workers is vital for successful community health worker programs in rural communities.

Integrating mobile health (mHealth) technology is a promising approach to improve DSMES access in nonclinical settings and to improve health services provided by community health workers [24,25]. Health care services included in the mHealth category rely on handheld mobile devices, including cell phones, tablets, and wearables, that enable mobile apps [26]. Evidence shows that the use of mHealth by community health workers improves communication, avoids unnecessary transportation, improves access to care resources, and results in positive effects on patient health [27,28]. However, the feasibility of a community health worker-led, mHealth-based DSMES program has not been evaluated in rural Latino persons with diabetes.

In this paper, we report results of a feasibility study to evaluate retention, delivery, usage, and acceptability of an mHealth-based DSMES program led by trained community health workers for Latino persons with diabetes living in rural South Texas. The impact of the intervention on weight loss and glycemic control was also explored.

XSL•FO

RenderX

Methods

Study Design and Recruitment

This was a single-arm, pre-post, National Institutes of Health Stage 1B study to examine the feasibility of combining an mHealth-based intervention that relied on community health worker facilitation to improve access to DSMES in a resource-poor rural community [22]. A 12-week intervention was delivered by 3 trained community health workers to 15 adults with type 2 diabetes living in rural South Texas. All community health workers were affiliated with the South Coastal Area Health Education Center, a local community health care intermediary aiming to improve access to quality health care for medically underserved communities in South Texas.

Participants were recruited through flyers posted at the Community Action Corporation of South Texas. Community health workers telephoned individuals who expressed interest in participation to assess their eligibility for enrollment. The inclusion criteria were as follows: (1) age ≥ 18 years, (2) a diagnosis of type 2 diabetes, (3) ability to read and write in English, (4) residency in Jim Wells County, (5) possession of a compatible smartphone with a data plan, and (6) readiness to make a lifestyle change. Participants were excluded if they were (1) on insulin treatment, (2) had a history of severe psychiatric disorder, (3) had difficulty in performing daily or regular activity, (4) had substance abuse issues, or (5) were planning a pregnancy or planning to breastfeed within the following 6 months. Participants gave verbal consent to participate. Prior to implementation of any study procedures, this project was reviewed by Office of the Institutional Review Board at the University of Texas Health Science Center at San Antonio and determined to be non-regulated research (HSC20190486N).

Theoretical Framework

Supporting behavior change is a key objective for DSMES programs [17]. This study was built upon self-regulation and social cognitive theory (SCT) [29] (Figure 1). Self-regulation theory posits that self-monitoring aids self-evaluation of progress made toward one's goals and aids self-reinforcement of one's progress. According to SCT, receiving self-management knowledge and skill support improves health behaviors by enhancing one's self-efficacy and ability to perform the self-management behaviors. The development of the mHealth intervention was guided by the Behavior Information Technology model that links targeted diabetes self-management behaviors with evidence-based behavior change techniques underlying the theoretical mechanisms of SCT to address the goals of DSMES (see Figure 2) [30]. Table 1 explains the operationalizations of the behavior change techniques for the targeted diabetes self-management behaviors (ie, the mHealth tool and frequency of access or use by the study participants).

This intervention adopted a unique "high-tech, high-touch" approach. We integrated self-monitoring data from multiple mHealth tools into a cloud-based platform so that (1) participants could increase self-efficacy for behavior change to improve health outcomes by reviewing data on the platform, (2) community health workers could access the platform and address participant barriers remotely, thereby promoting participant self-efficacy for behavior change and diabetes self-management, and (3) community health workers could obtain support from the research team for complex diabetes self-management cases and technological issues via video conferencing.

Figure 1. The "high-tech, high-touch" intervention model. Self-regulation theory and social cognitive theory provide theoretical support for the model. Self-regulation theory posits that self-monitoring aids self-evaluation of progress made towards one's goals and self-reinforcement of progress (shown in blue). According to social cognitive theory, providing self-management knowledge and skills and support improves health behaviors by enhancing self-efficacy toward performing self-management behaviors (shown in orange). Community health workers are involved in the "high-tech, high-touch" model to provide diabetes self-management education and support services (shown by oval).
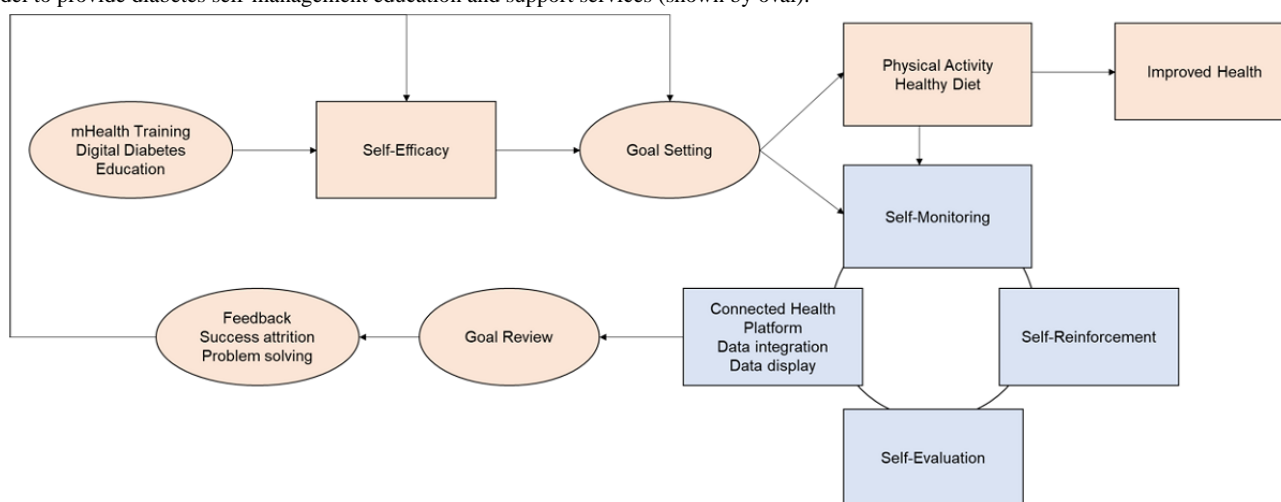
Figure 2. Intervention delivery flow diagram. Participants received digital diabetes education, performed mHealth-based self-monitoring, and maintained 2-way communication with the community health workers. Their performance was captured by the Connected Health Platform and the TalentLMS learning management system, which helped community health workers to provide personalized diabetes self-management educationand support services. CHW: community health worker.
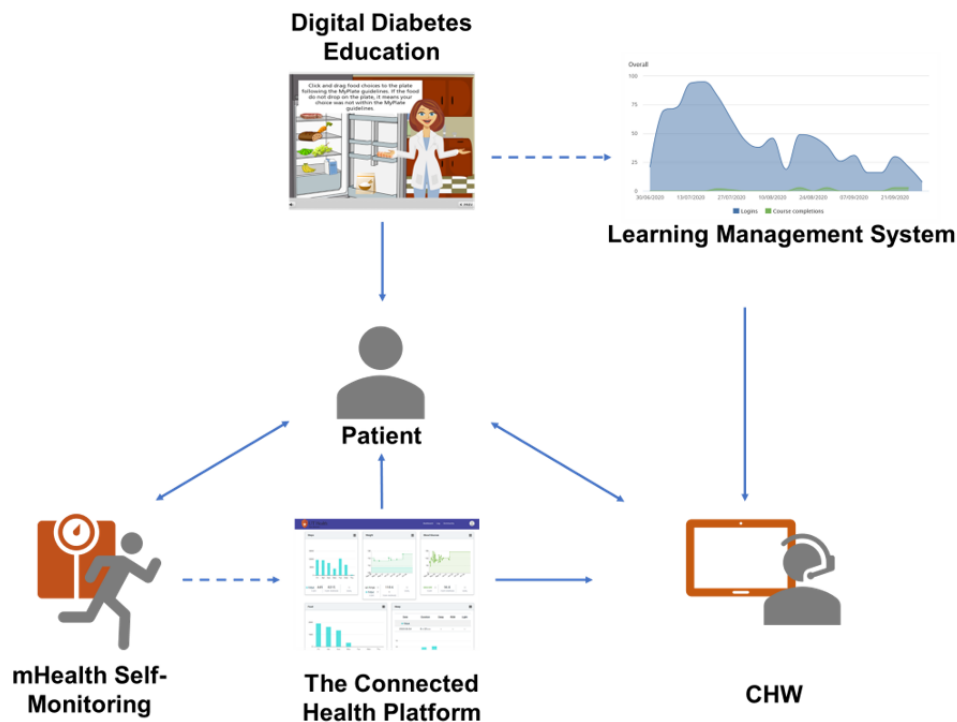
Table 1. Use of behavior change techniques and mHealth tools.

Behavior change techniques	Operationalization	mHealth tools	Frequency
Instruction on how to perform a behavior	Advise the participant how to adhere to diet and exercise self-monitoring goals.	Digital diabetes education session	Weekly
Self-monitoring of behavior	Ask the participant to wear a fitness tracker; ask the participant to record food intake.	Electronic logs; passive data collection	Daily
Establish a method for the person to monitor and record the outcomes of their behavior	Ask the participant to weigh themselves; ask the participant to monitor blood glucose.	Passive data collection	Daily
Feedback on outcomes of behavior	Inform the participant of how much weight they have lost and their blood glucose level.	Phone call or videoconference	Weekly
Feedback on behavior	Inform participant of how they performed on diet and physical activity goals.	Phone call or videoconference	Weekly
Discrepancy between current behavior and goals	Point out out-of-range blood glucose readings. Point out that recorded diet and exercise fell short of the goal. Point out lack of adherence to self-monitoring goals.	Phone call or videoconference	Weekly

Description of the Intervention

The pilot DSMES intervention was delivered over a 12-week period by community health workers via mHealth. Once enrolled, participants received mHealth and one-on-one training from community health workers (Table 2). To facilitate establishing rapport and communication, each community health worker was paired with 5 participants to provide individualized DSMES services.

To ensure fidelity of intervention delivery, all community health workers received a 1-day training session provided by a research staff member. The training covered a study description, diabetes

self-management, data collection, and intervention delivery. During the intervention, the study team met with community health workers weekly to resolve problems they encountered, following the ECHO (Extension for Community Health Care Outcomes) model [31].

Weekly digital diabetes education was delivered to increase the participants' diabetes knowledge and skills. Building upon the Diabetes Prevention Program Group Lifestyle Balance Program, the curriculum was tailored to local needs. For example, we modified group-based activities to add individual-based aligned lessons with the AADE7 (American Association of Diabetes Educators-7) framework [32]; tailored the content to the local

culture; added interactive components, including videos, quizzes, and webpages; and reduced the content length to less than 10 minutes per lesson. All lessons were reviewed by community health workers. The lessons were developed using eLearning authoring software (Articulate Storyline; Articulate Global LLC).

Collaborative goal setting between the community health workers and participants with diabetes was integral for DSMES [32]. Each week, the participants set daily SMART (specific, measurable, achievable, relevant, and time-bound) goals pertaining to physical activity and diet. The community health workers assisted the participants in choosing goals for physical activity and diet. Additionally, the participants set self-monitoring goals for frequency of weight self-monitoring, food logging, physical activity tracking, and blood glucose self-monitoring in week 1. Participants met with community health workers on weeks 2, 4, 6, and 10 to review goal achievement, address barriers, and make necessary modifications.

Table 2. Devices and apps used for mHealth and their functions.

mHealth devices and apps	Functions
Fitbit Inspire fitness tracker (Fitbit LLC)	Physical activity goal setting and self-monitoring
Fitbit app (Fitbit LLC)	Dietary goal setting and food logging
Fitbit Air body scale (Fitbit LLC)	Weight loss goal setting and self-monitoring
BioTel Care glucose meter (BioTelemetry, Inc)	Blood glucose self-monitoring
TalentLMS (Epignosis LLC)	eLearning management system for delivering asynchronous diabetes education lessons
The Connected Health Platform	For community health workers to monitor participants' progress toward goal achievement and provide ongoing support.
Online interactive diabetes education lessons created using Articulate Storyline 360 (Articulate Global LLC)	Education content for teaching diabetes self-management education and support services delivered to the study participants via TalentLMS.

Connected Health Platform

Data collected from the mHealth devices and apps was automatically synchronized and stored by the Connected Health Platform (Figure 3), an application programming interface integration platform developed by the study team [33]. This platform was designed to present self-monitoring data relevant to behavioral goals, as studies have found that combining physical activity and diet data with blood glucose self-monitoring has the potential to help community health workers provide personalized DSMES service [34].

Once logged, the community health workers could see 7-day plots of diet, including macronutrient details, calorie intake, and water consumption; activity, including exercise type, steps, sleep, and weight; blood glucose; and weekly behavioral goals. The community health workers could also select a date range to view self-monitoring data trends and interactions by overlaying multiple sources, and they could track participants' progress on goals, thereby enabling problem-solving strategies during behavioral follow-up sessions. The participants were also allowed access to the platform. Additionally, the platform served as a data storage tool from which the research team could download data from various mHealth sources.

Figure 3. Screenshot of the Connected Health Platform. The Connected Health Platform displayed details about the diet of the participants with diabetes, including food type, macronutrient consumption, and calorie intake (left). The community health workers set nutrition and physical activity goals in the Connected Health Platform (right).
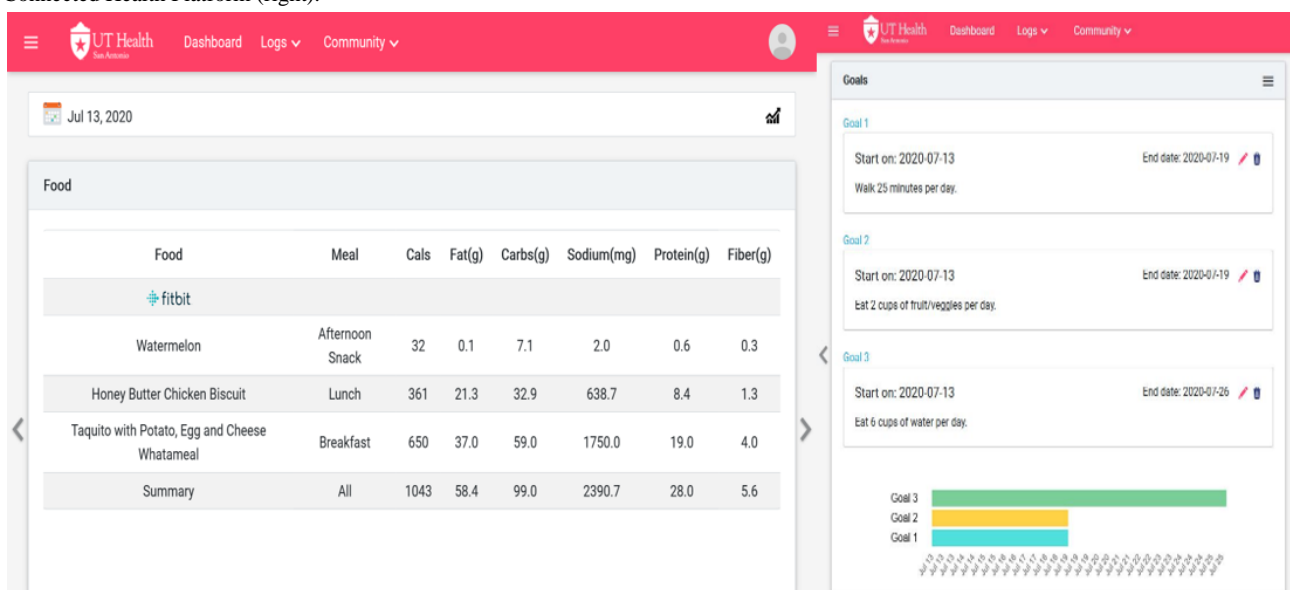
Study Measures

We addressed feasibility according to retention, actual intervention use, barriers to implementation, satisfaction, and preliminary health effects.

Retention

Retention rate was the percentage of enrolled participants who completed posttest data collection.

Actual Intervention Use

Actual use of digital education was quantified as the weekly number of days the lessons were accessed. Actual use of self-monitoring devices was operationalized as the weekly number of days with self-monitored weigh-ins, food logs, step counts, and blood glucose readings. All community health workers kept a log to record their contact with participants; data included call duration and issues addressed. We operationalized use of behavioral change strategies as the cumulative number of behavioral goals set during the study and reported the percentage of time during the week the participants accomplished these goals.

Barriers to Implementation

The participants reported barriers to achieving behavioral goals during behavioral follow-up sessions; at posttest, they listed life events that affected diabetes self-care using the Recent Life Event Questionnaire [35].

Satisfaction

Satisfaction was measured using Customer Satisfaction Questionnaire short version (CSQ-8) [36]. The CSQ-8 is a 4-point Likert scale with 8 items. The total score ranged between 8 and 32, with a higher score indicating a higher program satisfaction rate. To measure the participants' level of acceptance, we adapted the poststudy surveys used by Yin et al [37]. Specifically, the participants rated their level of satisfaction with each intervention component, its perceived benefits, and their confidence in continuing diabetes self-management. Patient satisfaction with digital education was measured at the end of each module on a 4-point Likert scale, with 1 indicating not acceptable; 2, fair acceptability; 3, good acceptability; and 4, excellent acceptability.

Preliminary Health Effects

All participants checked HbA_{1c} with their doctor pre- and posttest. Weight was self-measured to 0.1 lb (0.045 kg) and represented as the mean of 2 measurements. To assess participants' responses to the intervention, we plotted weekly changes in average daily steps and self-measured body weight.

We also measured changes in eHealth literacy and outcome expectations. The 14-item eHealth Literacy Toolkit assesses eHealth literacy as technology confidence, attitudes toward engaging with technology, and mobile technology familiarity [38]. Items were answered on a 10-point scale, from "completely disagree" to "completely agree." The 13-item Perceived Therapeutic Efficacy Scale (PTES) was used to assess perceived beliefs for the effect of each mHealth component on diabetes self-management [39]. Participants answered items on a 10-point scale (with 0 indicating "no confidence," and 10 indicating "highest confidence") [39].

Other Measures

At baseline, participants completed surveys on demographic information, including age, sex, educational background, language spoken, marital status, diabetes history, medication history, and experience with mHealth.

Data Analysis

All descriptive statistics are reported as the mean (SD) for continuous variables and frequencies and relative frequencies for categorical variables. A 2-tailed paired t test was used to determine intervention effects on weight loss, HbA_{1c}, technology efficacy, and PTES score. All statistical procedures were performed using R software (R Foundation for Statistical Computing). The threshold for statistical significance was a 2-sided P value of .05.

Results

All 15 participants completed the baseline assessment; 1 participant had missing data for posttest HbA_{1c} (for a retention rate of 93%). All participants attended the behavioral follow-up sessions at weeks 1, 2, 4, 6, and 10. Detailed demographic characteristics of the study participants are presented in Table 3. Participants were all Latino and were mainly older adults, female, and had at least a high school education. All participants had at least one type of health insurance. Participants had a long history of diabetes diagnosis (mean 15.2, SD 11.9 years). Thirteen participants took at least one type of diabetes medication. Most participants had no experience with mHealth.

Table 3. Participant characteristics at baseline (N=15).

Characteristics	Value
Age (years), mean (SD)	61.87 (10.67)
Sex (female), n (%)	9 (60)
Preferred language (English), n (%)	12 (80)
Education (≥ high school), n (%)	14 (93)
Marital status (married or living with partner), n (%)	8 (53)
Living with someone (yes), n (%)	14 (93)
Insurance status (insured), n (%)	15 (100)
Current internet service needs met (yes), n (%)	15 (100)
Answer to "How do you usually use the internet to search for health information?" n (%)	
Mobile phone	13 (87)
Laptop or personal computer	7 (47)
Tablet	6 (40)
Work computer	2 (13)
Public computer	1 (7)
Other	1 (7)
Answer to "How often do you use mobile health apps of any type?" n (%)	
Every day	1 (7)
Several days a week	2 (13)
About one day a week	0 (0)
(Almost) never	12 (80)
Answer to "How often do you use a digital health device?" n (%)	
Every day	4 (27)
Several days a week	1 (7)
About one day a week	1 (7)
(Almost) never	8 (53)

Actual Intervention Use

Digital education completion rates were high (mean 87.5%, SD 22.5%) with most (14/15, 93%) participants accessing all digital education modules and 8/15 (53%) completing all lessons. The participants accessed digital education modules multiple times during the week (2-5 times). There was a continual decline in the number of active users and average weekly logins as the study proceeded (Figure 4). The highest weekly logins occurred in week 4, with the 15 participants logging in an average of 4.3 times.

During the 12-week (84-day) intervention, the mean percentage of days that the participants self-monitored steps, food, blood glucose, and weight were 89% (SD 21%), 78% (SD 21%), 47% (SD 13%), and 81% (SD 16%), respectively. Overall, the percentage of participants who used self-monitoring technologies daily did not change significantly during the study course (Figure 5).

All participants set daily physical activity and diet goals with the community health workers and performed well in accomplishing these goals, as reported by the Connected Health Platform. Nearly one-third of the participants met their diet and physical activity goals on all days of the week. Most participants accomplished their daily dietary goals on more than half of the days of the week (Table 4).

On average, each participant made 16.73 (SD 8.0) calls to their community health worker, with each call lasting between 5 minutes and 2.5 hours.

Figure 4. Mean weekly digital lesson logins and mean number of participants accessing digital lessons by week of the trial, showing the mean weekly logins (in orange) and the number of participants accessing the digital lessons per week (in blue) over the 12-week study period. Mean weekly logins represents the number of times participants logged into the digital lessons. The number of participants is the number of participants that used the app at least once in that week.
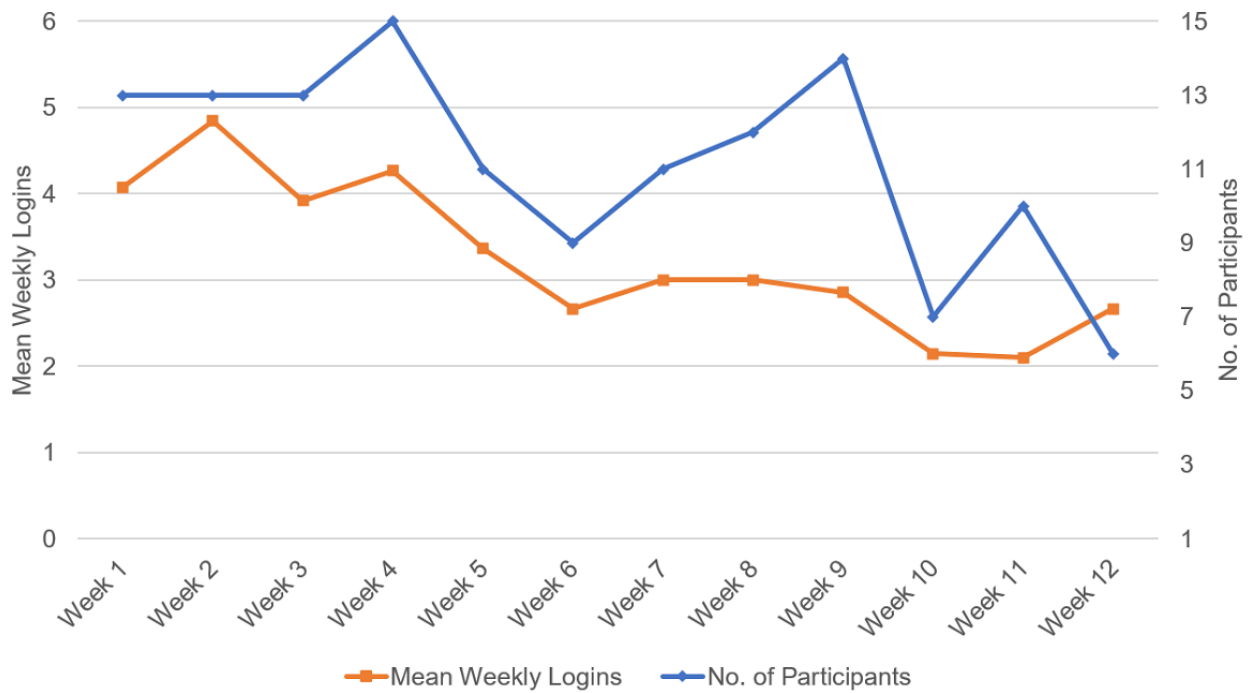

Figure 5. Proportion of participants using the mHealth self-monitoring technologies by day of the trial.
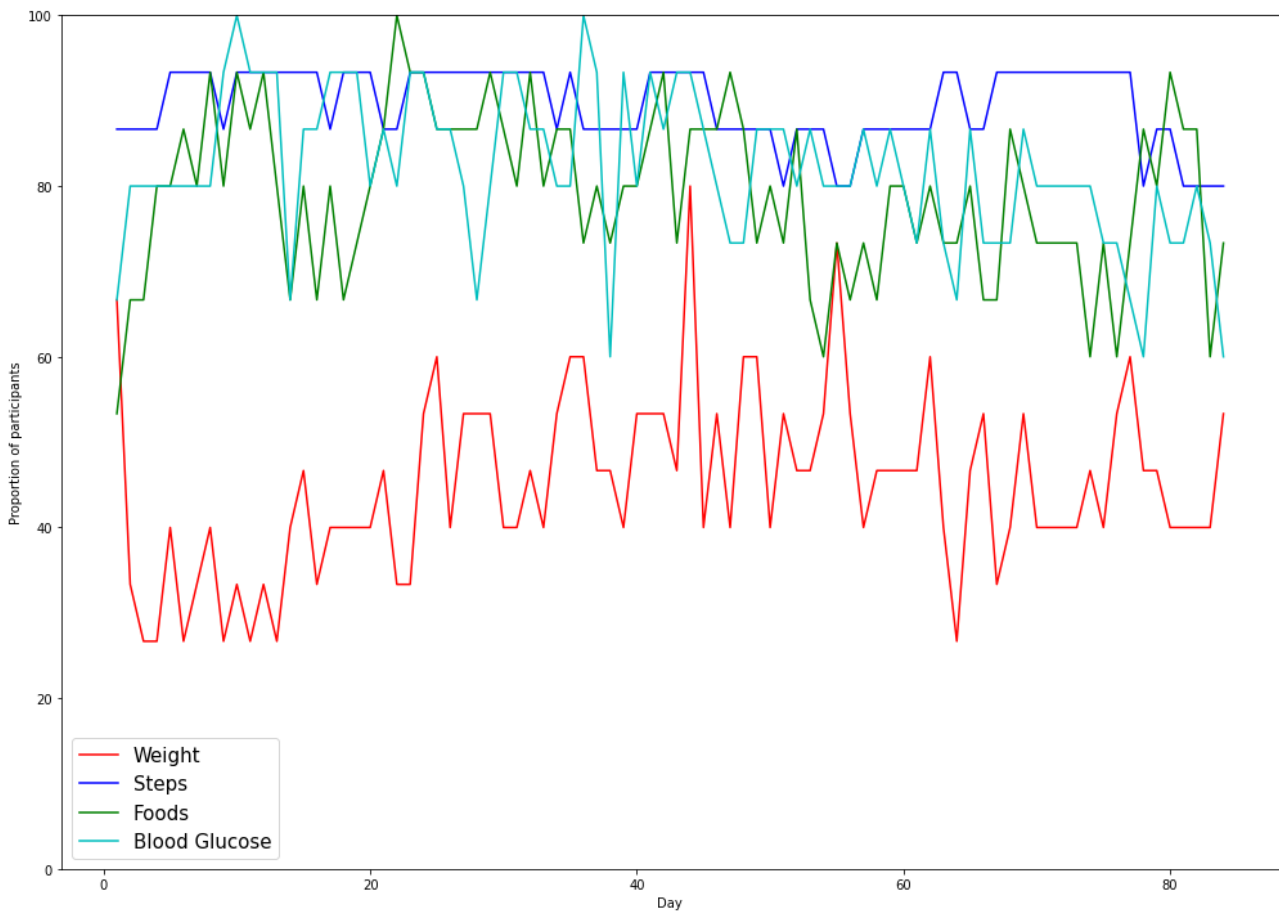
Table 4. Level of behavioral goal achievement captured by the Connected Health Platform. The total number of dietary goals was 172; the total number of physical activity goals was 93.

Reported percentage of time during the week participants achieved goals	No time (0%)	Little of the time (25%)	Some of the time (50%)	Most of the time (75%)	All the time (100%)
Dietary goals, n (%)	5 (3)	11 (6)	41 (24)	68 (40)	47 (27)
Physical goals, n (%)	15 (16)	17 (18)	10 (11)	18 (19)	33 (36)

Barriers to Implementation

Participants reported different types of barriers to completing the intervention activities. The most reported barriers were "motivation" for food logging, "time" for exercise self-monitoring, "technical" for weight self-monitoring, and "forgetfulness" for blood glucose self-monitoring.

The COVID-19 pandemic appeared to affect diabetes control. Participants reported the following life events that affected diabetes control: "having relatives or close friends seriously ill, injured, or die" (7/15, 47%), "having immediate family be seriously ill, injured, or die" (4/15, 27%), and "having major financial difficulties" (3/15, 20%).

Satisfaction

Overall, the participants were satisfied with the intervention (Table 5). The mean score for CSQ-8 was 29.53 (SD 3.04). All participants agreed that the community health workers provided needed support, and they liked the support. Participants agreed that the program helped them be active and eat healthfully. Participants also expressed the intention to continue the intervention activities. Most of the participants (14/15, 93%) indicated confidence to continue blood glucose self-monitoring and healthful eating (Table 5) and blood glucose self-monitoring and healthful eating became a high or essential priority for most participants.

The participants rated most digital education modules as "good." The highest score was given to the "Healthy Eating" lesson and the lowest score was given to the lesson on "Motivation" (Table 6).

Table 5. Poststudy survey on intervention satisfaction (N=15).

Questions	Strongly agree, n (%)	Agree, n (%)	Disagree/strongly disagree, n (%)
Did the program help you to be more physically active?	8 (53)	7 (47)	0 (0)
Are you still being active with the information from the program?	6 (40)	7 (47)	2 (13)
Did the program help you to eat healthy?	6 (40)	9 (60)	0 (0)
Are you still eating healthy with the information from the program?	6 (40)	8 (53)	1 (7)
Did the program help you to lose weight?	6 (40)	7 (47)	2 (13)
Did the program help you control you blood glucose?	5 (33)	8 (53)	2 (13)
Are you still trying to lose weight with the information from the program?	6 (40)	8 (53)	1 (7)
I liked the digital diabetes education lessons.	7 (47)	7 (47)	1 (7)
I learned how to change my lifestyle with information from the health education lessons.	7 (47)	6 (40)	2 (13)
Information in the health lessons was easy to understand.	9 (60)	5 (33)	1 (7)
I liked the support calls and text messages from the community health worker.	10 (67)	5 (33)	0 (0)
The community health worker provided the support I needed.	12 (80)	3 (20)	0 (0)
I liked setting the health goals.	5 (33)	9 (60)	1 (7)
I liked the videos on physical activity and diet.	5 (33)	8 (53)	2 (13)
I liked the videos with information on obesity and diabetes.	5 (33)	8 (53)	2 (13)
Compared with when the program started in the summer, I am confident that I can continue to exercise regularly now.	5 (33)	4 (27)	2 (13)
Compared with when the program started in the summer, I am confident that I can continue eating healthy now.	6 (40)	8 (53)	0 (0)
Compared with when the program started in the summer, I am confident that I can continue to monitor my blood sugar now.	10 (67)	5 (33)	0 (0)

Table 6. Digital diabetes education topics, session completion, session evaluation, and lesson completion rate.

Session topics and lessons	Rating (mean)[a]	Completion Rate (%)
1. Diabetes self-management	3.07	87
Diabetes self-management activities		93
Diabetes self-management skills		100
Be an active self-manager		60
Problem solving		93
2. Managing and monitoring your behavior	3.00	92
Blood glucose self-monitoring		60
Monitor your diet and weight		100
New ways to tip the calorie balance		100
Portion control		93
Food and nutrition labels		100
Monitor your exercise and physical activity		100
Exercise caution		87
Use digital tools to support your diabetes management		93
Quick tips to maintain a healthy lifestyle		93
3. Healthy plate	3.21	83
MyPlate: planning a meal		53
Start simple with MyPlate webtool		73
Resource: MyPlate action guide		100
Resource: MyPlate message toolkit		87
Learn to create your smart goal		93
4. Planning: healthy rating and physical activity	3.07	91
Community facilities		93
Healthy eating and food preparation		87
Exercise videos		93
5. Maintaining overall health	3.00	83
Be mindful: eating, exercise, and stress management		87
Maintain behavioral goals and gain social support		80
6. Taking medication	3.00	60
Diabetes medication and provider communication		60
7. Eating healthy away from home	3.21	87
Healthy eating on a budget		80
Healthy shopping tour		87
Healthy dining out		87
Problem and helpful social cues		93
8. Motivation techniques: how to stay motivated	2.86	85
How to stay motivated		80
Be good to yourself		87
What is your purpose now		87
Social support		87

[a]Participants rated the content of the lessons on a 4-point Likert scale at the end of each session (1, not acceptable; 2, fair; 3, good; and 4, excellent).

Preliminary Effects

Participants showed a significant reduction in body weight of 3.5 (SD 3.2) kg (P=.001) from baseline to posttest (Table 7). HbA_{1c} did not change significantly. We observed weekly improvement in weight loss and steps (Figure 6, Figure 7). Participants achieved the largest weight loss between weeks 6

and 10, when the greatest improvement in average steps was also observed.

Participants showed a significant improvement in PTES score of 50.86 (95% CI 36.61-65.10; t_{13}=7.71; P<.001) and eHealth literacy by 37.57 from baseline to posttest, (95% CI 16.72-58.42; t_{13}=3.89; P<.001) (Figure 8).

Table 7. Changes in preliminary efficacy outcomes from baseline to 3 months (N=14).

Outcomes	Baseline mean (SD)	3-month posttest mean (SD)	t test (df) (pre-post)	P value
Weight (kg)	86.1 (25.9)	82.6 (24.1)	1.9 (14)	.001
HbA_{1c} (%)	6.91 (1.28)	7.04 (1.66)	−.44 (13)	.668

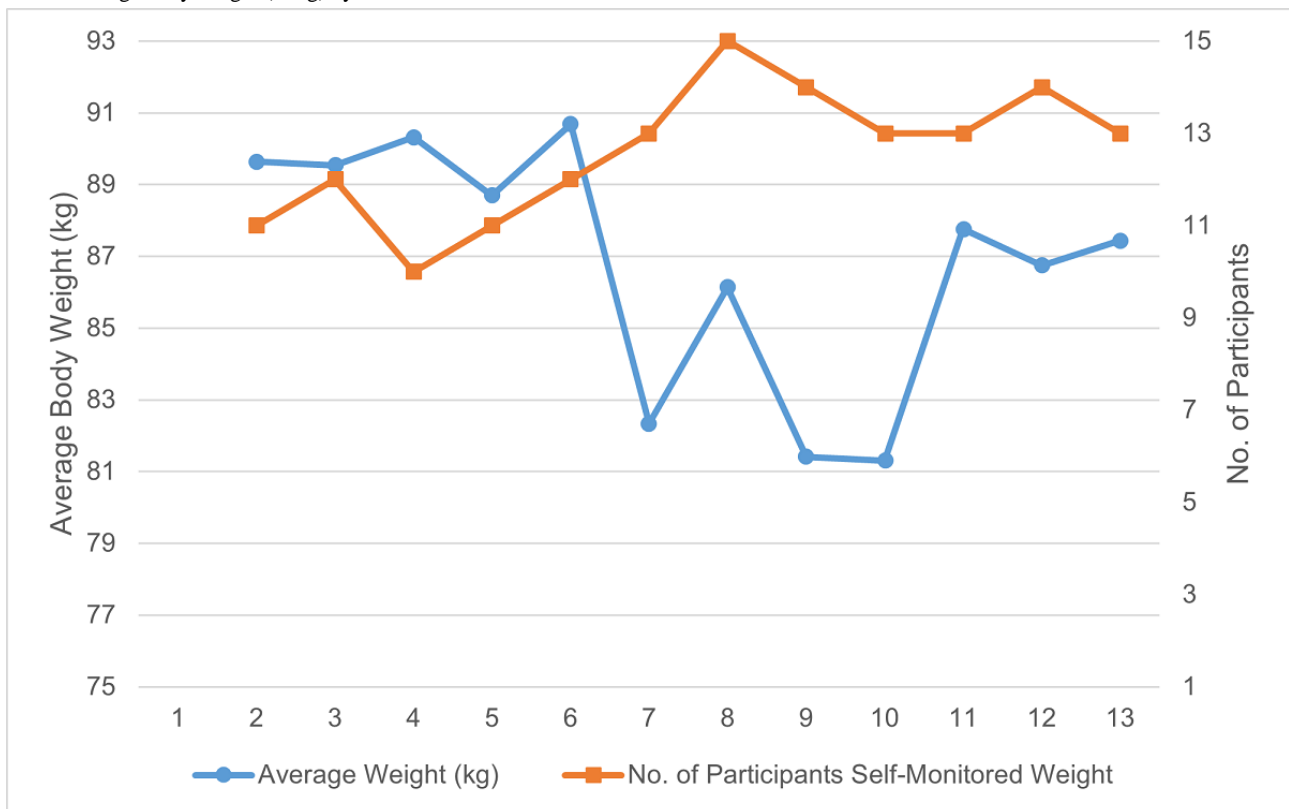**Figure 6.** Average body weight (in kg) by week.
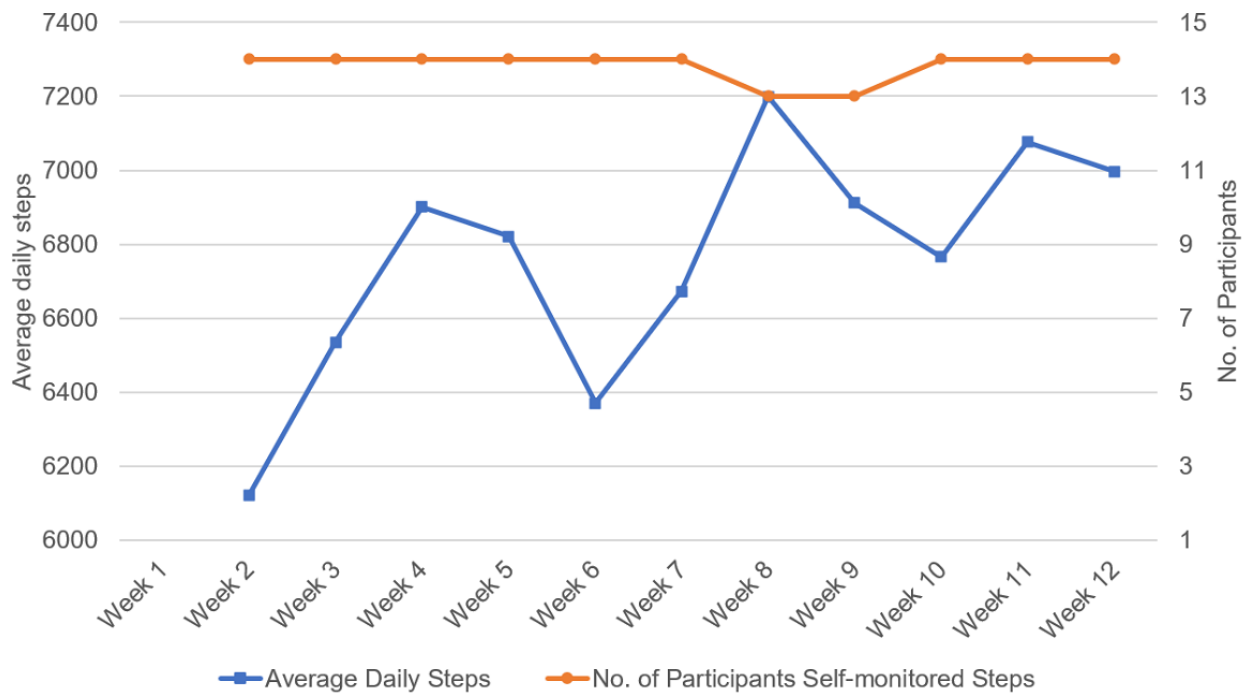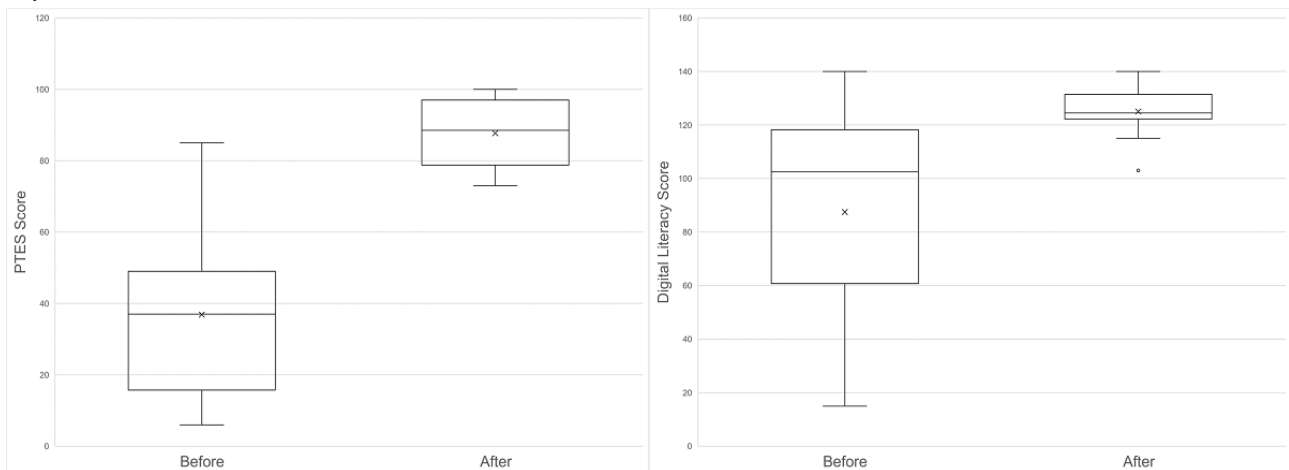
Figure 7. Average daily steps by week.

Figure 8. Pre- to poststudy changes in perceived therapeutic efficacy scale score (left) and eHealth literacy score (right). PTES: Perceived Therapeutic Efficacy Scale.

Discussion

Principal Findings

Latinos living in rural South Texas suffer high rates of diabetes, but their access to DSMES is poor. To address multidimensional access barriers, we designed an innovative DSMES intervention, combining the community health worker model and mHealth technologies. To our knowledge, this is the first published study to examine the combined impact of community health worker facilitation and mHealth in improving access to DSMES in a rural Latino population. Our findings demonstrate that an mHealth-based, community health worker-led approach is a feasible and acceptable means to augment DSMES services in South Texas. We found that mHealth facilitated community health worker engagement in delivering DSMES services. The intervention was well-received by the participants, as evidenced by their consistent use of mHealth and frequent

participant-community health worker interaction. The participants reported a high level of satisfaction with the intervention. Moreover, we observed improvements in self-care behaviors and health outcomes. Taken together, this study suggests that our unique "high-tech, high-touch" solution has the potential to be tested for efficacy in larger randomized controlled trials.

Our findings show that by using mHealth tools, community health workers can address the multidomain health determinants proposed by the National Institute on Minority Health and Health Disparities framework [16]. For example, we addressed individual knowledge and skill gaps, helped persons with diabetes overcome literacy barriers for using mHealth (individual-behavioral domains), and offered culturally tailored digital diabetes education (sociocultural environment) [20].

We achieved a higher retention rate than previous diabetes self-management programs conducted in rural communities [40,41] and observed consistent mHealth usage. High dropout rates and a decline in attendance are commonly reported in DSMES mHealth interventions [42]. While equipping participants with various technologies can overcome geographical and temporal barriers, the participation of community health workers allowed frequent communication with persons with diabetes and the maintenance of their participation. Previous rural DSMES interventions found a positive relationship between community health worker-participant telephone contacts and attendance rate [6]. Therefore, our findings demonstrate the value of adding community health workers to a high-tech program and show that this approach facilitates ongoing participation.

Consistent with other rural-based DSMES interventions, our sample reported high rates of satisfaction [6]. We speculate that such high satisfaction is due to a strong desire to feel supported and "cared for" among the population [43]. Participants' frequent use of the intervention strengthened this speculation. Therefore, a "high-tech, high-touch" intervention may address diabetes care disparities in South Texas and other underserved areas with similar features.

Low health and eHealth literacy are major barriers to implementing mHealth in underserved communities [43]. Our participants had little to no prior experience with mHealth. They also reported low expectations for mHealth on diabetes control at baseline. These low expectations did not limit mHealth engagement, as most participants started using mHealth in week 1 and used it consistently throughout the project period. In addition, the participants seldom reported technology as a barrier to diabetes self-care. The participants showed significant improvements in mHealth outcome expectancy and eHealth literacy at 12 weeks. Our findings indicate that a "high-touch, high-support" model might help persons with diabetes overcome health and eHealth literacy barriers and allow them to use mHealth for diabetes self-care. Looking forward, we will test this model with a longer follow-up period to determine if support from community health workers is sufficient for participants with diabetes to maintain diabetes self-care over the long term.

The high level of intervention acceptability could also be attributed to our integration of multiple personalization strategies [44]. Considering the complex needs of persons with diabetes, we acknowledge the irreplaceable role of community health workers in dynamic personalization strategies. Specifically, the community health workers were able to tailor DSMES to cultural values and context, literacy and numeracy abilities, and personal beliefs and concerns in real time, with mHealth as a complement to the personalization strategies [43]. For example, integrating self-monitoring data into the Connected Health Platform made it easier for the community health workers to provide personalized feedback [34]. To continuously engage persons with diabetes in DSMES, future research needs to leverage multidimensional personalization strategies enabled by community health workers and mHealth.

Poor integration of technology into health professionals' workflow could increase their workload and discourage them from adopting mHealth interventions. Considering that community health workers are a valuable resource that can affect intervention scalability [45], we aimed to integrate mHealth into community health workers' workflow with minimal barriers. Presenting a large amount of patient-generated self-monitoring data in an informative format is important for reducing the burden placed on community health workers by mHealth interventions [46]. We learned from a previous study that diabetes educators prefer a centralized system that allows a flexible view of self-monitoring information from persons with diabetes [34]. Therefore, we used the Connected Health Platform to allow community health workers to merge their preferred self-monitoring data and observe interactions in diet and activity with blood sugar or weight, which enabled them to quickly evaluate the self-care progress of participants with diabetes. Community health workers also met weekly with the study team via video conference, which may have raised their motivation and performance, resulting in improved DSMES service quality [47].

Consistent with previous DSMES programs in underserved communities, participants achieved 4.1% weight loss at 3 months. Participants also maintained good glycemic control at 3 months, similar to previous short-term mHealth-based DSMES interventions [35,36]. While a meta-analysis reported a 0.4% HbA$_{1c}$ reduction after mHealth interventions in persons with diabetes, these studies were conducted in persons with diabetes with poor baseline HbA$_{1c}$ and had longer study durations [37]. These findings warrant future examination of our intervention in rural Latinos with poorer glycemic control and extension of the study duration to examine the long-term effects of the intervention.

This study was conducted during the COVID-19 pandemic. At the time of the study, Latinos represented 43.5% of confirmed COVID-19 deaths in Texas [48]. Moreover, persons with diabetes experienced greater challenges during the pandemic, including more severe symptoms, a higher mortality rate, limited health care resources, concerns related to cross-infection, and emotional stress. [49]. Therefore, our study provides a timely digital solution to address the unique needs of persons with diabetes and to optimize allocation of health care resources in underserved communities.

Limitations

Several limitations need to be considered in interpreting our study findings. First, the duration was shorter than typical DSMES programs. Given that diabetes self-management requires long-term commitment, our study needs to be extended with a longer follow-up period. Second, the statistical findings of our study need to be interpreted with caution due to the small sample size. Third, we only included participants who had a digital data plan, which could limit the generalizability of our findings to rural Latinos with diabetes. Fourth, we only measured actual use of the intervention by the participants. Future studies should consider collecting data from community health workers to complement data from persons with diabetes to inform intervention scalability. Lastly, we did not collect data on recruitment, which could have provided valuable information on the potential reach of our program [50].

Conclusions

Our findings suggest that a "high-tech, high-touch" approach holds promise to reduce DSMES access barriers faced by rural Latino residents of South Texas. We found that mHealth facilitated self-care and remote monitoring by participants with diabetes, interaction between community health workers and participants with diabetes, and enabled community health workers to actively contribute to providing DSMES services. In the future, our findings should be tested in a fully powered randomized controlled trial to examine the efficacy of our methods in improving access to quality DSMES and glycemic control in persons with diabetes living in resource-poor rural communities.

Authors' Contributions

JW, ZY, JL, and SL designed the study. SL, BYC, and CL analyzed the data. SL and JW wrote the first draft of the paper, which was reviewed, modified, and approved by all other authors.

Conflicts of Interest

None declared.

References

1. Beck J, Greenwood DA, Blanton L, Bollinger ST, Butcher MK, Condon JE, 2017 Standards Revision Task Force. 2017 National Standards for Diabetes Self-Management Education and Support. Diabetes Educ 2018 Feb 18;44(1):35-50. [doi: 10.1177/0145721718754797] [Medline: 29346744]
2. O'Connor A, Wellenius G. Rural-urban disparities in the prevalence of diabetes and coronary heart disease. Public Health 2012 Oct;126(10):813-820. [doi: 10.1016/j.puhe.2012.05.029] [Medline: 22922043]
3. Ramirez AG, Thompson IM, Vela L. The South Texas health status review: A health disparities roadmap. Cham, Switzerland: Springer; Jun 29, 2013.
4. Ross S, Benavides-Vaello S, Schumann L, Haberman M. Issues that impact type-2 diabetes self-management in rural communities. J Am Assoc Nurse Pract 2015 Nov;27(11):653-660. [doi: 10.1002/2327-6924.12225] [Medline: 25776183]
5. Strauss K, MacLean C, Troy A, Littenberg B. Driving distance as a barrier to glycemic control in diabetes. J Gen Intern Med 2006 Apr;21(4):378-380 [FREE Full text] [doi: 10.1111/j.1525-1497.2006.00386.x] [Medline: 16686817]
6. Lepard MG, Joseph AL, Agne AA, Cherrington AL. Diabetes self-management interventions for adults with type 2 diabetes living in rural areas: a systematic literature review. Curr Diab Rep 2015 Jun 7;15(6):608 [FREE Full text] [doi: 10.1007/s11892-015-0608-3] [Medline: 25948497]
7. Bennett K, Olatosi B, Probst J. Health disparities: A rural-urban chartbook. Columbia, SC: South Carolina Rural Health Research Center; 2008. URL: https://sc.edu/study/colleges_schools/public_health/research/research_centers/sc_rural_health_research_center/documents/73healthdisparitiesaruralurbanchartbook2008.pdf [accessed 2022-05-09]
8. Texas Physician Supply and Demand Projections, 2018-2032. Texas Health and Human Services. URL: https://www.dshs.state.tx.us/legislative/2020-Reports/TexasPhysicianSupplyDemandProjections-2018-2032.pdf [accessed 2022-05-09]
9. Brewer-Lowry AN, Arcury TA, Bell RA, Quandt SA. Differentiating approaches to diabetes self-management of multi-ethnic rural older adults at the extremes of glycemic control. Gerontologist 2010 Oct 28;50(5):657-667 [FREE Full text] [doi: 10.1093/geront/gnq001] [Medline: 20110333]
10. Aging in Texas: Introduction. Texas Demographic Center. URL: https://demographics.texas.gov/resources/publications/2016/2016_06_07_aging.pdf [accessed 2022-05-09]
11. Titus SK, Kataoka-Yahiro M. A Systematic Review of Barriers to Access-to-Care in Hispanics With Type 2 Diabetes. J Transcult Nurs 2019 May 15;30(3):280-290. [doi: 10.1177/1043659618810120] [Medline: 30442075]
12. Lopez-Quintero C, Berry EM, Neumark Y. Limited English proficiency is a barrier to receipt of advice about physical activity and diet among Hispanics with chronic diseases in the United States. J Am Diet Assoc 2010 May;110(5 Suppl):S62-S67. [doi: 10.1016/j.jada.2010.03.009] [Medline: 20399300]
13. Cersosimo E, Musi N. Improving treatment in Hispanic/Latino patients. Am J Med 2011 Oct;124(10 Suppl):S16-S21. [doi: 10.1016/j.amjmed.2011.07.019] [Medline: 21939794]
14. Hu J, Amirehsani K, Wallace DC, Letvak S. Perceptions of barriers in managing diabetes: perspectives of Hispanic immigrant patients and family members. Diabetes Educ 2013 May 02;39(4):494-503 [FREE Full text] [doi: 10.1177/0145721713486200] [Medline: 23640301]

XSL•FO

RenderX

15. Mora N, Golden SH. Understanding Cultural Influences on Dietary Habits in Asian, Middle Eastern, and Latino Patients with Type 2 Diabetes: A Review of Current Literature and Future Directions. Curr Diab Rep 2017 Oct 23;17(12):126. [doi: 10.1007/s11892-017-0952-6] [Medline: 29063419]

16. Alvidrez J, Castille D, Laude-Sharp M, Rosario A, Tabor D. The National Institute on Minority Health and Health Disparities Research Framework. Am J Public Health 2019 Jan;109(S1):S16-S20. [doi: 10.2105/AJPH.2018.304883] [Medline: 30699025]

17. American Diabetes Association. ADA's Standards of Medical Care in Diabetes. Clin Diabetes 2021 Jan;39(1):128 [FREE Full text] [doi: 10.2337/cd21-pe01] [Medline: 33551565]

18. Walton J, Snead C, Collinsworth A, Schmidt K. Reducing diabetes disparities through the implementation of a community health worker-led diabetes self-management education program. Fam Community Health 2012;35(2):161-171. [doi: 10.1097/FCH.0b013e31824651d3] [Medline: 22367263]

19. Hunter CM, Salandy SW, Smith JC, Edens C, Hubbard B. Racial Disparities in Incidence of Legionnaires' Disease and Social Determinants of Health: A Narrative Review. Public Health Rep 2021 Jun 29:333549211026781. [doi: 10.1177/00333549211026781] [Medline: 34185609]

20. Fang CY, Ragin CC. Addressing Disparities in Cancer Screening among U.S. Immigrants: Progress and Opportunities. Cancer Prev Res (Phila) 2020 Mar;13(3):253-260 [FREE Full text] [doi: 10.1158/1940-6207.CAPR-19-0249] [Medline: 32132119]

21. Hughes MM, Yang E, Ramanathan D, Benjamins MR. Community-Based Diabetes Community Health Worker Intervention in an Underserved Chicago Population. J Community Health 2016 Dec;41(6):1249-1256. [doi: 10.1007/s10900-016-0212-8] [Medline: 27286843]

22. Kane EP, Collinsworth AW, Schmidt KL, Brown RM, Snead CA, Barnes SA, et al. Improving diabetes care and outcomes with community health workers. Fam Pract 2016 Oct;33(5):523-528. [doi: 10.1093/fampra/cmw055] [Medline: 27418587]

23. Jaskiewicz W, Tulenko K. Increasing community health worker productivity and effectiveness: a review of the influence of the work environment. Hum Resour Health 2012 Sep 27;10(1):38 [FREE Full text] [doi: 10.1186/1478-4491-10-38] [Medline: 23017131]

24. Braun R, Catalani C, Wimbush J, Israelski D. Community health workers and mobile technology: a systematic review of the literature. PLoS One 2013 Jun 12;8(6):e65772 [FREE Full text] [doi: 10.1371/journal.pone.0065772] [Medline: 23776544]

25. Early J, Gonzalez C, Gordon-Dseagu V, Robles-Calderon L. Use of Mobile Health (mHealth) Technologies and Interventions Among Community Health Workers Globally: A Scoping Review. Health Promot Pract 2019 Nov 10;20(6):805-817. [doi: 10.1177/1524839919855391] [Medline: 31179777]

26. Kay M, Santos J, Takane M. mHealth: new horizons for health through mobile technologies. World Health Organization. URL: https://apps.who.int/iris/bitstream/handle/10665/44607/9789241564250_eng.pdf?sequence=1 [accessed 2022-05-08]

27. Greenwood DA, Gee PM, Fatkin KJ, Peeples M. A Systematic Review of Reviews Evaluating Technology-Enabled Diabetes Self-Management Education and Support. J Diabetes Sci Technol 2017 Sep 31;11(5):1015-1027 [FREE Full text] [doi: 10.1177/1932296817713506] [Medline: 28560898]

28. White A, Thomas D, Ezeanochie N, Bull S. Health Worker mHealth Utilization: A Systematic Review. Comput Inform Nurs 2016 May;34(5):206-213 [FREE Full text] [doi: 10.1097/CIN.0000000000000231] [Medline: 26955009]

29. Burke LE, Sereika SM, Parmanto B, Beatrice B, Cajita M, Loar I, et al. The SMARTER Trial: Design of a trial testing tailored mHealth feedback to impact self-monitoring of diet, physical activity, and weight. Contemp Clin Trials 2020 Apr;91:105958 [FREE Full text] [doi: 10.1016/j.cct.2020.105958] [Medline: 32087342]

30. Mohr DC, Schueller SM, Montague E, Burns MN, Rashidi P. The behavioral intervention technology model: an integrated conceptual and technological framework for eHealth and mHealth interventions. J Med Internet Res 2014 Jun 05;16(6):e146 [FREE Full text] [doi: 10.2196/jmir.3077] [Medline: 24905070]

31. Arora S, Geppert CMA, Kalishman S, Dion D, Pullara F, Bjeletich B, et al. Academic health center management of chronic diseases through knowledge networks: Project ECHO. Acad Med 2007 Feb;82(2):154-160 [FREE Full text] [doi: 10.1097/ACM.0b013e31802d8f68] [Medline: 17264693]

32. Association of Diabetes CareEducation Specialists, Kolb L. An Effective Model of Diabetes Care and Education: The ADCES7 Self-Care Behaviors™. Sci Diabetes Self Manag Care 2021 Feb 11;47(1):30-53. [doi: 10.1177/0145721720978154] [Medline: 34078208]

33. Wang J, Zhang J. Adapting A Unified Electronic Health Record Usability Framework for Evaluation of Connected Health Care Technologies Linking Mobile Data. iproc 2015 Oct 27;1(1):e20 [FREE Full text] [doi: 10.2196/iproc.4477]

34. Wang J, Coleman DC, Kanter J, Ummer B, Siminerio L. Connecting Smartphone and Wearable Fitness Tracker Data with a Nationally Used Electronic Health Record System for Diabetes Education to Facilitate Behavioral Goal Monitoring in Diabetes Care: Protocol for a Pragmatic Multi-Site Randomized Trial. JMIR Res Protoc 2018 Apr 02;7(4):e10009 [FREE Full text] [doi: 10.2196/10009] [Medline: 29610111]

35. Hobson CJ, Kamen J, Szostek J, Nethercut CM, Tiedmann JW, Wojnarowicz S. Stressful life events: A revision and update of the social readjustment rating scale. Int J Stress Manag 1998;5(1):1-23. [doi: 10.1023/A:1022978019315]

36. Attkisson C, Greenfield T. The UCSF Client Satisfaction Scales: I. The Client Satisfaction Questionnaire–8. In: The use of psychological testing for treatment planning and outcomes assessment: Volume 3: Instruments for adults. Oxfordshire, UK: Routledge; 2004:461-464.

37. Yin Z, Lesser J, Paiva KA, Zapata J, Moreno-Vasquez A, Grigsby TJ, et al. Using Mobile Health Tools to Engage Rural Underserved Individuals in a Diabetes Education Program in South Texas: Feasibility Study. JMIR Mhealth Uhealth 2020 Mar 24;8(3):e16683 [FREE Full text] [doi: 10.2196/16683] [Medline: 32207694]

38. Karnoe A, Furstrand D, Christensen KB, Norgaard O, Kayser L. Assessing Competencies Needed to Engage With Digital Health Services: Development of the eHealth Literacy Assessment Toolkit. J Med Internet Res 2018 May 10;20(5):e178 [FREE Full text] [doi: 10.2196/jmir.8347] [Medline: 29748163]

39. Dunbar-Jacob J, Burke L, Schlenk E, Sereika S. The Perceived Therapeutic Efficacy Scale. In: Proceedings of the 17th international nursing research congress focusing on evidence-based practice. 2006 Presented at: The 17th international nursing research congress focusing on evidence-based practice; Jul 19-22, 2006; Montreal, QC.

40. Young L, Barnason S. Review Strategies to Recruit and Retain Rural Patient Participating Self-management Behavioral Trials. Online J Rural Res Policy 2015 Oct 22;10(2):1-12 [FREE Full text] [doi: 10.4148/1936-0487.1070] [Medline: 28580049]

41. Wang J, Cai C, Padhye N, Orlander P, Zare M. A Behavioral Lifestyle Intervention Enhanced With Multiple-Behavior Self-Monitoring Using Mobile and Connected Tools for Underserved Individuals With Type 2 Diabetes and Comorbid Overweight or Obesity: Pilot Comparative Effectiveness Trial. JMIR Mhealth Uhealth 2018 Apr 10;6(4):e92 [FREE Full text] [doi: 10.2196/mhealth.4478] [Medline: 29636320]

42. Alvarado MM, Kum H, Gonzalez Coronado K, Foster MJ, Ortega P, Lawley MA. Barriers to Remote Health Interventions for Type 2 Diabetes: A Systematic Review and Proposed Classification Scheme. J Med Internet Res 2017 Feb 13;19(2):e28 [FREE Full text] [doi: 10.2196/jmir.6382] [Medline: 28193598]

43. Mayberry LS, Lyles CR, Oldenburg B, Osborn CY, Parks M, Peek ME. mHealth Interventions for Disadvantaged and Vulnerable People with Type 2 Diabetes. Curr Diab Rep 2019 Nov 25;19(12):148 [FREE Full text] [doi: 10.1007/s11892-019-1280-9] [Medline: 31768662]

44. Jain SR, Sui Y, Ng CH, Chen ZX, Goh LH, Shorey S. Patients' and healthcare professionals' perspectives towards technology-assisted diabetes self-management education. A qualitative systematic review. PLoS One 2020;15(8):e0237647 [FREE Full text] [doi: 10.1371/journal.pone.0237647] [Medline: 32804989]

45. Feroz A, Jabeen R, Saleem S. Using mobile phones to improve community health workers performance in low-and-middle-income countries. BMC Public Health 2020 Jan 13;20(1):49 [FREE Full text] [doi: 10.1186/s12889-020-8173-3] [Medline: 31931773]

46. Akram A, Dunleavy G, Soljak M, Car J. Beyond Health Apps, Utilize Patient-Generated Data. In: Damaševičius R, Mikašytė V, editors. Information and Software Technologies. Cham, Switzerland: Springer; 2017.

47. Whidden C, Kayentao K, Liu JX, Lee S, Keita Y, Diakité D, et al. Improving Community Health Worker performance by using a personalised feedback dashboard for supervision: a randomised controlled trial. J Glob Health 2018 Dec;8(2):020418 [FREE Full text] [doi: 10.7189/jogh.08.020418] [Medline: 30333922]

48. Covid-19 - Cases. Texas Department of State Health Services. URL: https://www.arcgis.com/apps/dashboards/45e18cba105c478697c76acbbf86a6bc [accessed 2022-05-09]

49. Banerjee M, Chakraborty S, Pal R. Diabetes self-management amid COVID-19 pandemic. Diabetes Metab Syndr 2020 Jul;14(4):351-354 [FREE Full text] [doi: 10.1016/j.dsx.2020.04.013] [Medline: 32311652]

50. Young L, Montgomery M, Barnason S, Schmidt C, Do V. A Conceptual Framework for Barriers to the Recruitment and Retention of Rural CVD Participants in Behavior Intervention Trials. GSTF J Nurs Health Care 2015 Aug 31;2(2):19-24 [FREE Full text] [doi: 10.5176/2010-4804_2.2.71] [Medline: 28580381]

Abbreviations

CSQ-8: Customer Satisfaction Questionnaire short version
DSMES: Diabetes self-management education and support
HbA$_{1c}$: Hemoglobin A$_{1c}$
mHealth: Mobile Health
PTES: Perceived Therapeutic Efficacy Scale
SCT: social cognitive theory

XSL·FO
RenderX

Original Paper

Technological Proficiencies, Engagement, and Practical Considerations for mHealth Programs at an Urban Safety-Net Hospital Emergency Departments: Data Analysis

Sean Treacy-Abarca[1], MPH, MD; Janisse Mercado[2], BSc; Jorge Serrano[2], BSc; Jennifer Gonzalez[3], BSc; Michael Menchine[4,5], MD; Sanjay Arora[4,5], MD; Shinyi Wu[6,7], PhD; Elizabeth Burner[5,8], MPH, MSc, MD

[1]David Geffen School of Medicine, University of California Los Angeles, Los Angeles, CA, United States

[2]Keck School of Medicine, University of Southern California, Los Angeles, CA, United States

[3]University of Southern California, Los Angeles, CA, United States

[4]Schaeffer Center for Health Policy and Economics, University of Southern California, Los Angeles, CA, United States

[5]Department of Emergency Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA, United States

[6]Suzanne Dworak-Peck School of Social Work, University of Southern California, Los Angeles, CA, United States

[7]Viterbi School of Engineering, University of Southern California, Los Angeles, CA, United States

[8]Department of Preventative Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA, United States

Corresponding Author:
Sean Treacy-Abarca, MPH, MD
David Geffen School of Medicine
University of California Los Angeles
10833 Le Conte Ave
Los Angeles, CA, 90095
United States
Phone: 1 3108256373
Email: sean.e.treacy@gmail.com

Abstract

Background: Safety-net emergency departments often serve as the primary entry point for medical care for low income predominantly minority patient populations. Herein, we sought to provide insight into the feasibility, technological proficiencies, engagement characteristics, and practical considerations for a mHealth intervention at a safety-net emergency department.

Objective: We aimed to analyze patient technological proficiency to understand the feasibility of and draw practical considerations for mobile phone technology (mHealth) solutions for patients with chronic disease served by safety-net emergency departments.

Methods: We analyzed data from a previous diabetes randomized clinical mHealth trial for a diabetes social support intervention. Patients from a safety-net emergency department with preexisting diabetes who used SMS text messages, owned a mobile phone, and with hemoglobin A_{1c} levels >8.5% were enrolled. A text message–based mHealth program to improve disease self-management was provided to all patients. Supporters of patients were randomized to receive a mailed copy or mHealth-based curriculum designed to improve diabetes support. Among enrolled patients, we surveyed mobile technological capacity and frequency of use. We performed latent class analysis to identify classes of patients by level of technological proficiency and compared demographic characteristics between the latent classes to identify demographic subgroups that may require more training or tailoring of the mHealth approach. Study engagement between classes was assessed by comparing the mean number of text messages exchanged, loss to follow-up, and early termination.

Results: Of 1876 patients who were approached, 44.2% (n=829) of patients had a stable mobile phone and were able to use text messages. Among them 166 met the trial inclusion and enrolled, 90% (149/166) of the cohort were ethnically diverse. Significant variance was found in technology capacity and frequency of use. Our latent class analysis classified 75% (124/166) of patients as highly technologically proficient and 25% (42/166) patients as minimally technologically proficient. Age (*P*<.001) and level of education (*P*<.001) were associated with class membership. Highly technologically proficient patients were younger and had higher levels of education (45.74 years old; high school or more: 90%) than minimally technologically proficient patients (53.64 years old; high school or more: 18%). Highly technologically proficient participants exchanged a mean of 40 text messages with the system coordinators compared to a mean of 10 text messages by minimally technologically proficient patients (*P*<.001).

Conclusions: This study found that nearly half of the patients screened at the safety-net emergency department were equipped for an SMS text message–based mHealth intervention. In the small sample of patients who were enrolled, the majority were classified as highly technologically proficient. These highly proficient patients had greater study engagement. mHealth use in emergency departments may be an opportunity to improve health of ethnically diverse populations by pairing sophisticated chronic disease self-management program with SMS text message–based and traditional in-person interventions to reach patients through the method that is most familiar and comfortable.

Introduction

Over the past two decades, mobile phone technology interventions for health (mHealth) have expanded rapidly into most specialties, settings, and patient populations [1,2]. mHealth interventions have been used to improve self-management for a spectrum of chronic diseases, including hypertension, diabetes, and colon cancer. mHealth interventions have recently and successfully used reminders, feedback, and planning prompts to improve health care utilization and improve self-care of chronic illness [3-6]. The strength of mHealth interventions lies in their low financial costs and minimal requirements for additional human capital or new infrastructure [7]. However, the adoption of mHealth interventions has lagged in vulnerable populations such as low-income groups, racial and ethnic minorities, and underinsured or uninsured populations [1,8].

Descriptions of mHealth implementations for vulnerable populations in the United States are limited. Despite limited adoption of mHealth interventions in low-income Latino populations, preliminary studies highlight the missed opportunity to improve chronic disease self-management [9-11]. In these populations, mHealth has improved medication adherence, diabetes control, and health care utilization patterns and has reduced health care costs [12]. These benefits are evident regardless of a patient's baseline health literacy [7,13]. mHealth interventions have been shown to improve the care of minority and underserved Latino and African American patient populations [8]. The appropriate setting and the fundamental characteristics of mHealth implementation in Latino communities have not been fully explored as most interventions have been deployed in specialty clinics or with patients with existing access to primary care.

Safety-net health systems, which are charged with providing preventative and advance health services to those with limited ability to pay, have been considered for mHealth solutions, but a fundamental understanding of appropriate communication modalities is needed, which has hindered mHealth updates in this venue. Approaches to ensuring appropriate mHealth solutions deployed in safety-net health systems include the use of small focus groups [14]. Safety-net health system outpatient community care clinics with younger and more adequately insured patients with higher levels of socioeconomic standing are well equipped for mHealth solutions [15]. Although nearly 16,270 papers have been published in the mHealth arena, only 16 papers contributed knowledge on behalf of historically

underserved and minority populations [16]. Understudied minority patient populations have potential for mHealth success—successful mHealth strategies have been conducted in African American and Korean populations—including the delivery of HIV prevention strategies to black youth, mobile phone–based counseling among pregnant teen mothers, cervical cancer screening among Korean American women [17-19]. However, the limits of mHealth solutions in more clinical situations must be explored—most notably, in safety-net emergency departments primarily serving minority and medically underserved patients.

Emergency departments are underutilized settings for mHealth solutions despite their increasing role in chronic disease management. The role of emergency departments in acute and chronic care for low-income minority patients continues to evolve under the Affordable Care Act [14,15]. This group disproportionately uses safety-net emergency departments as a primary entry point to the medical system [16-18]. The Agency for Health care Research and Quality estimates that safety-net hospitals account for roughly 25% of all hospitals yet over 33% of all in-patient stays in the United States [19]. This intersection between low-income minority patient populations and their entry to medical care makes emergency departments a promising location for mHealth intervention strategies for chronic diseases. Additionally, mHealth solutions can provide asynchronous patient education and care, which is well suited for emergency departments given that providers may not have sufficient time to engage patients in lasting behavior change in the pressured environment of the emergency department.

Safety-net emergency departments may be an excellent setting for mHealth interventions, but information on large-scale feasibility and implementation for heterogenous patient populations is limited in the current literature. While mHealth implementation among minority and historically underserved patient populations has been documented, we do not have a full understanding of fundamental tenants of mHealth implementation for the diverse patients presenting to safety-net emergency departments in the United States. In the few reported studies, emergency department–based mHealth interventions have decreased overall emergency department utilization [20], improved patient knowledge on safe opioid use [15], and have been feasible in management of alcohol use disorder [11]. Additionally, complex determinants of health, such as social support, can improve with the use of an mHealth platform by patients in the emergency department [21]. Despite these initial

positive results, we do not know how technological proficiencies may affect engagement with mHealth solutions in populations using safety-net emergency departments or if patients with chronic diseases who use safety-net emergency departments are ready to engage with mHealth. mHealth trials conducted within minority, low socioeconomic status, and underserved populations have traditionally successfully recruited 13% to 40% of approached patients [22]. We have limited insight into the feasibility of mHealth utilization in busy safety-net emergency departments or into which approaches can be used to improve enrollment and the use of mHealth. National estimates do not accurately reflect the mobile technology use of underserved patients who present to these emergency departments [22]. Additionally, patients who visit emergency departments have less technology proficiency, such as lower app utilization rate compared to national estimates [23]. The modalities used by current mHealth solutions may not be congruent with the technological capacities of the understudied safety-net emergency department population.

Herein, we examine the feasibility of deploying mHealth solutions at a busy safety-net emergency department and describe the technological proficiency of a diverse cohort of patients with diabetes presenting to a safety-net emergency department by using data from a pragmatic mHealth randomized clinical trial on a text message–based social support intervention. We asked (1) are diverse safety-net emergency department patients equipped for mHealth interventions, (2) does diversity of patient demographics determine technological proficiency, and (3) is technological proficiency associated with mHealth engagement?

Methods

Ethics Approval

The study was approved by the Health Sciences Campus of University of Southern California Institutional Review Board (approval number HS-17-00406).

Study Population and Design

We used data from the TExT-MED+FANS mHealth randomized clinical trial [10]. The 6-month randomized clinical trial was conducted to understand the role of social support in improving chronic disease self-management by using an SMS text message–based bidirectional mHealth platform in the patient's choice of language (English or Spanish). All patients enrolled in the study were given access to the mHealth program [24] and asked to identify a supporter upon enrollment. A supporter was broadly defined as a patient's acquaintance, family, or spouse who shares the common goal of improving the well-being of the patient. Supporters of these patients were randomized to a mHealth intervention designed to improve diabetes specific support or to receive identical information provided as printed material in a pamphlet control. Patients were recruited from the Los Angeles County–University of South California Medical Center safety-net emergency department, which serves predominantly an ethnic minority (Latino ethnicity) patient population, with 132 beds and over 150,000 annual visits [23], was conducted from July 2017 to October 2018.

Study Procedures

Trained research assistants screened patients via a real-time emergency department electronic tracking board and health records for diabetes. Patients were ineligible to participate if they had hemoglobin A_{1c} levels less than 8.5%, could not identify a supporter, or denied having diabetes. Technology inclusion criteria were met if participants could send and receive text messages and had access to a mobile phone for more than 30 days.

Patients' self-reports of technological proficiency were collected at study enrollment, upon initial presentation to the emergency department. Information was collected via the Mobile Usage Survey derived from the Pew National Survey of Latinos to understand the capacity and frequency of respective technology use habits [2]. Demographic information included age, race, ethnicity, gender, primary language, English proficiency, and country of birth. Technological proficiency characteristics included access the internet and the ability and frequency to send or receive SMS text messages, send and receive instant messages, send and receive emails, and to use mobile phone apps. mHealth platform engagement metrics were assessed using data furnished by the third-party provider of the mHealth platform (Agile Health). Engagement metrics included the mean number of SMS text messages exchanged with the mHealth platform, study dropout rate, and requests for program termination.

Statistical Analysis

We used Stata (version 16; StataCorp LLC) for data analysis. Statistical differences were ascertained using chi-square tests. P values<.05 were statistically significant. Using data from the technological proficiency survey, we stratified study participants into an undefined number of underlying subgroups using latent class analysis. Prior studies [25] have employed latent class analysis to better understand subgroups of patients such as high utilizers of safety-net hospitals. Latent class analysis is a person-centered, finite mixture model technique which sorts survey participants into latent classes using observable variables, using probabilistic distribution functions with the goal of establishing the most parsimonious and interpretable set of classes [26]. We used M-plus (version 1.6; Muthén & Muthén) to fit a latent class model. We evaluated an increasing number of classes starting at a 1-class solution, using the following manifest variables: ability to send and receive SMS text messages, send and receive emails, access the internet, send and receive instant messages, or ability to use apps. Class size was increased by 1 in each sequential analysis and measures of fit (Akaike information criterion, Bayesian information criterion, and entropy) were examined at each step. Analysis continued sequentially until at least 2 sequential models showed a poorer fit than the best prior model. The 2-class model was found to have the highest entropy and lowest Akaike information criterion and Bayesian information criterion–penalized likelihood criteria.

The manifest variables defining technological proficiency were examined to describe the 2 classes—highly technologically proficient or minimally technologically proficient. Demographic differences between the 2 classes were assessed using independent 2-tailed t test and chi-square test P values.

Information derived from the technology survey and latent class analysis was used to understand if baseline technological proficiency characteristics were associated with study engagement. *Texts exchanged* with study coordinators were compared using the 2-sample *t* test. Additionally, we assessed differences in study dropout rate as well as SMS text message termination requests between the classes of participants using nonparametric tests.

Results

Feasibility of Screening and Recruitment

In total, 3835 emergency department patients were screened: 1959 patients were not approached due to a variety of factors including the patient's severity of illness, the patient was not alert or oriented, the patient declined to hear about the study, or the patient was discharged before research staff could approach them (Figure 1). Of the 1876 patients approached, we successfully identified 44.2% (n=829) of patients as owning a mobile phone and capable of sending and receiving text messages. This shows the safety-net emergency department

patients, who are primarily of Latino ethnicity, are equipped for mHealth interventions.

An additional 670 patients were ineligible because hemoglobin A_{1c} levels were <8.5% (n=394), no supporter was identified (n=122), they denied having diabetes (n=65), or they declined to participate (n=25). Moreover, 7 patients did not complete enrollment on mHealth platform. Thus, 166 patients were fully enrolled into the study, and all received access to the mHealth platform.

Of 166 enrolled patients, 82 (49.4%) were male, and 84 (50.6%) were female; none selected nonbinary. Most patients identified as racial and ethnic minorities (Table 1). The majority of participants were foreign born Mexico: 131 (78.7%) patients were born in Mexico or Central America, and 116 (69.9%) patients preferred Spanish. All patients owned mobile phones, and 5% (8166) reported sharing their phone with another family member. Patients had a variety of mobile phone service plans: 33.7% of patients (56/166) reported having a contract-based mobile phone, 53% of patients (88/166) paid per month, and 13% of patients (22/166) had some other type of payment arrangement.

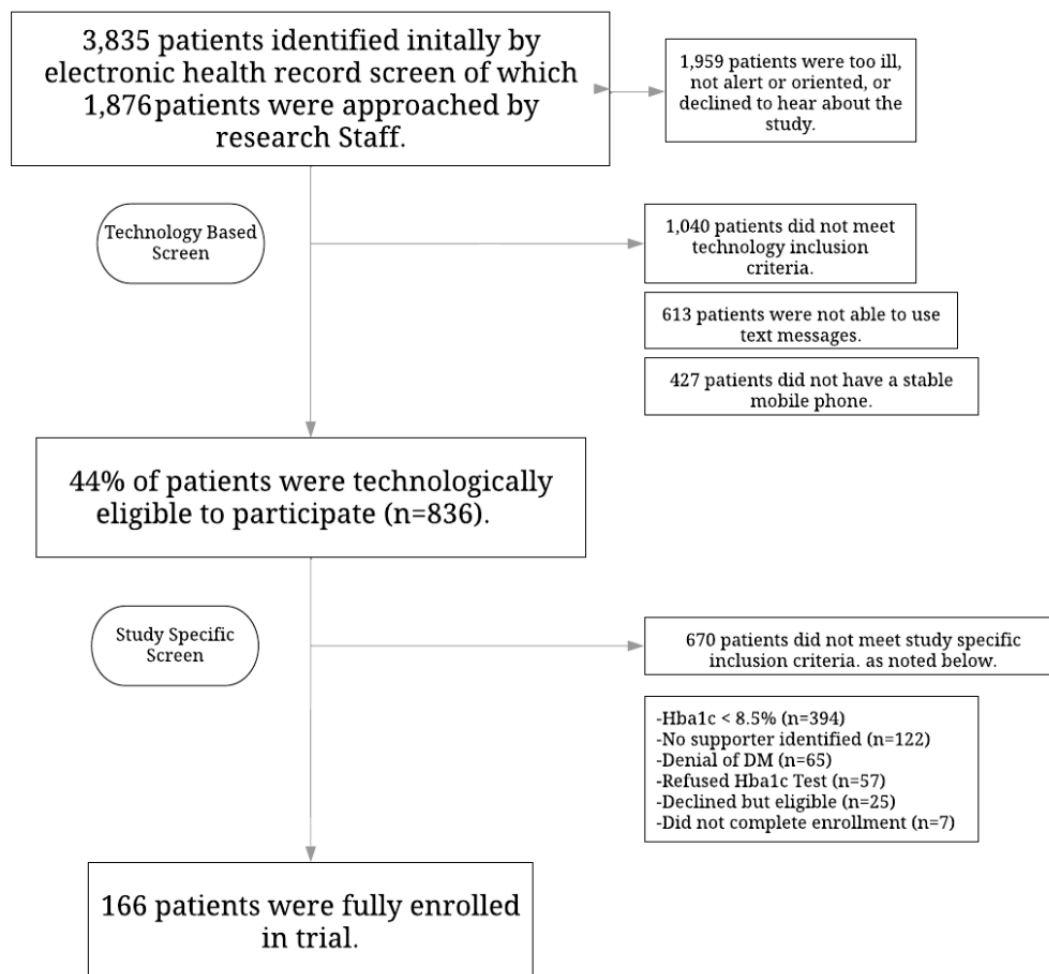**Figure 1.** Recruitment diagram. DM: diabetes; HbA_{1c}: hemoglobin A_{1c}.

Table 1. Participant demographic data.

Characteristic	Value (n=166), n (%)
Gender	
Male	82 (49.4)
Female	84 (50.6)
Nonbinary	0 (0)
Ethnicity	
Hispanic or Latino	156 (94.0)
Not Hispanic or Latino	9 (5.4)
Unknown or not reported	1 (0.6)
Race	
American Indian/Alaskan Native	5 (3.0)
Asian	2 (1.2)
Black or African American	9 (5.4)
White	74 (44.8)
Mixed	3 (1.8)
Unknown or not reported	72 (43.6)
Country of birth	
Mexico	100 (61.0)
United States	35 (21.3)
El Salvador	11(6.7)
Other	18 (11.0)
Language preference	
English	50 (30.1)
Spanish	116 (69.9)
Level of education	
No formal education	4 (2.4)
Grammar	53 (32.1)
High school	77 (46.7)
College or vocational	29 (17.6)
Professional	2 (1.2)

Latent Class Analysis of Study Participants' Technology Use

In the latent class analysis, a 2-class model best identified underlying classes with 75% (124/166) of patients classified as highly technologically proficient and 25% (42/166) of patients as minimally technologically proficient. The 2 classes differed in technology capacity and frequency of technology use (Figure 2), except for SMS text message capability. All highly technologically proficient patients and 95% of the minimally technologically proficient patients used SMS text messages. Compared with minimally technologically proficient patients, highly technologically proficient patients were more likely to use email (65% vs 12%, *P*<.001), use instant messages (93% vs 12%, *P*<.001), use apps (92% vs 2%, *P*<.001), and access the internet (94% vs 24%, *P*<.001). Similarly, highly

technologically proficient patients more frequently reported daily use of SMS text messaging (87% vs 55%, *P*<.001), email (46% vs 5%, *P*<.001), instant messages (73% vs 5%, *P*<.001), app use (81% vs none, *P*<.001), and internet use (78% vs 10%, *P*<.001).

We also compared latent class differences in demographic characteristics of race, ethnicity, age, language proficiency, and country of birth between classes. No differences between patient classes were found for gender (*P*=.17), race (*P*=.62), ethnicity (*P*=.82), country of birth (*P*=.50), or language preference (*P*=.07) (Table 2). However, there were differences between the 2 patient classes in level of education (*P*<.001) and mean age (*P*<.001) (Table 2). Highly technologically proficient patients' mean age was 45.74 years compared to 52.73 years for minimally technologically proficient patients (*P*<.001). Lastly, highly technologically proficient patients had statistically

significant (P=.05) greater engagement with the mHealth platform, exchanging an average of 40.94 exchanged SMS text messages through the 6-month study duration compared to 10.79 SMS text messages for minimally technologically proficient patients (Table 2). No statistical differences (P=.85) in study loss to follow-up or request for SMS text message curriculum termination were noted between the 2 patient classes.

Figure 2. Baseline (a) technological capacity and (b) frequency of use of mobile phone by patient class.
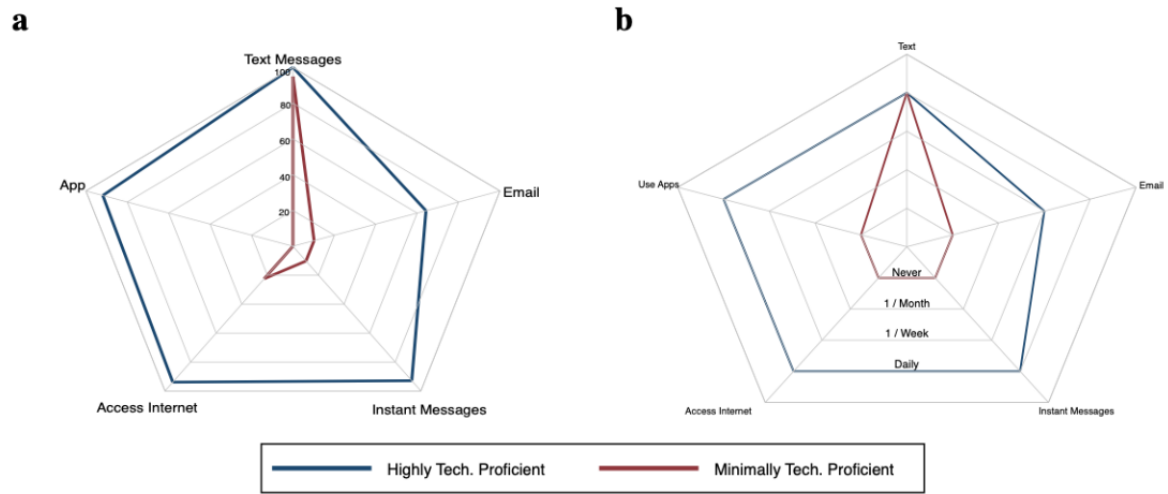
Table 2. Demographic and study participation measures by patient class.

Demographic measures	Highly proficient (n=124)	Minimally proficient (n=42)	P value
Gender, n			.17
Female	59	25	
Male	65	17	
Age (years)	45.74	52.73	<.001
Ethnicity, n			.82
Hispanic or Latino	116	40	
Not Hispanic or Latino	7	2	
Unknown	1	0	
Race, n			.62
American Indian/Alaska Native	3	1	
Asian	2	0	
Black or African American	6	3	
White	58	16	
Mixed	3	0	
Unknown or not reported	52	22	
Country of birth, n			.50
United States	28	7	
Mexico	74	28	
El Salvador	7	4	
Other	15	3	
Language preference, n			.07
English	42	8	
Spanish	82	34	
Other	0	0	
Education level, n			<.001
No formal education	3	1	
Grammar	29	23	
High school	62	17	
College or vocational	28	1	
Professional school	2	0	
Engagement measures			
Text messages, mean	40.94	10.79	.05
6-month loss to follow-up, %	41.46	39.53	.82
Early text message termination, %	7.32	2.33	.24

Discussion

Principal Findings

Most emergency department patients with diabetes who could engage in mHealth were highly technologically proficient. We found that age and level of education differed between highly and minimally technologically proficient counterparts but that other demographic characteristics did not differ between classes. We provide practical suggestions for designers planning to expand mHealth use among the diverse patient populations served at safety-net emergency departments (Table 3).

Safety-net emergency departments are feasible clinical settings for mHealth solutions for underserved patient populations, with a good portion of patients having sufficient capacity to engage: 44.2% of patients (829/1876) that we approached in the emergency department fulfilled basic technology-based eligibility criteria. A cohort of users was recruited and enrolled despite the acuity and fast paced environment of the emergency

department. Our success here is consistent with those of other mHealth solutions provided to minority, low income, and underserved patient populations from other clinical settings, which have reported eligibility success between 13% to 41% [22,23,27]. A particular strength of our study is the racial and ethnic diversity of our cohort with respect to the general population that have been traditionally studied for mHealth interventions. We found that only age and education influenced technological capacity, in line with the findings of a previous study [8] that both age and indicators of socioeconomic status,

such as education, were associated with improved mHealth solution uptake. Gender, ethnicity, race, country of birth, and language were not determinants of highly technologically proficient status. Future researchers on mHealth solutions at safety-net emergency departments should take into consideration both patient age and education when designing mHealth interventions, but a diverse patient cohort is not an impediment toward successful mHealth solutions at safety-net emergency departments.

Table 3. Findings and practical considerations for mHealth interventions for chronic diseases in safety-net emergency departments.

Finding	Implication
Safety-net emergency departments allow for recruitment of diverse patient cohorts	Recruitment for mHealth intervention trials is feasible among across culturally, linguistically, racially or ethnically, and geographically diverse populations.
Optimal mHealth technological modalities exist in safety-net emergency department patients	Future designs should consider text message–based interventions as a primary modality, as well as instant message–based modalities, and app-based modalities.
Less optimal mHealth technological modalities exist in this diverse study cohort	Email-based mHealth interventions are particularly poorly suited as email was used the least by either patient classification, and serial surveys of technological proficiency should be conducted as capacities evolve and new technology becomes available.
Most demographic characteristics are not associated with to highly technologically proficient classification	In our study population, gender, ethnicity, race, country of birth, or language preference were not associated with classification as highly technologically proficient and should not be used for mHealth intervention eligibility.
Age and level of education are associated with highly technologically proficient classification	Additional research is needed to understand to how to harness this finding for improvement in clinical outcomes, and differential design of studies.
Highly technologically proficient patients had greater mHealth engagement	Future studies should be conducted to improve engagement among minimally technologically proficient patients and to understand the costs and benefits of targeted training for patients to improve engagement.

While safety-net emergency departments are feasible settings for mHealth, we must carefully consider which technological modalities to deploy. Text messages, web-based, instant message–based, and apps may be well suited modalities for safety-net hospital systems if age and educational considerations are built into the design of the interventions. Interestingly, email-based capacity for use and frequency of use were low for both classes. The finding of limited email use is a departure from mHealth solutions conducted at clinical settings that are not safety-net hospitals [3]. Visits to safety-net emergency departments by minority and historically underserved patient populations can be capitalized on by expanding mHealth solutions as emergency departments serve as primary entry points to primary care and specialty care [18]. Such expansion can be aided by considering suitable technological modalities, technological capacity within this population, drivers of technological capacity, and effect on engagement with mHealth solutions. We found that highly technologically proficient patients had better engagement with the mHealth platform, understanding how to increase engagement in low-resource settings may be critical to successful interventions [28].

As the field of mHealth expands into resource-limited settings and participants, our study presents unique insights into patients that could be targeted for optimization of mHealth solutions and increasing patient engagement. The minimally technologically proficient cohort lacked robust use of most technological modalities beyond text messages. The communication modality selected for mHealth interventions in

safety-net emergency departments may need to be congruent with patients' technological capacity to be most effective. Minimally technologically proficient patients at safety-net emergency departments may be candidates for future mHealth interventions, which can be optimized by selecting appropriate technological modalities: SMS text messages, instant messages, and, to a lesser extent, app-based modalities. Training strategies for minimally technologically proficient patients may help increase engagement and should be studied further. The inability to use text messages was the most common of the technological ineligibility criteria. This presents an opportunity to examine the role of basic mobile training or subsidized cellular connectivity to increase intervention effectiveness in this patient population. Technological proficiencies have improved over the course of successive Pew National Survey of Latinos Mobile Usage Surveys [2], as well in surveys at our own institution [22]. Institutional stakeholders interested in mHealth interventions for patient populations at safety-net emergency departments should periodically survey patients technological capacities to determine which technological modality to use.

Future emergency department–based mHealth interventions should embrace the diversity encountered at safety-net emergency departments as most demographic characteristics among our participants were not associated with classification as highly technologically proficient. Moreover, recruiting diverse patient populations to clinical trials can highlight nuances in intervention effectiveness in racial and ethnic subgroups [29,30]. We were able to capture different

characteristics (race and ethnicity, country of birth, and primary languages spoken) than those of the national population. Resource-limited emergency departments serving minority and historically underserved patient populations should be considered uniquely suited for mHealth interventions. These emergency department patients can improve the design of mHealth trials by increasing ethnic and socioeconomic diversity among participants. We encourage other mHealth researchers to consider safety-net emergency departments as viable clinical settings to recruit a patient cohort with different demographic characteristics.

Limitations

There are limitations to our analysis. The study was conducted at a single medical center. Multicenter studies are needed to understand the full scope of technological proficiencies nationally. However, this institution allowed us to focus on an understudied patient cohort recruited directly from a busy urban safety-net emergency department. Our cohort also had an overrepresentation of patients of Hispanic and Latino ethnicity. Future studies should include centers with more diverse representation. We only collected detailed demographic and mobile phone use information from patients enrolled in the mHealth intervention; therefore, we were unable to analyze all screened patients in the technology proficiency latent class analysis. Additionally, technological proficiency was self-reported introducing potential information bias, but it allowed us to examine what patients believed they were capable of, which may be a better indicator of modalities they will adopt. We did not offer mobile technology training to patients, which may have impacted engagement metrics. Future studies are needed to examine the costs and benefits of training patients in unfamiliar modalities.

Conclusions

Emergency department–based mHealth interventions should allow institutional stakeholders to take advantage of costly unscheduled emergency care to engage patients in chronic disease management. Safety-net emergency departments are feasible for mHealth interventions; in our study, nearly one-fifth of emergency department patients with diabetes were equipped with the technological ability and access to participate in SMS text message–based interventions. Future intervention developers should consider the age and level of education of participants as they may be associated with variations in mHealth engagement, as found in our latent class analysis.

Conflicts of Interest

The intellectual property rights to the original TExT-MED program were licensed from the University of Southern California by Agile Health. SA and MM consult for Agile Health. Agile Health did not participate in study design, data analysis, or manuscript preparation.

References

1. Stockman M, Modzelewski K, Steenkamp D. Mobile health and technology usage by patients in the diabetes, nutrition, and weight management clinic at an urban academic medical center. Diabetes Technol Ther 2019 Jul;21(7):400-405. [doi: 10.1089/dia.2018.0369] [Medline: 31045447]
2. Mobile fact sheet. Pew Research Center. 2021 Jun 03. URL: https://www.pewresearch.org/internet/fact-sheet/mobile/ [accessed 2021-06-03]
3. Sarfati D, McLeod M, Stanley J, Signal V, Stairmand J, Krebs J, et al. BetaMe: impact of a comprehensive digital health programme on HbA1c and weight at 12 months for people with diabetes and pre-diabetes: study protocol for a randomised controlled trial. Trials 2018 Mar 05;19(1):161 [FREE Full text] [doi: 10.1186/s13063-018-2528-4] [Medline: 29506562]
4. Nepper MJ, McAtee JR, Wheeler L, Chai W. Mobile phone text message intervention on diabetes self-care activities, cardiovascular disease risk awareness, and food choices among type 2 diabetes patients. Nutrients 2019 Jun 11;11(6):1314-1319 [FREE Full text] [doi: 10.3390/nu11061314] [Medline: 31212683]
5. Huo X, Krumholz HM, Bai X, Spatz ES, Ding Q, Horak P, et al. Effects of mobile text messaging on glycemic control in patients with coronary heart disease and diabetes mellitus: a randomized clinical trial. Circ Cardiovasc Qual Outcomes 2019 Sep;12(9):e005805. [doi: 10.1161/CIRCOUTCOMES.119.005805] [Medline: 31474119]
6. Fortmann AL, Savin KL, Clark TL, Philis-Tsimikas A, Gallo LC. Innovative diabetes interventions in the U.S. Hispanic population. Diabetes Spectr 2019 Nov;32(4):295-301 [FREE Full text] [doi: 10.2337/ds19-0006] [Medline: 31798285]
7. Schweitzer J, Synowiec C. The economics of eHealth and mHealth. J Health Commun 2012 May 02;17 Suppl 1(sup1):73-81 [FREE Full text] [doi: 10.1080/10810730.2011.649158] [Medline: 22548602]
8. Mayberry LS, Lyles CR, Oldenburg B, Osborn CY, Parks M, Peek ME. mHealth interventions for disadvantaged and vulnerable people with type 2 diabetes. Curr Diab Rep 2019 Nov 25;19(12):148-147 [FREE Full text] [doi: 10.1007/s11892-019-1280-9] [Medline: 31768662]

9. Burner E, Terp S, Lam CN, Neill E, Menchine M, Arora S. Access to care, nativity and disease management among Latinos with diabetes in a safety-net healthcare setting. AIMS Public Health 2019;6(4):488-501 [FREE Full text] [doi: 10.3934/publichealth.2019.4.488] [Medline: 31909069]

10. Burner E, Mercado J, Hernandez-Saenz A, Peters A, Mack W, Baezconde-Garbanati L, et al. Design and patient characteristics of the randomized controlled trial TExT-MED + FANS A test of mHealth augmented social support added to a patient-focused text-messaging intervention for emergency department patients with poorly controlled diabetes. Contemp Clin Trials 2019 May;80:1-8 [FREE Full text] [doi: 10.1016/j.cct.2019.03.003] [Medline: 30878623]

11. Burner E, Zhang M, Terp S, Ford Bench K, Lee J, Lam CN, et al. Feasibility and acceptability of a text message-based intervention to reduce overuse of alcohol in emergency department patients: controlled proof-of-concept trial. JMIR Mhealth Uhealth 2020 Jun 04;8(6):e17557 [FREE Full text] [doi: 10.2196/17557] [Medline: 32496203]

12. Mayberry LS, Mulvaney SA, Johnson KB, Osborn CY. The messaging for diabetes intervention reduced barriers to medication adherence among low-income, diverse adults with type 2. J Diabetes Sci Technol 2017 Jan;11(1):92-99 [FREE Full text] [doi: 10.1177/1932296816668374] [Medline: 27595710]

13. Bergner EM, Nelson LA, Rothman RL, Mayberry L. Text messaging may engage and benefit adults with type 2 diabetes regardless of health literacy status. Health Lit Res Pract 2017 Oct;1(4):e192-e202 [FREE Full text] [doi: 10.3928/24748307-20170906-01] [Medline: 29214241]

14. Nikpay S, Freedman S, Levy H, Buchmueller T. Effect of the Affordable Care Act Medicaid expansion on emergency department visits: evidence from state-level emergency department databases. Ann Emerg Med 2017 Aug;70(2):215-225.e6. [doi: 10.1016/j.annemergmed.2017.03.023] [Medline: 28641909]

15. McCarthy DM, Curtis LM, Courtney DM, Cameron KA, Lank PM, Kim HS, et al. A multifaceted intervention to improve patient knowledge and safe use of opioids: results of the ED EMC randomized controlled trial. Acad Emerg Med 2019 Dec;26(12):1311-1325 [FREE Full text] [doi: 10.1111/acem.13860] [Medline: 31742823]

16. Menchine MD, Vishwanath A, Arora S. Prevalence, health and demographics of emergency department patients with diabetes. West J Emerg Med 2010 Dec;11(5):419-422 [FREE Full text] [Medline: 21293757]

17. Arora S, Marzec K, Gates C, Menchine M. Diabetes knowledge in predominantly Latino patients and family caregivers in an urban emergency department. Ethn Dis 2011;21(1):1-6. [Medline: 21462722]

18. Bazargan M, Smith J, Cobb S, Barkley L, Wisseh C, Ngula E, et al. Emergency department utilization among underserved African American older adults in south Los Angeles. Int J Environ Res Public Health 2019 Apr 02;16(7):1175 [FREE Full text] [doi: 10.3390/ijerph16071175] [Medline: 30986915]

19. Pagon Sutton J, Washington RE, Fingar KR, Elixhauser A. Characteristics of Safety-Net Hospitals. National Center for Biotechnology Information. 2014. URL: https://www.ncbi.nlm.nih.gov/books/NBK401306/ [accessed 2022-02-09]

20. Arora S, Peters AL, Burner E, Lam CN, Menchine M. Trial to examine text message-based mHealth in emergency department patients with diabetes (TExT-MED): a randomized controlled trial. Ann Emerg Med 2014 Jun;63(6):745-54.e6. [doi: 10.1016/j.annemergmed.2013.10.012] [Medline: 24225332]

21. Burner ER, Menchine MD, Kubicek K, Robles M, Arora S. Perceptions of successful cues to action and opportunities to augment behavioral triggers in diabetes self-management: qualitative analysis of a mobile intervention for low-income Latinos with diabetes. J Med Internet Res 2014;16(1):e25 [FREE Full text] [doi: 10.2196/jmir.2881] [Medline: 24476784]

22. Arora S, Ford K, Terp S, Abramson T, Ruiz R, Camilon M, et al. Describing the evolution of mobile technology usage for Latino patients and comparing findings to national mHealth estimates. J Am Med Inform Assoc 2016 Sep;23(5):979-983. [doi: 10.1093/jamia/ocv203] [Medline: 26995564]

23. VonHoltz LAH, Hypolite KA, Carr BG, Shofer FS, Winston FK, Hanson CW, et al. Use of mobile apps: a patient-centered approach. Acad Emerg Med 2015 Jun;22(6):765-768 [FREE Full text] [doi: 10.1111/acem.12675] [Medline: 25998446]

24. mHealth patient platform. Agile Health. 2021 Jan 06. URL: https://agilehealth.com/ [accessed 2020-07-28]

25. Rinehart DJ, Oronce C, Durfee MJ, Ranby KW, Batal HA, Hanratty R, et al. Identifying subgroups of adult super-utilizers in an urban safety-net system using latent class analysis: implications for clinical practice. Med Care 2018 Jan;56(1):e1-e9 [FREE Full text] [doi: 10.1097/MLR.0000000000000628] [Medline: 27632768]

26. Hand D, McLachlan G, Basford K. Mixture models: inference and applications to clustering. Applied Statistics 1989 Jan 01;38(2):384. [doi: 10.2307/2348072]

27. Formann AK, Kohlmann T. Latent class analysis in medical research. Stat Methods Med Res 1996 Jun;5(2):179-211. [doi: 10.1177/096228029600500205] [Medline: 8817797]

28. Victorson D, Banas J, Smith J, Languido L, Shen E, Gutierrez S, et al. eSalud: designing and implementing culturally competent ehealth research with latino patient populations. Am J Public Health 2014 Dec;104(12):2259-2265. [doi: 10.2105/AJPH.2014.302187] [Medline: 25320901]

29. Wright JT, Dunn JK, Cutler JA, Davis BR, Cushman WC, Ford CE, ALLHAT Collaborative Research Group. Outcomes in hypertensive black and nonblack patients treated with chlorthalidone, amlodipine, and lisinopril. JAMA 2005 Apr 06;293(13):1595-1608. [doi: 10.1001/jama.293.13.1595] [Medline: 15811979]

30. Clark LT, Watkins L, Piña IL, Elmer M, Akinboboye O, Gorham M, et al. Increasing diversity in clinical trials: overcoming critical barriers. Curr Probl Cardiol 2019 May;44(5):148-172. [doi: 10.1016/j.cpcardiol.2018.11.002] [Medline: 30545650]

Abbreviations

mHealth: mobile health

XSL•FO
RenderX

Original Paper

Informing a Randomized Control Trial in Rural Populations: Adaptation of a Diabetes Self-Management Education and Support Intervention

Tamara K Oser[1*], MD; Linda Zittleman[1*], MSPH; Kristen Curcija[1*], MPH; Bethany Kwan[1*], MSPH, PhD; Shawnecca Burke[2*], MD; Sindy Gonzalez[1*], MPH; Kelsey Huss[2*], MEd; Marilee Johnson[2*]; Norah Sanchez[2*]; Julie Neuberger[3*], BS; Eli Iacob[4*], PhD; Juliana Simonetti[3*], MD; Michelle Litchman[3,4*], PhD

[1]Department of Family Medicine, School of Medicine, University of Colorado, Aurora, CO, United States

[2]Community Advisory Council, High Plains Research Network, Aurora, CO, United States

[3]Department of Internal Medicine, University of Utah, Salt Lake City, UT, United States

[4]College of Nursing, University of Utah, Salt Lake City, UT, United States

[*]all authors contributed equally

Corresponding Author:
Tamara K Oser, MD
Department of Family Medicine
School of Medicine
University of Colorado
12631 East 17th Avenue
Box F496
Aurora, CO, 80045
United States
Phone: 1 303 724 2060
Email: TAMARA.OSER@CUANSCHUTZ.EDU

Abstract

Background: Over 34 million people in the United States have diabetes, with 1.5 million diagnosed every year. Diabetes self-management education and support (DSMES) is a crucial component of treatment to delay or prevent complications. Rural communities face many unique challenges in accessing DSMES, including geographic barriers and availability of DSMES programs that are culturally adapted to rural context.

Objective: Boot Camp Translation (BCT) is an established approach to community-based participatory research used to translate complex clinical and scientific information into concepts, messages, and materials that are understandable, meaningful, and relevant to community members and patients. This study aimed to utilize BCT to adapt an existing DSMES program for delivery in rural primary care for English- and Spanish-speaking people with diabetes.

Methods: The High Plains Research Network (HPRN) Community Advisory Council (C.A.C.) partnered with researchers at the University of Colorado and University of Utah to use BCT to aid in translating medical jargon and materials from an existing DSMES program, called "Diabetes One Day (D1D)." BCT consisted of 10 virtual meetings over a 6-month period among the C.A.C., which included 15 diverse community stakeholders. Both English-speaking and bilingual Spanish-English–speaking C.A.C. members were recruited to reflect the diversity of the rural communities in which the adapted program would be delivered.

Results: The BCT process guided adaptations to D1D for use in rural settings (R-D1D). R-D1D adaptations reflect both content and delivery to assure that the intervention is appropriate and likely to be accepted by rural English- and Spanish-speaking people with diabetes. Additionally, BCT informed the design of recruitment and program materials and identification of recruitment venues. During the BCT process, the importance of tailoring materials to reflect culture differences in English- and Spanish-speaking patients was identified.

Conclusions: BCT was an effective strategy for academic researchers to partner with rural community members to adapt an existing DSMES intervention for delivery in rural areas to both English- and Spanish-speaking patients with diabetes. Through BCT, adaptations to recruitment materials and methods, program content and delivery, and supplemental materials were developed. The need to culturally adapt Spanish materials with input from stakeholders rather than simply translate materials into Spanish

XSL•FO
RenderX

was highlighted. The importance of increasing awareness of the connection between diabetes and depression or diabetes distress, adaptations to include local foods, and the importance of the relationship between people with diabetes and their primary care practices were identified.

Introduction

Diabetes is a chronic, progressive disease affecting over 34 million people and is the 7th leading cause of the death in the United States [1]. Diabetes contributes to serious micro- and macrovascular complications leading to disability and poor quality of life [2]. Diabetes self-management is the cornerstone of avoiding or delaying diabetes complications. Self-management behaviors include a challenging daily diet, medication, exercise, and a glucose monitoring regimen. Diabetes self-management education and support (DSMES) is needed to help people with diabetes adopt self-management behaviors and is recommended by the American Association of Diabetes Educators and the American Diabetes Association as standard of care [3]. DSMES can improve outcomes in both type 1 diabetes (T1D) and type 2 diabetes (T2D), including lower glycated hemoglobin (HbA_{1C}), improved quality of life, and healthy coping [4-7]. However, disparities in access to high-quality DSMES are influenced by social determinants of health, leading to downstream health inequity in diabetes outcomes. Notably, there is a lack of culturally appropriate, local DSMES for those who live in rural areas and those who do not speak English, which contributes to higher rates of diabetes-related complications in this population relative to those who live in more urban areas [8,9].

To address the need for improved DSMES, a team led by a nurse-practitioner researcher developed the Diabetes One Day (D1D) Program, an interdisciplinary DSMES program for patients with diabetes and their care partners that enhances diabetes distress and diabetes self-care behaviors through several strategies. The in-person 1-day (8-hour) DMSES intervention provided a hybrid education program that included individual and small group sessions delivered by interdisciplinary diabetes specialists (eg, certified diabetes care and education specialist, pharmacist, licensed clinical social worker, chef). Topics included pathophysiology, medications, weight management, exercise and being active, healthy eating, troubleshooting glucose levels, diabetes technology, and coping with diabetes. Each particiant was encouraged to bring a care partner (family or friend). Sessions were interactive, allowing for peer support. Participants also received written and digital education materials. D1D has been shown to be feasible to deliver through a remote team and to significantly reduce HbA_{1C} in participants seen at an academic endocrinology center [10].

In rural eastern Colorado, rates of diabetes average 12.3% compared with the state average of 7.3% [11]. Clinicians and practice staff in the High Plains Research Network (HPRN) and the HPRN Community Advisory Council (C.A.C.) consistently identify diabetes and the lack of diabetes management support as health priorities during visits to practices and annual research convocations. The HPRN C.A.C. identified the D1D Program as a potential resource to help address disparities in diabetes prevalence and outcomes in rural eastern Colorado. However, existing DSMES programs might rely on resources that are not available in rural regions. Factors that influence program fit with rural primary care and communities include access to practice staff with the training, resources, and time to provide DSMES; patient education materials that do not reflect the social and physical environment (eg, access to sidewalks, fitness centers, a diversity of restaurants and large grocery stores); and cultural and technological infrastructure needs.Therefore, the HPRN C.A.C. and academic research team sought to review and adapt the D1D program for rural eastern Colorado. Boot Camp Translation (BCT) is an evidence-based participatory community engagement method [12] that diverse populations have used to translate scientific evidence-based guidelines into new, locally relevant messages, materials, and dissemination strategies that use local assets [13-18]. For this study, the community-academic partnership used BCT to adapt the existing D1D program delivery method and materials to help increase access to effective DSMES for English- and Spanish-speaking patients, caregivers, and primary care practices in rural eastern Colorado.

We describe the use of BCT to adapt the D1D and the resulting messages and materials that created the Rural Diabetes One Day (R-D1D) program. Results are useful to patients, clinical teams, and researchers in other rural regions lacking DSMES across the United States, as the adaptations may apply to other rural communities outside of rural Colorado, particularly in the Western region of the United States.

Methods

Context and Setting

The study was conducted in northeast Colorado, which is part of the HPRN. The HPRN is a primary care- and community-based research network in 16 counties in rural eastern Colorado. The network is housed in the University of Colorado Department of Family Medicine. Of the 16 counties in the HPRN region, 15 counties are in a geographic or income-based primary care health professional shortage area, and approximately 27% of the population is Hispanic, with 12% of the population speaking Spanish at home [19]. Only 5 diabetes care and education specialists are located in the entire 16-county region of the HPRN [20], which covers 30,000 square miles.

The Diabetes One Day DSMES Program

The D1D Program is an interdisciplinary DSMES program for patients with diabetes and their care partners. D1D was originally designed to be delivered in person over 8 hours in 1 day. Program components are outlined in Textbox 1.

Textbox 1. Adaptations to the Diabetes One Day (D1D) Program structure and content for patients seen in rural primary care practices.

Original Diabetes One Day (8 hours)

1. Diabetes Overview (60 min)

2. Medication Options (30 min)

3. Weight Management and Diabetes (20 min)

4. Importance of Exercise (20 min)

5. Healthy Eating/Carbohydrate Counting (60 min)

6. Meal Demonstration and Lunch (60 min)

7. Individual Visit With Nurse Practitioner/Medical Doctor (90 min)

8. Troubleshooting Glucose Levels (25 min)

9. Diabetes Technology (20 min)

10. Healthy Coping With Diabetes (45 min)

Rural Diabetes One Day Schedule (5.5 hours)

1. Coping With Diabetes (60 min)

2. What is Diabetes? (15 min)

3. Diabetes Complications (15 min)

4. Self-Care Behaviors (20 min)

5. Sick Day Management (10 min)

6. Troubleshooting Glucose Levels (20 min)

7. Weight and Diabetes (15 min)

8. Healthy Eating (50 min)

9. Medication Options (20 min)

10. Shared Medical Visit (60 min)

11. How to Work With the Health Care Practitioner Team (10 min)

Adaptation Using Boot Camp Translation

BCT has been used by partnerships of community members, academic researchers, and health professionals around the country on a range of health topics to translate medical information and clinical guidelines into concepts, messages, and materials that are understandable, meaningful, and engaging to community members and patients and disseminated in testable health interventions [21]. A full description of the standard BCT process has been previously reported [22]. We used the BCT process in this study to modify and adapt the existing D1D program for implementation in rural primary care practices and communities.

Community partners consisted of 15 people from diverse backgrounds. Partners included members of the HPRN C.A.C., including ranchers, a teacher, a retired social worker, an agricultural business manager, a school support staff worker, a practice administrator, and locally based HPRN community research liaison/practice facilitators. Ad hoc members were added to round out expertise and perspectives, including 4 people living with T1D or T2D. The HPRN Director, who

practices at one of the participating primary care practices, and co-Director facilitated and participated in all BCT meetings. Of the members, 5 care for someone with diabetes, and 5 were Hispanic or Latino, the latter which were all bilingual English-Spanish speaking. Participants also included 3 research partners from the University of Utah who developed the D1D program. A clinician with expertise in diabetes who identifies as Latino and is Spanish-speaking provided the educational presentation and clinical guidance throughout the process.

The BCT process occurred over a 6-month period. Due to the COVID-19 pandemic, the BCT was conducted virtually (using Zoom), and the traditional cycle of meetings and calls was slightly modified to accommodate this format. The process started with a 4-hour kick-off meeting with an expert presentation that provided information about diabetes, evidence-based guidelines for DSMES, and description of the current D1D program. Four 2-hour meetings interspersed by five 45-minute meetings were used to determine content (program messages and materials) and context (program delivery mode, structure) adaptations and to develop recruitment materials.

Ethics Approval

Required institutional review board approvals and data use agreements among participating organizations have been established. Study procedures were approved by The University of Utah Multiple Institutional Review Board on October 28, 2020 (approval #00133179).

Results

The BCT process resulted in new study recruitment materials and strategies; new and adapted messages and materials for English- and Spanish-speaking patients; and adaptations to the delivery, structure, and content of the DSMES intervention.

Recruitment Messages and Materials

The D1D Program was originally offered to patients seen at an academic endocrinology center. This study aimed to implement the program in rural primary care settings. Because many rural communities have only 1 primary care practice, the C.A.C. developed materials for distribution in the practice as well as the broader community. Materials included versatile "inserts"—large, bookmark-sized flyers placed on countertops (such as at clinic check-in areas), in exam rooms, in church bulletins, attached to pharmacy and other retail bags, among other locations. "Inserts" were modified to create 11x17 posters to be hung at various locations in practices and communities. Building on social distancing cues related to COVID-19, floor decals were created for exam rooms and other areas at practices. Recruitment materials were designed for both English- and Spanish-speaking patients. The C.A.C. recommended placing recruitment materials at multiple and diverse locations, including the grocery stores, dollar store, butcher, pharmacy, Mexican bakery, school, church, community center, and meat factory where many Spanish-speaking patients with diabetes are employed.

Recruitment materials carried attention-grabbing messages. The need to care for yourself for the sake of your family was identified as a key message for Spanish-speaking communities, resulting in the message "Porque mi familia importa!" The commonly used term "azúcar" refers to diabetes in the Spanish recruitment materials. Community partners stated that the local rural culture often includes a "take care of yourself" approach to health, and that for some conditions, such as diabetes, people believe they did something wrong and feel guilty. In response, materials for English-speaking participants promoted the message that "Eastern Colorado is worth it!" and that "People with diabetes deserve to live a healthy life." Images of the landscape and people from the local area were used to give materials an authentic rural look and potential face recognition. Multimedia Appendix 1 offers a description, distribution efforts, and image of the materials developed.

Participant Program Materials

The D1D Program offers multiple resources for participants. These include the Calorie King book, a Healthy Plate handout developed by the Centers for Disease Control and Prevention (CDC), a handout on SMART goals, copies of the presentations (eg, PowerPoint slides) given during the program, and copies of diabetes management magazines. The C.A.C. identified several adaptations to existing materials and new resources with messages they believed would improve the cultural relevance and, in turn, usefulness of the program in the study region. The adaptations are described in the following sections.

Recipe Book

Many of the foods and restaurants included in the Calorie King book are not available in eastern Colorado, and the book was not available in Spanish. The C.A.C. adapted this concept into a book with local recipes. "From Our Home to Yours" contains recipes collected from the C.A.C. and friends and a series of tips based on evidence-based guidelines and their lived experiences for participants to use while grocery shopping, preparing meals, and eating. Recipes use affordable foods easily available in eastern Colorado and that reflect the local rural and, within that, Hispanic/Latino culture. All recipes were reviewed by a certified dietician, and slight modifications were suggested to reduce carbohydrate or fat content and portion size, as needed. The book also includes a section introducing the concept of carbohydrates. The C.A.C. wrote the forward to include motivational messages reflected in recruitment materials. The book is available in English and Spanish.

Healthy Plate Place Mats

This rural region is largely ranch land, and beef is a common food and source of income for a substantial number of people in the region. Instead of promoting foods less common in the region, the C.A.C. worked with their academic partners to offer strategies for healthier consumption of beef than people often practice. The image of salmon found in the original Healthy Plate was replaced with lean beef. Healthy lifestyle recommendations and personal stories from the Recipe Book were added surrounding the Healthy Plate. The "handout" format was converted to a place mat with the intention of increasing exposure to the information. The new Healthy Plate place mat includes the plate and tips on one side and eastern Colorado images on the other.

Diabetes Distress/Mood Matters Handout and Mood Tracker

The D1D program includes a session on mental health, emphasizing realistic diabetes management goals and coping strategies. The C.A.C. determined that R-D1D needed to enhance the content related to mental health and the connection to diabetes. The resulting colorful handout specifically calls out the connection between diabetes and depression and the reality of diabetes distress. The C.A.C. chose to use the word "mood" to make the concept of depression more accessible and potentially less stigmatizing to participants. With the heading "Mood Matters," the handout includes actionable strategies for talking with clinical care teams about mood changes. For example, for some people, discussing a change in mood in relation to a physical condition might be easier than when framed solely as a mental health issue. The material includes a combination of evidence-based distress coping strategies from the literature reviewed by the C.A.C. and suggestions based on their own experience, which were reviewed by the partnering clinical diabetes experts. The R-D1D materials include a journal with prompting questions to encourage participants (and care

partners) to track their mood and talk with their health care team about changes in mood and how that might impact their diabetes.

Presentation Handouts

The C.A.C. confirmed the importance of each participant having a copy of the presentation slides. Color copies were printed and included in participant packets.

Cinch Bag

Materials were provided to participants in a tote bag with the simple message "I'm worth it" on one side and "Yo valgo la pena" on the other side. The bag is intended to increase exposure to this simple message among participants and potentially generate conversations with others in the community about diabetes and the R-D1D program.

Program Delivery, Structure, and Content

D1D was designed to be delivered in person over 8 hours in 1 day. Broad dissemination by the D1D team to other regions of the country requires a virtual platform (eg, Zoom). The C.A.C. deemed the delivery of a telehealth intervention to participant homes acceptable as long as the virtual platform was easy to use. Further, the program was offered such that participants could participate from their home or join other participants at the primary care clinic where they obtain care, using the practice's video-conferencing technologies. The resulting program followed the practice's COVID-19 protocols and allowed participants an option based on their preferences or needs.

The C.A.C. was concerned that attrition would be high if R-D1D was delivered as an 8-hour virtual course, and they expressed concern that a 4-hour course would provide an incomplete, unsatisfying educational experience without enough time spent on topics identified as being especially important, such as self-care and coping. The program was thus restructured to last 5.5 hours and include breaks and maintain multiple interactive and experience-sharing components.

Textbox 1 describes adaptations to the original D1D program content. Specifically, the C.A.C. recommended increasing the amount of time devoted to the "Coping with Diabetes" section and emphasizing the link between diabetes and depression, the reality of diabetes distress, and the new Mood Matters handout and Mood Tracker. Rural populations receive mental health treatment for depression and other mood disorders less frequently than urban counterparts [23], and the C.A.C. felt that many in the community were not aware of the link between diabetes and depression or diabetes distress. Thus the C.A.C. recommended starting R-D1D with a session on "Coping with Diabetes," in addition to lengthening the time spent on this topic and including an additional session on Self-Care Behaviors. Food choices and eating behaviors emerged as a particularly relevant component of successful diabetes self-management. As a result, the Healthy Eating session was retained and bolstered with the addition of the new Recipe Book and Healthy Plate place mat. Although understanding the concept of carbohydrates was determined important, the group removed the section on carbohydrate counting, noting that a general understanding of low and high carbohydrate foods was more

relevant in their experiences and higher priorities for the program. The HPRN C.A.C. valued the evidence supporting the effectiveness of medications to help manage diabetes. A 1-hour shared medical visit with a clinician (nurse practitioner or physician) replaced individual meetings with 3 providers. They chose to retain the D1D's group format with open discussion, based on a positive experience in Utah. Although participants might feel uncomfortable sharing their health information, the C.A.C. recommended this format to tap into their rural community culture of "neighbor helping neighbor" and made clear that R-D1D clinicians allow participants to opt out of group discussion if they prefer. The Importance of Exercise session was not selected to remain as a stand-alone DSMES strategy in the R-D1D. Instead, the new recipe book and Healthy Plate place mats included encouraging messages and tips related to physical activity. The C.A.C. also advised the R-D1D training team to eliminate references to gym memberships due to the severe limited number of gyms in the region. Given the delivery of R-D1D during the COVID-19 pandemic, the C.A.C. recommended the addition of a session on Sick Day Management. To highlight the partnership between R-D1D and local primary care practices, it was recommended to include a session on How to Work With Your Healthcare Team and that referral notes summarizing patient goals and medication recommendations be sent back to the primary care clinician after their patient attended R-D1D.

Discussion

Principal Findings

Our community-academic partnership successfully used the BCT process to adapt the original D1D DSMES program to optimize fit in rural primary care and communities, while retaining the essential elements of the intervention.

Built on the principles of community-based participatory research, BCT values and requires an equitable exchange of perspectives and expertise of its community members, academic research, and clinician participants [24]. This creates an environment of co-learning. The HPRN C.A.C. and staff learned more about diabetes, DSMES evidence, and the reasoning behind certain aspects of the original D1D program. The D1D research team learned about factors in this rural region that might influence a patient's willingness and capacity to receive health information and follow health guidelines (cultural norms, local resources) and ability to receive information (access to technology, literacy, local language). With this information, the D1D research team could understand the rationale behind the C.A.C.'s recommendations and decisions.

This environment of co-learning allowed the group to negotiate several adaptations. For example, the C.A.C. wondered if participants would retain more information over multiple shorter sessions versus 1 extended session. The group reviewed the implementation and clinical evidence (eg, attendance, change in HbA_{1c}) that supported the 1-day D1D structure and discussed how attendance often drops substantially during multisession programs. A 1-day structure reduces barriers to attendance, such as the need to adjust one's work schedule multiple times, find childcare, and, if attending virtually at the local practice, to find

transportation or drive a long distance, which is common in rural regions, multiple times. As a result, the group agreed to testing the feasibility of a 5.5-hour, 1-day program. The importance of creating recruitment and program materials that were inclusive to both English- and Spanish-speaking people with diabetes living in rural areas was identified. As a result, separate messages and materials were created that were contextually adapted rather than just translated from English to Spanish and included images of the local area and people living in eastern Colorado. The D1D research team learned more about the increased rates of depression and other mood disorders in rural areas, and the C.A.C. learned about the evidence between diabetes and depression or diabetes distress. Changes in content and delivery, as well as supplemental materials, were developed as a result of this shared learning to decrease stigma and increase awareness. Another strategy employed to support the translation of evidence-based guidelines was having a certified dietician review the recipes submitted by the community members. Recipes were to use locally available affordable ingredients, acknowledge—and actually tap into—the local rural and Hispanic and Latino/a cultures, and generally be healthy. However, rather than changing original recipes, the dietician provided suggestions for alternative ingredients and portion sizes, where applicable, which were added to the original recipes. The relationship between people with diabetes and their primary care practice in rural areas was discussed. As a result, a session was added to foster communication with the health care team, as well as development of materials to convey information back to the primary care clinician after R-D1D attendance.

Limitations

Although other communities, primary care practices, public health educators, and others in rural communities may find these specific results useful, one limitation of these results is that they may not offer broad generalizability. However, the types of adaptations to consider when delivering an intervention in a new community should be more broadly applicable.

Comparisons With Prior Work

Our results are responsive to calls for more thorough descriptions of the processes and results of community-engaged research activities throughout the research process. Further, this report builds on previous research aiming to more thoroughly describe adaptions to interventions as they are implemented in broad, real-world settings [25-27]. Our findings offer transparent changes to an intervention and can be applied to future R-D1D implementation and dissemination efforts. Telehealth is growing in popularity partially due to its ability to reach populations across broad geographic regions. Although reach is essential, health program researchers, developers, and educators should consider factors that impact program implementation and effectiveness. Patients with diabetes living in rural communities do not have easy access to large endocrinology centers and diabetes care and education specialists and rely heavily on primary care to administer their care. Self-management resources such as the R-D1D program can support patient-provider relationships and effective diabetes management. However, diabetes education in rural eastern Colorado needs to take into account local contextual factors related to rural and Hispanic and Latino/a culture and assets. The R-D1D program development is one example of maximizing medical professional expertise and real-world expertise from people in rural communities and balancing program dissemination goals with "reinventing the wheel" for local relevance [12]. These results matter to patients, families, primary care practices, public health educators, and others in rural communities because good diabetes care should not be dependent on where you live.

Conclusions

The use of BCT resulted in unique and contextually adapted recruitment and program materials and strategies and changes in program structure and delivery for use in the R-D1D DSMES intervention delivered to English- and Spanish-speaking people with diabetes in rural eastern Colorado, while retaining fidelity to the concepts of the original program. The study team is implementing the R-D1D program. A report on its feasibility and clinical outcomes will be reported separately.

Conflicts of Interest

TKO serves on a Physician Advisory Panel for Dexcom Inc as a Primary Care Consultant for Cecelia Health, Diabetes and as a volunteer Media Spokesperson for the Association of Diabetes Care and Education Specialists. TKO received investigator-initiated grant funding from Abbott. ML received investigator-initiated grant funding from Abbott.

Multimedia Appendix 1
Recruitment and program materials.
[DOCX File , 1559 KB - diabetes_v7i2e35664_app1.docx]

XSL•FO
RenderX

References

1. Statistics About Diabetes. American Diabetes Association. URL: https://www.diabetes.org/resources/statistics/statistics-about-diabetes [accessed 2022-04-09]

2. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States. Centers for Disease Control and Prevention. URL: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf [accessed 2022-04-09]

3. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes self-management education and support in type 2 diabetes: a joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Educ 2015 Aug 05;41(4):417-430. [doi: 10.1177/0145721715588904] [Medline: 26047627]

4. Chrvala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. Patient Educ Couns 2016 Jun;99(6):926-943 [FREE Full text] [doi: 10.1016/j.pec.2015.11.003] [Medline: 26658704]

5. Cooke D, Bond R, Lawton J, Rankin D, Heller S, Clark M, U.K. NIHR DAFNE Study Group. Structured type 1 diabetes education delivered within routine care: impact on glycemic control and diabetes-specific quality of life. Diabetes Care 2013 Feb 08;36(2):270-272 [FREE Full text] [doi: 10.2337/dc12-0080] [Medline: 23139374]

6. Strawbridge L, Lloyd J, Meadow A, Riley G, Howell B. One-year outcomes of diabetes self-management training among Medicare beneficiaries newly diagnosed with diabetes. Med Care 2017 Apr;55(4):391-397. [doi: 10.1097/MLR.0000000000000653] [Medline: 27753746]

7. Sturt J, Dennick K, Due-Christensen M, McCarthy K. The detection and management of diabetes distress in people with type 1 diabetes. Curr Diab Rep 2015 Nov 28;15(11):101. [doi: 10.1007/s11892-015-0660-z] [Medline: 26411924]

8. Maez L, Erickson L, Naumuk L. Diabetic education in rural areas. Rural Remote Health 2014;14(2):2742 [FREE Full text] [Medline: 24930474]

9. Siminerio LM, Piatt G, Zgibor JC. Implementing the chronic care model for improvements in diabetes care and education in a rural primary care practice. Diabetes Educ 2005;31(2):225-234. [doi: 10.1177/0145721705275325] [Medline: 15797851]

10. Litchman ML, Wang X, Delaney RK, Neuberger J, Reeder A, Jones SR, et al. 474-P: durable reductions in A1C and diabetes distress with a one-day hybrid DSMES intervention. Diabetes 2021 Jun 21;70(Supplement 1):474. [doi: 10.2337/db21-474-p]

11. VISION: Visual Information System for Identifying Opportunities and Needs. Colorado Department of Public Health and Environment. URL: https://cdphe.colorado.gov/vision-visual-information-system-for-identifying-opportunities-and-needs [accessed 2022-05-22]

12. Westfall JM, Zittleman L, Felzien M, Norman N, Tamez M, Backlund-Jarquin P, et al. Reinventing the wheel of medical evidence: how the boot camp translation process is making gains. Health Aff (Millwood) 2016 Apr;35(4):613-618. [doi: 10.1377/hlthaff.2015.1648] [Medline: 27044960]

13. Fernald DH, Zittleman L, Gilchrist EC, Brou LI, Brou LI, Niebauer L, et al. UPSTREAM! Together evaluation results from community efforts to prevent mental, emotional, and behavioral health problems. Eval Program Plann 2021 Dec;89:102000. [doi: 10.1016/j.evalprogplan.2021.102000] [Medline: 34555734]

14. Curcija K, Zittleman L, Fisher M, Nease DE, Dickinson LM, de la Cerda D, et al. Does a rural community-based intervention improve knowledge and attitudes of opioid use disorder and medication-assisted treatment? A report from the IT MATTTRs study. J Rural Health 2022 Jan 26;38(1):120-128. [doi: 10.1111/jrh.12545] [Medline: 33244841]

15. Muvuka B, Combs RM, Ali NM, Scott H, Williams MT. Depression is real: developing a health communication campaign in an urban African American community. Prog Community Health Partnersh 2020;14(2):161-172. [doi: 10.1353/cpr.2020.0029] [Medline: 33416639]

16. English AF, Dickinson LM, Zittleman L, Nease DE, Herrick A, Westfall JM, et al. A community engagement method to design patient engagement materials for cardiovascular health. Ann Fam Med 2018 Apr 09;16(Suppl 1):S58-S64 [FREE Full text] [doi: 10.1370/afm.2173] [Medline: 29632227]

17. Nease DE, Daly JM, Dickinson LM, Fernald DH, Hahn DL, Levy BT, et al. Impact of a Boot Camp Translation intervention on self-management support in primary care: A report from the INSTTEPP Trial and Meta-LARC Consortium. J Patient Cent Res Rev 2018 Oct 29;5(4):256-266 [FREE Full text] [doi: 10.17294/2330-0698.1635] [Medline: 31414011]

18. Simpson MJ, Daly JM, Fernald DH, Westfall JM, Michaels LC, Levy BT, et al. How to translate self-management support tools into clinical practice: a report from the INSTTEPP Trial and Meta-LARC Consortium. J Patient Cent Res Rev 2018 Oct 29;5(4):276-286 [FREE Full text] [doi: 10.17294/2330-0698.1636] [Medline: 31414013]

19. Census Profile: Northeast Colorado - Eastern Plains Region PUMA, CO. Census Reporter. URL: https://censusreporter.org/profiles/79500US0800100-northeast-colorado-eastern-plains-region-puma-co/ [accessed 2022-04-09]

20. Find a Diabetes Education Program in Your Area. Association of Diabetes Care & Education Specialists. URL: https://www.diabeteseducator.org/living-with-diabetes/find-an-education-program [accessed 2022-04-09]

21. Zimmerman EB. Researching Health Together: Engaging Patients and Stakeholders, From Topic Identification to Policy Change. London, England: Sage Publications, Inc; 2020.

22. Norman N, Bennett C, Cowart S, Felzien M, Flores M, Flores R, et al. Boot camp translation: a method for building a community of solution. J Am Board Fam Med 2013 May 08;26(3):254-263 [FREE Full text] [doi: 10.3122/jabfm.2013.03.120253] [Medline: 23657693]

23. Morales DA, Barksdale CL, Beckel-Mitchener AC. A call to action to address rural mental health disparities. J Clin Transl Sci 2020 May 04;4(5):463-467 [FREE Full text] [doi: 10.1017/cts.2020.42] [Medline: 33244437]

24. Israel BA, Schulz AJ, Parker EA, Becker AB, Community-Campus Partnerships for Health. Community-based participatory research: policy recommendations for promoting a partnership approach in health research. Educ Health (Abingdon) 2001 Jul 1;14(2):182-197. [doi: 10.1080/13576280110051055] [Medline: 14742017]

25. Huebschmann AG, Leavitt IM, Glasgow RE. Making health research matter: a call to increase attention to external validity. Annu Rev Public Health 2019 Apr 01;40:45-63. [doi: 10.1146/annurev-publhealth-040218-043945] [Medline: 30664836]

26. Fort MP, Paniagua-Avila A, Beratarrechea A, Cardona S, Figueroa JC, Martinez-Folgar K, et al. Stakeholder engagement in the translation of a hypertension control program to Guatemala's public primary health care system: lessons learned, challenges, and opportunities. Glob Heart 2019 Jun 01;14(2):155-163 [FREE Full text] [doi: 10.1016/j.gheart.2019.05.005] [Medline: 31324370]

27. Kwan BM, Rementer J, Richie N, Nederveld AL, Phimphasone-Brady P, Sajatovic M, et al. Adapting diabetes shared medical appointments to fit context for practice-based research (PBR). J Am Board Fam Med 2020 Sep 28;33(5):716-727 [FREE Full text] [doi: 10.3122/jabfm.2020.05.200049] [Medline: 32989066]

Abbreviations

BCT: Boot Camp Translation
C.A.C.: Community Advisory Council
CDC: Centers for Disease Control and Prevention
D1D: Diabetes One Day
DSMES: diabetes self-management education and support
HbA$_{1c}$: glycated hemoglobin
HPRN: High Plains Research Network
R-D1D: rural Diabetes One Day
T1D: type 1 diabetes
T2D: type 2 diabetes

XSL•FO
RenderX

Viewpoint

Accuracy of the Standard GlucoNavii Mentor in Blood Glucose Monitoring According to International Organization for Standardization 15197:2013 Criteria

Heeyoung Hwang[1*], BSc; Luca Leonardi[2*], MSc; Antonio Nicolucci[3], MD

[1]SD Biosenser, Suwon-si, Republic of Korea

[2]PIKDARE S.p.A., Casnate con Bernate, Italy

[3]CORESEARCH Srl, Center for Outcomes Research and Clinical Epidemiology, Pescara, Italy

[*]these authors contributed equally

Corresponding Author:
Heeyoung Hwang, BSc
SD Biosenser
C-4&5 Floor
16, Deogyeong-daero 1556beon-gil, Yeongtong-gu
Suwon-si, 16690
Republic of Korea
Phone: 82 43 909 3009
Fax: 82 43 909 3098
Email: hwhy@sdbiosensor.com

Abstract

This study was performed to assess the system accuracy of the blood glucose monitoring system SD GlucoNavii Mentor (SD Biosensor Inc, Korea). The study procedures were based on International Organization for Standardization 15197:2013, in that capillary blood samples from 100 participants' fingertips were measured with three reagent system lots of the self-monitoring blood glucose system. Samples were collected for comparison measurements on a hexokinase-based glucose analyzer (Cobas Integra400 Plus, Roche Instrument Center, Switzerland). Glucose concentrations were distributed as required by International Organization for Standardization 15197. For each of the 100 evaluable samples, duplicate measurements were taken from three different reagent lots, for a total of 600 measurements. Overall, 98.3% (590/600) of individual measurement results (185/186, 99.5% for glucose values <100 mg/dl and 405/414, 97.8% for glucose values ≥100 mg/dl) were within ±15 mg/dl or ±15% of the corresponding comparison method results. All results (100%) fell into the consensus error grid zones A and B, indicating only clinically acceptable results. In conclusion, the blood glucose monitoring system SD GlucoNavii Mentor device fulfilled the system accuracy criteria of the International Organization for Standardization 15197, indicating measurement accuracy sufficient for diabetes therapy.

Introduction

Measurement accuracy of blood glucose monitoring systems (BGMSs) is a relevant aspect in diabetes management. The International Organization for Standardization's (ISO) 15197:2013 [1] describes requirements for BGMSs to set a minimum acceptance criteria for BGMSs' measurement accuracy.

This study was performed to assess the system accuracy of the BGMS SD GlucoNavii Mentor (SD Biosensor Inc, Korea).

According to the manufacturer, this BGMS is substantially equivalent to the BGMS Pic GlucoTest (PIKDARE S.p.A., Italy) and Pic GlucoTest Diary (PIKDARE), which has additional Bluetooth connectivity (data on file).

Methods

The study was conducted at the Institut für Diabetes-Technologie, Forschungs- und Entwicklungsgesellschaft mbH an der Universität Ulm, Ulm, Germany. Ethics approval was obtained from the

Ethik-Kommission der Landesärztekammer Baden-Württemberg (MP-2012-009). In addition, the study was exempted from approval by the regulatory authority Bundesinstitut für Arzneimittel und Medizinprodukte (95.06 - 5661 - 7848).

Study procedures were based on ISO 15197:2013, in that capillary blood samples from at least 100 participants' fingertips were measured with three reagent system lots of the self-monitoring blood glucose (SMBG) system. Samples were collected for comparison measurements on a hexokinase-based glucose analyzer (Cobas Integra400 Plus, Roche Instrument Center, Switzerland), which is traceable according to the requirements of ISO 17511 [2]. Glucose concentrations were distributed as required by ISO 15197, and samples with concentrations ≤50 mg/dl or >400 mg/dl could be adjusted by glycolysis or glucose supplementation. A total of 114 samples from 110 participants were taken. In total, 14 samples were excluded from analysis for different reasons: the glucose concentration category was already filled, the glucose concentrations were unstable, the comparison method's quality control measurement was out of range, and the oxygen partial pressure of adjusted samples was outside of the range found in native blood samples [3]. For each of the 100 evaluable samples, duplicate measurements were taken from three different reagent lots, for a total of 600 measurements.

For data analysis, system accuracy criteria of ISO 15197 were applied: at least 95% of each individual reagent system lot's results have to be found within ±15 mg/dl or ±15% of comparison method results (for glucose concentrations <100 mg/dl and ≥100 mg/dl, respectively), and at least 99% of all results have to fall into clinically acceptable consensus error grid zones A and B [1,4].

Results

Overall, 98.3% (590/600) of individual measurement results (185/186, 99.5% for glucose values <100 mg/dl and 405/414, 97.8% for glucose values ≥100 mg/dl) were within ±15 mg/dl or ±15% of the corresponding comparison method results (Table 1). All results (100%) fell into consensus error grid zones A and B, indicating only clinically acceptable results. The SMBG system exhibited small positive measurement bias, ranging from 1.7% to 3.6%.

Table 1. System accuracy results for the SD GlucoNavii Mentor.

Glucose concentration range	Results within prespecified ranges of the comparison method results, n (%)		
	±5 mg/dl or ±5%[a]	±10 mg/dl or ±10%[a]	±15 mg/dl or ±15%[a]
<100 mg/dl (n=186)	109 (58.6)	164 (88.2)	185 (99.5)
≥100 mg/dl (n=414)	231 (55.8)	363 (87.7)	405 (97.8)
Overall (n=600)	340 (56.7)	527 (87.8)	590 (98.3)

[a]Differences were assessed for comparison method glucose concentrations <100 mg/dl, and relative differences were assessed for comparison method glucose concentrations ≥100 mg/dl.

Conclusions

In conclusion, in this study, the investigated BGMS SD GlucoNavii Mentor device fulfilled the system accuracy criteria of ISO 15197, indicating measurement accuracy sufficient for diabetes therapy.

Conflicts of Interest

HH is an employee of SD Biosensor, Republic of Korea. LL is an employee of PIKDARE S.p.A., Italy. AN received research grants from PIKDARE S.p.A., Italy.

References

1. International Organization for Standardization. In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 2013:5197. [doi: 10.3403/02816037]
2. International Organization for Standardization. In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values assigned to calibrators and control materials. ISO 2003:7511. [doi: 10.3403/02874017]
3. Freckmann G, Schmid C, Baumstark A, Pleus S, Link M, Haug C. Partial pressure of oxygen in capillary blood samples from the fingertip. J Diabetes Sci Technol 2013 Nov 01;7(6):1648-1649 [FREE Full text] [doi: 10.1177/193229681300700627] [Medline: 24351193]

XSL•FO
RenderX

4.   Parkes JL, Slatin SL, Pardo S, Ginsberg BH. A new consensus error grid to evaluate the clinical significance of inaccuracies
        in the measurement of blood glucose. Diabetes Care 2000 Aug;23(8):1143-1148 [FREE Full text] [doi:
        10.2337/diacare.23.8.1143] [Medline: 10937512]

Abbreviations

BGMS: blood glucose monitoring system
ISO: International Organization for Standardization
SMBG: self-monitoring blood glucose

XSL•FO
RenderX

<u>Original Paper</u>

Implementing the Digital Diabetes Questionnaire as a Clinical Tool in Routine Diabetes Care: Focus Group Discussions With Patients and Health Care Professionals

Maria Svedbo Engström[1,2], RN, PhD; Unn-Britt Johansson[3,4], RN, PhD; Janeth Leksell[5], RN, PhD; Ebba Linder[6], RN; Katarina Eeg-Olofsson[6,7,8], MD, PhD

[1]School of Health and Welfare, Dalarna University, Falun, Sweden

[2]Center for Clinical Research Dalarna, Uppsala University, Falun, Sweden

[3]Sophiahemmet University, Stockholm, Sweden

[4]Department of Clinical Sciences and Education, Södersjukhuset, Karolinska Institutet, Stockholm, Sweden

[5]Department of Medical Sciences, Clinical Diabetology and Metabolism, Uppsala University, Uppsala, Sweden

[6]Swedish National Diabetes Register, Center of Registers Västra Götaland, Gothenburg, Sweden

[7]Sahlgrenska Academy, Gothenburg University, Gothenburg, Sweden

[8]Sahlgrenska University Hospital, Gothenburg, Sweden

Corresponding Author:
Maria Svedbo Engström, RN, PhD
School of Health and Welfare
Dalarna University
Högskolegatan 2
Falun, SE-79188
Sweden
Phone: 46 701918605
Email: msd@du.se

Abstract

Background: The Diabetes Questionnaire is a digital patient-reported outcome and experience measure for adults living with diabetes. The Diabetes Questionnaire is intended for use in routine clinical visits in diabetes care and to enable patient perspectives to be integrated into the Swedish National Diabetes Register. The Diabetes Questionnaire was developed on the basis of patients' perspectives, and evidence for its measurement qualities has been demonstrated. Patients receive an invitation to complete the questionnaire before clinical visits, and the patient and health care professional (HCP) can discuss the findings, which are instantly displayed during the visit. Implementation processes for new tools in routine care need to be studied to understand the influence of contextual factors, the support needed, and how patients and HCPs experience clinical use.

Objective: The aim of this study was to describe patients' and HCPs' experiences of initiating the use of the digital Diabetes Questionnaire as a clinical tool in routine diabetes care, supported by a structured implementation strategy involving initial education, local facilitators, and regular follow-ups.

Methods: In this qualitative study, semistructured focus group discussions were conducted 12 months after the use of the Diabetes Questionnaire was initiated. Participants were diabetes specialist nurses and physicians (20 participants in 4 groups) at hospital-based outpatient clinics or primary health care clinics and adults with type 1 or type 2 diabetes (15 participants in 4 groups). The audiotaped transcripts were analyzed using inductive qualitative content analysis.

Results: The results revealed 2 main categories that integrated patients' and HCPs' experiences, which together formed an overarching theme: *While implementation demands new approaches, the Diabetes Questionnaire provides a broader perspective*. The first main category (*The Diabetes Questionnaire supports person-centered clinical visits*) comprised comments expressing that the digital Diabetes Questionnaire can initiate and encourage reflection in preparation for clinical visits, bring important topics to light during clinical visits, and broaden the scope of discussion by providing additional information. The second main category (*The process of initiating the implementation of the Diabetes Questionnaire*) comprised comments that described differences in engagement among HCPs and their managers, challenges of establishing new routines, experiences of support

during implementation, thoughts about the Diabetes Questionnaire, need to change local administrative routines, and opportunities and concerns for continued use.

Conclusions: The Diabetes Questionnaire can broaden the scope of health data in routine diabetes care. While implementation demands new approaches, patients and HCPs saw potential positive impacts of using the questionnaire at both the individual and group levels. Our results can inform further development of implementation strategies to support the clinical use of the questionnaire.

Introduction

Background

The Diabetes Questionnaire is a digital patient-reported outcome and experience measure (patient-reported outcome measure [PROM] and patient-reported experience measure [PREM]) for adults living with diabetes. This measure is primarily designed for use in clinical visits, but can also be used to enable patient perspectives to be integrated into the Swedish National Diabetes Register (NDR). The questionnaire was developed on the basis of patients' perspectives, and evidence for its measurement qualities has been demonstrated. Stemming from 33 items, the questionnaire generates scores from 0 to 100 on dimensions such as general well-being, mood and energy, freedom from worries, management of daily life activities, and experiences of support from diabetes care [1-5]. Patients receive an invitation to complete the questionnaire before clinical visits, and the patient and health care professional (HCP) can discuss the findings, which are instantly displayed during the visit. Thus, the Diabetes Questionnaire has the potential to facilitate patient participation and support steps toward person-centered care [2].

Patient participation and person-centered care are emphasized in the guidelines for diabetes care [6-15] and Swedish legislation [16]. In addition, the inclusion of patients' perspectives in the outcomes of clinical diabetes care has been encouraged in recent decades [6-9,12,17-19]. Although results from randomized controlled trials are limited, it has been suggested that user-friendly PROMs used in routine practice can strengthen the patient's role, centralize information [20-23], and facilitate improvements in diabetes care [20]. Compared with paper-and-pen questionnaires, digital tools have been found to be quicker and easier to use for administration, completion, and presentation of results and have lower costs and better data quality [24]. Furthermore, the possibility of visualizing results during clinical visits has been found to facilitate insight into the patient's situation and improve communication between patients and HCPs [24]. Additional research is needed to learn more about the perspectives of HCPs and patients regarding the implementation and use of PROMs in clinical practice [25-27].

The implementation of a new tool such as the digital Diabetes Questionnaire in a clinical setting is challenging and needs to be undertaken with caution and in a structured manner. Implementation processes need to be studied to learn about contextual influencing factors, required support, and how

patients and HCPs experience clinical use [28]. To study the initial implementation process, we conducted a 2-part qualitative study. The first part of the study [29] addressed patients' and HCPs' perceptions and attitudes about implementing the digital Diabetes Questionnaire in routine diabetes care before the implementation was started. The findings indicated the potential usefulness of the Diabetes Questionnaire to support a more person-centered approach to care and for patients to reflect on their situation and everyday life with diabetes. Expressing hopes and concerns about digital technology in general, the participants emphasized the need for HCPs to be trained in practically handling the digital Diabetes Questionnaire and addressing patients' questionnaire responses [29]. This paper describes the second part of the study, focusing on experiences after initiating the implementation of the digital Diabetes Questionnaire as a clinical tool for routine diabetes care using a structured implementation strategy. Inspired by Moore et al [28], this implementation strategy included introductory information for patients, education for HCPs about the digital Diabetes Questionnaire and its administrative tools, and engagement of local facilitators to support the work with regular follow-up.

Aim of the Study

The aim of this study was to describe patients' and HCPs' experiences of initiating the use of the digital Diabetes Questionnaire as a clinical tool in routine diabetes care, supported by a structured implementation strategy involving initial education, local facilitators, and regular follow-up.

Methods

Research Design

A descriptive qualitative design was used in this follow-up study. The interviews were conducted through focus group discussions with HCPs and adult patients with diabetes.

Participants and Setting

Participants were recruited through purposive sampling from the same sample that was included in the first part of this qualitative study [29]. Of the initial 14 hospital-based outpatient clinics and 8 primary health care clinics that participated in the first part of the study (52 individuals), 13 (93%) hospital clinics and 6 (75%) primary health care clinics had the possibility to participate in the second part of the study. The clinics were active users of the NDR and were located in different regions in Sweden. Diabetes specialist nurses, physicians, and adult

patients with type 1 or type 2 diabetes were included in a total sample of 35 participants.

The Implementation Strategy

Inspired by Moore et al [28], the structured implementation strategy for initiating the use of the digital Diabetes Questionnaire as a clinical tool in routine diabetes care included initial education for HCPs and patients about the questionnaire and the digital tool for administering and answering the questionnaire. The strategy also included the engagement and education of local facilitators to support clinics with regular follow-up. The implementation strategy is outlined in Textbox 1.

Textbox 1. The implementation strategy.

Initial education in respective groups

- Health care professionals (HCP)

  - Short film introduction on the Diabetes Questionnaire—including patients' and HCPs' perspectives

  - Information about the concepts of patient-reported outcome and experience measures (patient-reported outcome measures and patient-reported experience measures)

  - Background and overview of how the Diabetes Questionnaire was developed and constructed with questions and dimensions

  - Preparatory training on how to send and receive the answered questionnaires using the digital tool for administering the questionnaire

  - Examples of how questionnaire responses are presented and can be discussed at clinical visits

- Patients

  - Short film introduction on the Diabetes Questionnaire—including patients' and HCPs' perspectives

  - Information about the concepts of patient-reported outcome measure and patient-reported experience measures

  - Background and overview of how the Diabetes Questionnaire was developed and constructed with questions and dimensions

  - Preparatory training on how to log in and answer the digital questionnaire

  - Examples of how the responses are presented

Education for local facilitators

- Initial education as in the HCP group

- Information on how to facilitate, for example, to contact the local clinics, offer support, and be available to answer questions from the clinics

Regular follow-ups

- Conducted by facilitators

  - The facilitators contacted all the participating clinics by email at least once during the study to support and provide the HCPs the opportunity to discuss various problems or thoughts regarding the use of the questionnaire

  - The facilitators offered additional contact and support according to the clinic's needs

- Conducted by study team

  - Follow-up contact with the local facilitators during the study

  - Follow-up to the local facilitator regarding the clinics' sent and received questionnaires

---

Data Collection

A total of 8 focus groups were conducted. Of these, 50% (4/8) were conducted with adult patients living with either type 1 or type 2 diabetes and 50% (4/8) were conducted with HCPs. Background data are presented in Table 1. In accordance with the implementation strategy and study follow-up time of 12 months, both patients and HCPs had acquired initial experience in using the Diabetes Questionnaire. At the time of the focus group discussions, all HCPs had sent invitations to patients to answer the questionnaire and had discussed the answers with patients more than once. Most of the participating HCPs had undertaken several such conversations with different patients, but the number of conversations differed between the HCPs. As anticipated, the participating patients answered only 1 questionnaire since being invited to participate in this study, because routine clinical visits occur only once or a few times in a year. All patients except 1 (14/15, 93%) were given the opportunity to answer the Diabetes Questionnaire on 1 occasion. All patients who answered the questionnaire followed up the answers with their nurse or physician, some during clinical visits and some by telephone.

Table 1. Background data of the focus groups.

Focus group and characteristics	Patients with diabetes[a] (n=15)	Health care professionals[b] (n=20)
Groups, n	4	4
Sex, n (%)		
Male	8 (53)	5 (25)
Female	7 (47)	15 (75)
Diabetes type, n (%)		N/A[c]
Type 1	11 (73)	
Type 2	4 (27)	
Profession, n (%)	N/A	
Diabetes specialist nurse		16 (80)
Physician		4 (20)

[a]All except 1 patient (14/15, 93%) had answered 1 questionnaire before the focus group discussion.

[b]In total, 1465 questionnaire invitations were sent and 577 (39.39%) answered questionnaires were received before the focus group discussion.

[c]N/A: not applicable.

The focus group discussions were based on semistructured interview guides for the patient and HCP groups (Multimedia Appendix 1). Follow-up questions such as "Could you please further describe the situation using a concrete example?" were used as needed. KEO and JL moderated the focus groups, and EL facilitated the discussions. The focus group discussions were conducted at hospital-based outpatient clinics, primary health care clinics, and the Center of Registers Västra Götaland. The discussions lasted between 0.8 and 1.2 hours, were audio recorded with a digital voice recorder, and subsequently transcribed by a medical secretary.

Data Analysis

The interviews were analyzed using qualitative content analysis [30], with an inductive approach. Each interview was considered as the unit of analysis. The verbatim transcripts (221 pages; 78,955 words) were read several times to identify the essential features (EL, KEO, and MSE). EL, KEO, and MSE agreed that data saturation was satisfactory as the material was nuanced and rich and that there were repetitive contents between transcripts. Units of meaning were identified (EL and KEO), condensed, and labeled with descriptive codes similar to the wording in the text. The codes from all the interviews were assembled and grouped into subcategories according to their content. Continuing the abstraction process, subcategories were pooled into categories and main categories and given an overarching descriptive theme. Each category was based on codes that were judged to belong together and collectively form the basis of meaningful content that was different from that of other categories. Researcher triangulation was used to discuss each step of the analysis process, moving back and forth as

needed (EL, KEO, and MSE), finishing with a discussion to reach consensus about the categorization and theme between all authors (EL, JL, KEO, MSE, and UBJ). The analysis process was conducted manually using a word-processing program (Word; version 2202; Microsoft 365). The use of figure labels enabled the back-and-forth process while keeping track of each text segment throughout the analysis.

Ethics Approval

The Swedish Ethical Review Authority in Gothenburg (317-18) approved the study. A letter provided to participants informed them about the study's purpose, voluntary nature of their participation, confidentiality measures and methods of handling their personal data, NDR, contact details, and right to withdraw consent at any time and with immediate effect without specifying a reason. This information was also provided verbally at the beginning of each focus group. All participants provided written informed consent, and the study was completed in accordance with the Declaration of Helsinki [31].

Results

Overview of Main Categories and Theme

The 2 main categories that emerged in the analysis were the following: *The Diabetes Questionnaire supports person-centered clinical visits* and *The process of initiating the implementation of the Diabetes Questionnaire*. These main categories constituted the overarching theme, *While implementation demands new approaches, the Diabetes Questionnaire provides a broader perspective* (Textbox 2). The main categories are described in the following sections, with exemplifying quotes.

Textbox 2. Theme, main categories, and categories.

Theme

- While implementation demands new approaches, the Diabetes Questionnaire provides a broader perspective

Main category 1

- The Diabetes Questionnaire supports person-centered clinical visits

Categories

- Initiating preparation and reflection before clinical visits

- Bringing important topics to light during clinical visits

- Broadening understanding by providing new information

Main category 2

- The process of initiating the implementation of the Diabetes Questionnaire

Categories

- Differences in engagement among health care management and coworkers

- Starting and establishing new routines

- Health care professionals' experiences of support during implementation of the questionnaire

- Pros and cons regarding the questionnaire and its items and dimensions

- Administration and completion of the Diabetes Questionnaire

- Future opportunities and concerns

The Diabetes Questionnaire Supports Person-Centered Clinical Visits

Initiating Preparation and Reflection Before Clinical Visits

Participants described the Diabetes Questionnaire as a tool that initiated preparation and enabled reflection in preparation for clinical visits, for both HCPs and patients. Patients and HCPs expressed that the completion of the questionnaire and obtaining dimension scores encouraged patients to reflect on aspects of their everyday life and their care that were not working well and actively prepare topics to discuss during clinical visits. A patient expressed the following:

> Completing the questionnaire made me take time to sit down and reflect about what it really was [that I wished to discuss]. This was different to the usual routine of just showing up at the clinic. [patient, group 4]

Similarly, patients and HCPs discussed the ways in which HCPs could prepare for clinical dialogue by reflecting on their patients' scores.

Bringing Important Topics to Light During Clinical Visits

Although some HCPs found that the Diabetes Questionnaire was just another way of identifying topics that were already addressed, patients and HCPs expressed that the Diabetes Questionnaire can be a valuable tool for bringing important topics to light in the dialogue during clinical visits. Patients and HCPs emphasized the need to discuss the questionnaire scores

and for the patients to explain and describe the reasons for their ratings. HCPs understood from the dialogue that patients had been reflecting on their ratings, but also expressed that not all patients wanted to talk about their scores or problems and that this choice must be respected. Patients reported 2 prerequisites for a good discussion: that they had completed the questionnaire beforehand and that they had completed it recently enough that the responses were still relevant and they remembered the reasoning behind their responses. Patients found the Diabetes Questionnaire to be a useful tool for remembering and prioritizing topics they felt were important to discuss, because clinical visits are time-constrained. Patients expressed that they also wanted time to discuss topics other than those raised in the questionnaire:

> The time for clinical visits is limited. The questionnaire is a helpful aid for getting to the questions you need to discuss. [patient, group 3]

Patients discussed how the dialogue related to the Diabetes Questionnaire could broaden HCPs' understanding of their patients as human beings. HCPs discussed how working with the questionnaire made them better at taking a step back, lecturing less, and encouraging patients to talk about the topics that are important to them. This helped HCPs better understand their individual patients' perspectives, the problems their patients experience, and what life with diabetes can be like. HCPs also discussed how the questionnaire helped patients realize that it is appropriate to talk about their personal experiences and topics other than medical matters and that talking to an HCP can be particularly valuable for patients who do not have anyone in their social sphere who understands what they are going through. HCPs found that using the questionnaire

meant that clinical visits were more likely to be on the patient's terms by facilitating joint discussion and encouraging patients to be more active in speaking their minds, which enhanced patient participation and more individualized care. Patients discussed how the Diabetes Questionnaire facilitated dialogue with HCPs and increased the extent to which HCPs behaved in a supportive manner. However, patients found that the responsibility for everyday self-management was not affected and still rested with the individual with diabetes:

> I'm the only person who can do something about it. My diabetes nurse and physician can't solve all of my problems. I see them as tools for support for when something isn't working and I don't understand why. As for the rest of it, I'm in charge. That's how it was both before and after the questionnaire, so it doesn't affect that. [patient, group 1]

Patients and HCPs stated the importance of discussing about questionnaire scores even if the problems were not directly related to diabetes. Patients and HCPs had similar experiences that general well-being and difficulties in everyday life impact individuals with diabetes and affect their ability to manage their condition. Sometimes, HCPs encountered patients with dimension scores that were higher or lower than anticipated, thus increasing the importance of dialogue and the need to obtain more information from their patients. This process was described as a balancing act with a need for dialogue when the medical parameters indicated problems but the questionnaire scores did not. Patients and HCPs expressed that the questionnaire was most needed when changes were made, for meetings with patients who were less communicative, or for meetings between patients and HCPs who had not met previously. HCPs suggested that the questionnaire may become more important given the increasing focus on technology and quantitative data, which they described as potentially receiving a lot of attention:

> Perhaps it will become more and more important because the role of technology is increasingly dominant in clinical visits. The focus is very much on graphs [showing data from glucose sensors] and insulin pumps and so on. It's easy to forget about the most important question: 'How are you doing, really?' [HCP, group 1]

Broadening Understanding by Providing New Information

Patients and HCPs discussed how the Diabetes Questionnaire could broaden the scope of understanding by providing more information, deepening the dialogue, and leading to new insights. Although the received information did not always contain new insights, participants found that the questionnaire provided a more nuanced picture of their individual situation by raising topics in clinical dialogue that may not have been addressed previously, despite several years of contact in many cases. HCPs expressed that this new focus helped them and their patients to see the situation from other points of view. In addition, the questionnaire revealed to HCPs and patients the different aspects of an individual's life that have an impact on the patient's self-managed treatment and medical outcomes. This perspective enabled HCPs to understand that the patient's

general well-being was of special importance. The questionnaire was helpful for focusing on the most important topics by pinpointing what patients themselves saw as their most pressing problems and needs and where there was scope for improvement. Both patients and HCPs remarked that the perspectives of patients and diabetes care staff may differ. Patients expressed that it can be difficult for them to convey their needs and problems if they have doubts about the HCP's interest in those topics, but that the Diabetes Questionnaire affirmed the importance of the patients' perspective, and the related dialogue helped them realize that HCPs wanted to help them:

> When you have this questionnaire, there's an opportunity. They're saying 'We want to help you, fill it in, be honest.' [...] After all, perhaps you do want help with something...It definitely changed my perspective. [patient, group 4]

Patients appreciated the questionnaire for taking their overall life situation into account and discussed it as a means for themselves and their HCPs to recognize and talk about how they may not feel as good as they would like to or as they pretend to. HCPs also discussed having learned that, despite its challenges, diabetes can be experienced as less of a barrier to a good life than they initially thought. HCPs discussed their experiences of having observed discrepancies between medical parameters and patient perspectives that were previously unknown to them, sometimes leading to new insights. For example, HCPs described having learned that patients with well-controlled blood glucose levels, who they thought were doing well, may have problems such as diminished general well-being, being hampered by diabetes in their everyday life, struggling with worries about diabetes-related everyday security, and future risks of long-term complications. The following was expressed by an HCP:

> 'You're the ideal patient with no problems.' That's what it can feel like when you look at a patient's medical records. But the patient might actually be very limited by their illness in their everyday life. [HCP, group 4]

Other issues that were experienced as being highlighted by the questionnaire were patients' feelings of loneliness; experiences of lack of support from family, friends, and colleagues; and lack of employment security. Both patients and HCPs realized that HCPs are often unaware of these types of lack of support. Some patients expressed that they initially considered lack of social support to be their own responsibility to cope with, but that they were prompted to think about it more when they noticed that their HCP was concerned about it. By addressing these issues, patients suggested that the Diabetes Questionnaire could be a tool for involving their significant others in their diabetes care and to highlight the needs of significant others in terms of receiving support from diabetes care staff.

HCPs felt that the Diabetes Questionnaire conveyed that a good life is possible with diabetes and that it supported them to give patients positive feedback related to high scores. However, HCPs also expressed that they found it natural to focus the discussion on low scores, particularly on the dimension related

to general well-being. They found it important to discuss these low scores openly, reporting that, sometimes, other topics had to be set aside. Sometimes, low scores were considered by HCPs as being difficult to handle when they were not able to offer help, despite wanting to do so. Although some HCPs doubted their own competence in addressing some of the issues raised through the questionnaire, some also expressed that, sometimes, it was enough just to listen and acknowledge low scores, convey that it is okay to not feel good, and confirm what they can do to support. Low scores could also reveal the need for patients to be referred to a psychologist or welfare officer; however, some HCPs were concerned about being unable to make some of these referrals.

Patients and HCPs valued the way in which dialogue about experiences of support in diabetes care was initiated by the Diabetes Questionnaire. Some patients stated that the questionnaire provided acknowledgment that they had the support they needed from diabetes care. For others, the questionnaire helped to reveal the need for different or increased support. Although some HCPs had expected to learn more, they valued instances in which the potential for improvement was indicated. The questionnaire initiated constructive discussions about the need for medical devices or being referred to a dietician, frequency of clinical visits to the diabetes nurse and physician, distribution of these visits, and continuity in meeting with the same HCPs. Occasionally, the questionnaire led to the patient being invited for clinical visits to another HCP. Among HCPs, it was speculated that it may be difficult for patients to talk about low scores in these dimensions, and some HCPs wondered whether patients dared to be honest. Some patients expressed concerns about how HCPs, as individuals and as diabetes carers, may react to these evaluations and whether they see the results as a basis for constructive improvements or merely as criticism. Some patients suggested that perhaps a different HCP should perform the follow-up if a patient's scores regarding the experience of support from diabetes care are very low.

The Process of Initiating the Implementation of the Diabetes Questionnaire

Differences in Engagement Among Health Care Management and Coworkers

The extent to which HCPs described the implementation of the Diabetes Questionnaire as a team effort or the work of a few people or an individual varied. HCPs who described implementation as a team effort found it helpful. Discussing and presenting the implementation and results from the Diabetes Questionnaire at team meetings were suggested as necessary strategies for involving the team. However, the predominant experience discussed was being the only person who had to take the lead and do all the work related to the questionnaire by themselves. Some HCPs had chosen to try the Diabetes Questionnaire themselves first to understand whether it would be a strain for others. Others sought to involve their coworkers, but experienced lack of engagement. The lack of engagement was typically described as noninterest or being caused by time constraints rather than them being actively opposed to the Diabetes Questionnaire. Some HCPs who intentionally made a

small-scale start found themselves at crossroads, either in terms of involving the rest of the team or discontinuing because it was challenging. Coworkers expressed having much to do and lack of time, which made it difficult to motivate them to add another task:

> There are lots of things going on at the clinic: staff are being cut down, there are new routines and everyone feels like there's no time. So it's hard to motivate co-workers by saying 'Spend a little extra time on this.' You know they're already struggling with everything else. [HCP, group 3]

Patients and HCPs discussed potential differences in interests, roles, and prerequisites between diabetes specialist nurses and physicians in relation to working with the Diabetes Questionnaire. Although a substantial responsibility was taken by enthusiastic diabetes nurses, there were clinics where physicians were actively involved. The central barriers mentioned as being specific to physicians were lack of time because of the large number of patients and the need to attend to many different medical topics during short clinical visits. It was also suggested that there may be lack of interest. Patients reported that the physician's role regarding the Diabetes Questionnaire could be experienced as unclear. Although some patients proposed that it was reasonable for the diabetes nurse to have the main responsibility, the discussion revealed that it may depend on which physician was involved and that the physician's participation may be beneficial in the long run.

As experienced by HCPs and suggested by patients, the clinic managers affected the prerequisites for engaging with the Diabetes Questionnaire. Managers with a positive attitude who actively engaged in NDR data and related discussions were valued for their support, whereas managers who did not provide resources or engage were seen as barriers to implementation. Some HCPs doubted that their manager knew about the implementation, whereas others described their manager as being informed but not interested. HCPs discussed time as a resource provided by management. Some HCPs had been able to lengthen their clinical visits, whereas others described their managers as expecting the implementation to be completed with no extra time. Some HCPs had started using the questionnaire and then found themselves lacking the necessary time to prioritize it when there was lot of work to do. The discussion revealed that some managers seemed to consider the Diabetes Questionnaire and related participation in project meetings as being beneficial for the individual HCP rather than being important for the clinic.

Starting and Establishing New Routines

Although some participants found it easy, the Diabetes Questionnaire had not yet become part of the established routines for many patients and HCPs. All related activities were new for patients and HCPs (the invitation to complete the questionnaire, completion of the questionnaire, related dialogue, and documentation of questionnaire scores in the patients' records), highlighting the need to establish new routines. The logistics either for postal invitations or for patients to complete the questionnaire in the waiting room were important steps that needed new routines. Patients and HCPs described that both

invitations and completion were easily forgotten and that not all patients realized that they were supposed to complete the questionnaire before the clinical visit. HCPs referred to a need for routines to be locally developed, and some also described difficulties in taking the first step and knowing how to start. Team discussions were emphasized as important for finding and adhering to new routines. HCPs also stressed a need to acknowledge that finding, learning, and incorporating new routines into practice requires time and effort, with some suggesting that it could take several years before using the Diabetes Questionnaire becomes the default approach.

Working with the Diabetes Questionnaire during clinical visits was not seen by HCPs as technically difficult, but rather as a question of people being familiarized with strategies to engage in the necessary dialogue. Although some patients experienced differences in the way in which their clinical visits were organized, these differences were not major. Patients' experiences varied from adequate, open, and useful dialogue to finding that their responses were given little or no attention. Patients suggested that differences in dialogue may be related to the quality of the relationship between the HCP and the patient. Having confidence in the diabetes nurse or physician was described as making the dialogue easier, whereas having a poor relationship with the HCP or having a novice HCP were seen as barriers:

> It might be related to the kind of relationship a patient has with their physician and nurse...If a patient has a bad relationship, then it might be difficult to use the questionnaire. [patient, group 1]

HCPs described the different approaches that were applied and found it helpful to discuss how to practically handle the questionnaire and the scores during clinical visits with their peers. Although some HCPs found the questionnaire to be a useful starting point for opening the dialogue, others combined aspects of the questionnaire together with other topics such as medical parameters and educational elements about diet or physical activity. Other HCPs saved the questionnaire for the end of the visit. HCPs who used the questionnaire as a starting point found that this meant that the meeting was directly targeted at the patient's problems, thoughts, and queries and found this to be more fruitful than conducting it as the last component of the visit. These HCPs let the dialogue be directed by the patient's scores and what the patient found as most important to talk about at the time. Some HCPs discussed sometimes having missed the completed questionnaires or forgetting to talk about the scores during clinical visits, and some of them felt bad about neglecting the patient's responses. Other HCPs described forgetting other things in favor of the Diabetes Questionnaire. HCPs who had not invited all patients to participate in the questionnaire reported the need for strategies to remember which patients to ask for responses.

Some HCPs found that the questionnaire saved time during clinical visits, whereas others found that it took more time to do something extra and that it competed with other important aspects of their work. Patients expressed that the discussion related to the questionnaire did not necessarily take a long time. HCPs mentioned that, sometimes, it felt overwhelming to make

the time to talk about everything during a clinical visit, suggesting that they were only able to focus on a few topics at each visit. In addition, HCPs reported that, sometimes, it was a difficult balancing act between what the patients wanted to talk about and what information diabetes care is obliged to offer. Some of the HCPs who described the questionnaire as not adding more work still struggled to deal with several different topics during a clinical visit. Some HCPs suggested that other aspects had to be excluded in favor of the questionnaire:

> I can't see anything negative related to the questionnaire. However, because it's an extra task, there might still be a need to remove something else to make time for it. [HCP, group 2]

HCPs hoped for high response rates over time and discussed strategies to encourage patients to understand that the Diabetes Questionnaire was a way to prioritize their perspectives in the operations of the clinic. HCPs suggested that it would be useful to provide more information and reminders for patients, provide reminders to the whole team to talk about the questionnaire with patients, feature the Diabetes Questionnaire in the waiting room, and be in contact with those in transition from pediatric care to diabetes care for adults. Patients reported that insufficient dialogue regarding questionnaire scores during clinical visits gave the impression that there was no point in them completing it. The reasons for this included HCPs forgetting to address the questionnaire, not having looked at the results beforehand, or leaving it as the last thing to be addressed during the visit. Patients mentioned that, sometimes, it was difficult for them to take the lead in ensuring that the questionnaire was discussed.

HCPs' Experiences of Support During Implementation of the Questionnaire

Although HCPs described having access to support from facilitators during the implementation of the questionnaire, not all of them used it. The videos, information, and recommended strategies presented during project meetings were described as instructive, and some HCPs felt that more support was not needed. Those in need of more support found that help from facilitators was easily available via the internet and that the support met their needs. Some HCPs consulted the local information technology department to receive the support they needed to solve practical issues. Among HCPs experiencing lack of support from the managers at their clinic, there was a desire for additional information from the NDR, particularly, information directed to managers to encourage them to sanction this work.

Project meetings, during which HCPs from different clinics came together, were strongly appreciated as being motivational and providing opportunities to discuss and receive advice from peers regarding administrative and practical solutions. HCPs expressed a desire for more peer support, which was suggested as a potential means of supporting the dissemination of the questionnaire to coworkers at the clinic. Organizing peer meetings was not expected from the project facilitator, but was considered as something that the HCPs could, and did, arrange by themselves:

We're going to have a collaborative meeting to compare notes and learn about what the others have done. We're going to get some ideas about how to move forward with a few things. [HCP, group 1]

Pros and Cons Regarding the Questionnaire and Its Items and Dimensions

Patients' general perceptions varied from seeing the Diabetes Questionnaire as a useful tool for highlighting their perspectives to a general reluctance toward questionnaires and their results. This variation corresponded to HCPs' perceptions of their patients' views. Some patients described the questionnaire as a tool for reflecting on their own situation in a new way. In positive terms, patients expressed that the results could strengthen their self-esteem and the feeling that they were handling their situation well. However, concerns were raised about the opposite outcome if the questionnaire emphasized their difficulties:

> *When I looked at the scores, I felt like I was doing very well. This can fortify your self-esteem, and make you feel like things aren't so bad after all. But it can also be the other way around.* [patient, group 4]

Patients expressed that they appreciated the digital format, which enabled the results to be directly viewed and automatically transferred to the system. In addition, they felt that, sometimes, a printed copy may be useful for remembering what was said. In general, patients found the items relevant and easy to respond to, even though the relevance of some items and the total number of items could be questioned from an individual perspective. Some patients felt that there were too few response alternatives for some items and that it was difficult to choose between them. Patients also mentioned the difficulty of grading a feeling and concerns about the undue influence of factors that were unrelated to diabetes or their current state on the day when answering the items.

HCPs felt familiar with dialogue at the dimension level. Patients and HCPs found that dimension scores made it easier to identify areas in which there was scope for improvement. The dimensions were generally found to confirm the patient's experience; however, scoring was sometimes questioned by patients for not matching their responses and giving an overly negative picture. HCPs sometimes found that their patients paid much attention to the actual scores, thus inhibiting dialogue related to the contents of the dimensions. HCPs compared the dimension scores with each other, focusing the dialogue on dimensions with low scores. However, some HCPs expressed that it could be difficult to interpret the score levels and determine the level that constituted a low score. Scores that were neither high nor low were considered the most difficult to handle because of concerns about neglecting something important. HCPs experienced situations in which patients interpreted items differently, emphasizing the need for dialogue and individualized approach. HCPs suggested that it would be helpful for the system to show responses from individual items.

Administration and Completion of the Diabetes Questionnaire

Although patients generally found the digital format easy to handle without assistance, some asked next of kin for practical assistance. Some patients speculated that older people may have difficulty and suggested that diabetes nurses could provide initial assistance if a patient lacked self-confidence. HCPs believed that there were no technical impediments for their patients to complete the questionnaire. HCPs found the digital format as advantageous and reported that their older patients found it as fun and had higher response rate than younger patients. Most clinics invited their patients to complete the questionnaire before visiting the clinic, whereas some asked their patients to complete the questionnaire in the waiting room. To give time to reflect and provide honest responses, patients expressed a preference for completing the questionnaire at home by themselves in peace and quiet. Patients suggested that it would be useful to have the ability to highlight items that are in need of dialogue upon completion.

The clinics had different approaches regarding which patients were invited to complete the Diabetes Questionnaire. Some clinics invited all patients who were asked to attend a clinical visit. Others described that although the long-term goal was to invite all patients at least once, they aimed for a small-scale start and described different methods of selection. For example, they may select from patients with physician appointments, those invited to the first and last appointments during the day, or those assumed to have the most need. Reasons for nonselection included patients with dementia, those assumed to have difficulties with the digital format, or those known to not speak Swedish. Some HCPs found it difficult to know how to choose patients to invite.

Some HCPs were concerned about what they deemed to be a low response rate and inability to reach those for whom the questionnaire could be most useful. Interested in the reasons for low response rates, the HCPs pondered whether this was related to lack of time or interest or technical difficulty or if the aim of the Diabetes Questionnaire was not clear enough. Suggested strategies for increasing the response rates included explaining the intention of the questionnaire as a clinical tool, offering technical solutions to complete the questionnaire in the waiting room, and the possibility of offering a pen-and-paper version. The possibility of enabling the questionnaire to be completed by patients with visual impairment or those who did not speak Swedish was also suggested.

HCPs reported that the digital NDR tool for administering the Diabetes Questionnaire was easy to use. However, there were local administrative barriers that were time-consuming in some cases when inviting the patients to complete the questionnaire when they were summoned to clinical visits. Although HCPs sought to temporarily solve the administrative routines during this project, they stated a need to overcome these local barriers to enable them to implement the questionnaire as an established routine offered to more of their patients:

> *I think one of the most important things is how to organize the process to make sure that it works. It's a practical question of how to send these*

[questionnaire invitations] to the patients so that patients respond to them. It needs to be simple. [HCP, group 2]

Future Opportunities and Concerns

Patients and HCPs saw potential positive long-term impacts of using the Diabetes Questionnaire related to patients' individual needs, HCPs' professional needs, and group-level assessment of diabetes care. However, participants stressed that some effort from diabetes care was required. Patients emphasized that if they were to consider completing the questionnaire, there must be scope for dialogue about their scores during clinical visits. Similarly, HCPs stressed the importance of being attentive to patients' scores. Patients and HCPs emphasized the necessity for diabetes care to have the organizational readiness and resources to undertake the actions needed regarding questionnaire outcomes. In addition, patients and HCPs suggested that HCPs may need support for learning how to handle, interpret, and act on questionnaire scores. A patient expressed the following:

What actions are we going to link to these things? How much time do we have? We need to have strategies that are ready to use. There needs to be support for the people who are actually going to handle this. [patient, group 1]

Patients were interested in opportunities for individual longitudinal follow-up, possibly related to the changes made. However, they reflected on the extent to which the HCPs had the time required for engaging in dialogue related to the questionnaire on a routine basis, which added to their administrative burden. HCPs who intended to continue using the Diabetes Questionnaire suggested that ways of working may need to be changed to create the time needed. Some HCPs experienced the implementation of the questionnaire as being helped by workplaces making efforts to implement more person-centered care. In addition, some HCPs suggested that implementing the questionnaire added another dimension to the pleasure they experienced in their work, leading to professional development and increased commitment and enjoyment.

Patients and HCPs speculated about the opportunities for and value of cross-sectional and longitudinal group-level analyses following the broad implementation of the questionnaire. HCPs described the potential for actively conducting analysis in the same manner as for the traditional NDR data, with the Diabetes Questionnaire adding new aspects. For quality improvement, HCPs stressed the value of assessment of local data and comparisons with other clinics. Both patients and HCPs stressed that by including the questionnaire as part of the NDR, there was the potential to influence managers and politicians. However, some patients also expressed that the greatest benefits of the questionnaire were related to the dialogue about their individual situation, and they spoke against a strict focus on scores and statistics. Patients suggested the possibility of using the questionnaire to identify patients in need of support with educational activities or sharing experiences with peers. Moreover, some patients raised concerns about the potential for diminished access to care for patients with high questionnaire scores if diabetes care prioritized patients with low scores.

Discussion

Principal Findings

The findings of the focus groups in this qualitative study revealed 2 main categories that integrated patients' and HCPs' experiences and together formed the overarching theme, *While implementation demands new approaches, the Diabetes Questionnaire provides a broader perspective.* The first main category (*The Diabetes Questionnaire supports person-centered clinical visits*) was based on comments expressing that the digital Diabetes Questionnaire encouraged reflection in preparation for clinical visits, brought important topics to light during clinical visits, and broadened the scope of discussion by providing additional information. The second main category (*The process of initiating the implementation of the Diabetes Questionnaire*) comprised comments that expressed differences in engagement among HCPs and their managers, the challenges associated with establishing new routines, experiences of support during the implementation of the Diabetes Questionnaire, thoughts about the questionnaire, the need to implement local administrative routines, and opportunities and concerns regarding continued use.

Comparison With Previous Work

Overview

During the implementation of PROMs, it is important to consider the needs and perspectives of patients and HCPs [27]. This is the first study focusing on patients' and HCPs' experiences of using the digital Diabetes Questionnaire in routine diabetes care clinical visits. In addition to valuable input to the specific project related to Swedish diabetes care and NDR, this study contributes to the collective learning process on the use and implementation of PROMs and PREMs in routine care.

Using PROMs and PREMs as Clinical Tools to Support Person-Centered Care

In accordance with previous proposals regarding the clinical use of PROMs [20-24], the current results suggest that the use of the digital Diabetes Questionnaire can support person-centered clinical visits for adults living with diabetes. This confirms the suggested potential benefits from the initial component of this study [29]. Although person-centered care can be defined in different ways, common characteristics involve active patient engagement; partnership; shared decision-making; and the need for care to be respectful of and responsive to individual patient preferences, needs, and values [32,33]. For diabetes care, it has been emphasized that HCPs and patients have a shared responsibility to make person-centered clinical visits possible. A central prerequisite is that both parties be adequately prepared. Patients have an important responsibility to raise topics that are important to them, and HCPs are expected to be up-to-date with each patient's records and ongoing progress [34]. In this study, the digital Diabetes Questionnaire was found to support reflection and active preparation for patients and HCPs. During clinical visits, the questionnaire helped to bring important and sometimes newly revealed topics to light and strengthened collaboration and mutual participation. Comparable findings were reported in Swedish rheumatology

care [35], where the use of PROMs has been found to strengthen patients' involvement and support interaction and shared decisions between HCPs and patients.

Although strengthening patient perspectives in diabetes care has been a topic of research interest for many years [6-8,16,36], research continues to show a gap between recommendations and patient experiences. Adults with diabetes still describe a lack of person-centered care and a desire for HCPs to understand more about their situation and needs and which actions and approaches of HCPs are most helpful [37]. More structured strategies for incorporating patients' perspectives and encouraging active patient participation in clinical visits are warranted [38]. As a clinical tool, the Diabetes Questionnaire can provide a helpful step in the direction of systematically strengthening patient perspectives. However, this does not exclude the need for other actions. Initiatives such as digital web-based tools for self-monitoring and interacting with diabetes specialist nurses for self-management support [39] may be well suited for use in combination with the questionnaire.

A unique feature of the Diabetes Questionnaire is that, in addition to elucidating experiences in daily life, it includes experiences of support from diabetes care. In the first part of this study [29], concerns were raised regarding whether patients would be comfortable about being honest and whether HCPs and patients would be comfortable discussing the relevant issues [29]. However, in accordance with previous studies describing the basis for and development of the Diabetes Questionnaire [3,5], the results from this study confirm the value of discussing the extent to which patients experience adequate support from diabetes care. Aspiring for collaboration and partnership, it should be possible to discuss questions such as the extent to which the individual patient experiences the support they need and whether the patient feels able to talk about the topics that are most important to them during clinical visits. However, in cases where PREM scores were very low, patients suggested that it may be appropriate to involve a different HCP in the follow-up.

In Norway, a related project investigated the assessment of diabetes distress in diabetes care for young adults with type 1 diabetes. This previous study used the Problem Areas In Diabetes (PAID) scale in conjunction with an empowerment-based communication manual to guide nurses in reviewing and discussing PAID scores [40-42]. In accordance with the current results, the researchers reported that their approach promoted reflective thinking and dialogue and facilitated patient-provider relationships and person-centeredness [42]. Another similarity between the results of the 2 studies is that the questionnaire scoring was enlightening for HCPs [42,43]. Satisfactory glycemic control can obstruct HCPs' understanding of the patient's situation, thus concealing significant challenges they face in everyday life. Questionnaire data can reveal important information about adults with diabetes, for whom the everyday personal cost of well-controlled glucose levels can be high. Similar to PAID scale [42], the Diabetes Questionnaire can be helpful for focusing on individual patient experiences and topics other than medical matters that potentially affect medical outcomes. Another similarity with the Norwegian results [42] is the importance of discussing the

patients' responses and the need for patients to be able to clarify the nuances and rationale behind their responses. Furthermore, excessive focus is sometimes placed on numerical scores. Instead, it may be preferable for questionnaires to be used as conversation starters that make the dialogue more constructive and facilitate participation.

As in the current results, the young adults in the Norwegian project appreciated the enhanced emphasis on their situation and expressed that it was worth the time required to complete the questionnaire as preparation for clinical visits. However, the findings also revealed that completing PAID scale and discussing their responses made patients feel exposed, uncomfortable, and vulnerable and that some items were painful to answer [42]. We did not find similar reactions to the Diabetes Questionnaire in this study. As highlighted in an increasing number of studies [44-48], the careful and reflective use of language is important in diabetes care, and the words used can impact how individuals view diabetes and themselves. During the development of the Diabetes Questionnaire, special effort was made to reflect the phrasing used by adults living with diabetes and to avoid being disrespectful or offensive or adding to the burden of diabetes [2,3]. In this study, the Diabetes Questionnaire was found to encourage the idea that a good life is possible with diabetes and support HCPs in giving positive feedback to patients. However, during clinical visits, HCPs found it natural to focus on dimensions with low scores and felt that it was important to do so openly. In addition to the positive statements from patients, some participants remarked that there may also be a risk of emphasizing the difficulties. This risk will be important to be examined in more detail in future studies. In addition to differences between the 2 questionnaires' content or wording, differences in experiences may also be related to practices regarding discussion of patient experiences in clinical visits or the specific focus on young adults with type 1 diabetes in the Norwegian studies [40-42]. Another related initiative is the recently announced Danish implementation of a nation-specific digital tool for patient-reported outcomes [49]. Similar to this study, the researchers targeted adults with type 1 and type 2 diabetes more broadly.

Implementing PROMs and PREMs in Routine Practice

The current results have many similarities to the facilitators and barriers to implementing PROMs and PREMs in organizations delivering health-related services identified in a review of reviews reported by Foster et al [27] and in a summary of case studies reported by Stover et al [50]. In accordance with the current results, a central message is that integration into routine care requires effort and time [27,50]. Central traits that have been reported to facilitate implementation include the experience of specific PROM or PREM measures as a meaningful and useful approach for strengthening patient perspectives. Another important trait is the existence of evidence that these tools have satisfactory measurement quality [27,50]. Consistent with the findings of previous studies [1-4,29], the current results add to the increasing evidence suggesting that the Diabetes Questionnaire possesses the necessary central traits.

In addition to these central traits, the identified facilitating characteristics for PROMs and PREMs include application at

the individual level, absence of license costs, user-friendly technical systems, and directly and easily available data. Further facilitating characteristics include the possibility to adapt data collection and clinical use to organizational work processes and appointment schedules [27,50]. The Diabetes Questionnaire is intended for use at the individual level, and there is no license cost for clinics connected to the NDR. This study shows that the provided digital tool was easy to use for data collection and presentation of scores. However, HCPs experienced barriers related to the local administrative procedures and systems for invitation. Similar to the findings reported by Stover et al [50], the HCPs in our study suggested that these administrative barriers needed to be resolved locally to fit each clinic's resources, existing routines, technical systems, and workflows.

Currently, there is lack of information regarding the potential need to prepare patients for the use of PROMs [27]. Patients in our study found the digital questionnaire easy to use, and special training other than information from their HCP was not requested. However, it was suggested that the diabetes nurse could potentially be of assistance for the first time the questionnaire is introduced. The participating patients in this study received information about the intentions of using the Diabetes Questionnaire and the data collection process during an introductory meeting for the study. Consequently, future evaluations are needed to determine whether the information provided by HCPs during clinical visits is sufficient. A potential negative aspect related to digital PROMs highlighted in a review by Meirte et al [24] is that some patients, particularly those who are older, may have difficulties in using technology. This was also suggested in our focus groups with patients; however, it was not directly experienced by our participants. In contrast, HCPs in our study reported that their older patients had higher response rate than their younger patients. Similar to Meirte et al [24], our focus groups suggested that a paper version could be offered to those who were less familiar with technical tools.

Some HCPs found it natural to integrate the Diabetes Questionnaire into the dialogue, reporting that it did not necessarily take more time and, possibly, even saved time. However, as described by Stover et al [50], we found that it could be challenging for HCPs to know how to initiate related dialogue. This dialogue was also experienced as interfering with other responsibilities during the limited time available during clinical visits. Barriers related to competing priorities and worries regarding workload have also been described in previous studies [43,50]. In the Norwegian project using PAID scale in diabetes care mentioned previously [43], substantial challenges were described regarding time and resources and the need to balance between addressing patients' emotional concerns and HCPs' other duties. The competing responsibilities described were mainly technical issues for diabetes nurses and biomedical issues for physicians [43]. While patients in our study clearly stressed the need to discuss their questionnaire scores, concerns were raised about whether the HCPs would have the time needed on a routine basis. Patients expressed that the main benefits of the questionnaire were related to the clinical dialogue about their individual situation. Similar to the previously reported barriers regarding group-level monitoring of PROM data alone [27], patients in our study questioned the benefits of completing

the questionnaire if there was no related dialogue. Potential benefits of cross-sectional and longitudinal group-level analyses and quality improvement informed by PROM and PREM data were discussed by both patients and HCPs. However, the patients expressed that regardless of the value of the data, this should only be seen as an additional benefit of broad implementation at the individual level, rather than being the main objective.

The implementation of the Diabetes Questionnaire was predominantly taken on by small groups or solitary enthusiastic individuals. The engagement and support experienced from coworkers and managers varied. This does not appear to be a unique situation. According to Foster et al [27], the main workload often falls on a few members of the working team. The current results also revealed that HCPs who described team effort and engaged support from their manager found this situation helpful. Contextual factors such as leadership, organizational culture, and readiness for change have been reported in several implementation frameworks to influence implementation [51]. In situations where the implementation process is proposed by the organization, it has been recommended that the manager needs to be engaged to motivate the use of PROMs and lead the implementation process [27]. However, there is a knowledge gap regarding cases in which clinicians want PROMs to be implemented but the organizational culture or manager is not receptive to change [27]. In this study, the managers had to agree to their clinic's participation. However, the wish to implement the Diabetes Questionnaire generally came from HCPs and not from their managers. Some HCPs described their managers as being genuinely engaged. However, some HCPs described managers who did not consider the implementation to be sufficiently important for the clinic to invest time in, but rather as being beneficial for the individual HCP, who should be thankful for being allowed to implement it. Integrating patients' perspectives in clinical visits and outcome assessments of care at the individual and group levels is recommended in the guidelines for diabetes care [6-15]. The current results support previous reports [27,43] that the use of PROMs often comes with conditions, requiring the capacity and resources to handle the responses in individual clinical visits and health care organizations and in the long term [27,43]. The implementation of the questionnaire cannot rely on solitary enthusiastic individuals and should not be seen as a measure that only benefits HCPs. Clinic managers, decision makers, and health care organizations need to provide prerequisites and support for HCPs to be able to focus on the emotional aspects of diabetes. To achieve this goal in routine care, considerable amount of important work remains to be done.

Methodological Considerations

To strengthen the credibility of the current findings, we included participants with various perspectives [52-54]: patients, specialist nurses, and physicians working with diabetes at different hospital-based clinics or in primary care. The focus groups [55] generated nuanced and rich data from discussions that led participants to reflect on their different or shared experiences and thoughts. A limitation of this study was that patients had less experience in using the Diabetes Questionnaire

than HCPs, and our results may more strongly reflect the perspectives of individuals who felt more positively about the Diabetes Questionnaire. To strengthen credibility and address dependability, researcher triangulation [52-54] was conducted throughout the analysis, thoroughly discussing each step to gain a shared understanding and avoid misinterpretation of the data. Together, the research group (all were women) has considerable collective experience in qualitative research and diabetes care, including the perspectives of both registered nurses (EL, JL, MSE, and UBJ) and a physician (KEO). EL (registered nurse) and KEO (PhD) work at the NDR; EL as a development manager and KEO as the director. KEO also works as a consultant in diabetes care and with clinical research. JL (associate professor), MSE (PhD), and UBJ (professor) teach in higher education and conduct clinical research at universities. All members of the research group have been involved in the previous development process of the Diabetes Questionnaire in various ways. The research group had no established relationship with the participants before the study. For the reader to be able to judge the transferability to other settings, we strived for transparency and rich descriptions of results.

Implications and Future Perspectives

The long-term goal is for the digital Diabetes Questionnaire to be used as a clinical tool to strengthen patient perspectives in routine diabetes care and to be considered together with medical variables in the Swedish NDR. For this goal to be realized, there is considerable amount of work to be done. Use at the individual level is the foundation of implementation. On the basis of the current results and advice from researchers such as Foster et al [27], ongoing and future studies will be required to evaluate whether a further developed implementation strategy including clear advice for inviting all patients at the clinics; more formally appointed implementation leaders; and more formal, structured, and recurring involvement of clinicians, coworkers, and clinic managers could result in greater collective effort and a clear mandate for change. This study focused on the initial experiences of initiating the use of the Diabetes Questionnaire. It is also important to study the long-term impact of the questionnaire by focusing on experiences from recurrent use,

particularly from patients' perspectives. In addition, it is important to consider a long-term perspective on the implementation process. Guided by normalization process theory [56-59], in future studies, we plan to focus on the support and strategies needed to embed the use of the Diabetes Questionnaire as a natural and continuous part of routine clinical diabetes care. Long-term use presents opportunities for longitudinal follow-up at the individual level and sufficient data for group-level analysis as the basis for quality improvement. Being part of the NDR, this will also enable evaluations combining PROM and PREM data with medical variables. These opportunities and potential benefits from continued use of the Diabetes Questionnaire were expressed by patients and HCPs. We aim to evaluate these possibilities in future studies. These potential outcomes are also consistent with increasing call for patients' perspectives to play a greater role in assessing outcomes of diabetes care and to be incorporated into diabetes registries [60,61].

The NDR has comprehensive long-term experience in secure data management of medical variables. Since the start of the PROM and PREM project, the NDR has continuously sought to ensure that technical solutions conform to regulations and that patients' questionnaire data are handled in a secure manner. As addressed by Meirte et al [24], these aspects are essential for making broad and long-term implementations in routine care possible. Together with practical issues related to the different digital systems used in health care organizations, the security, lawfulness, and feasibility of data handling continue to be highly important factors.

Conclusions

The Diabetes Questionnaire can broaden the scope of health data in routine diabetes care. While implementation demands new approaches, patients and HCPs saw potential positive impacts of using the questionnaire at both the individual and group levels. These results can inform further development of implementation strategies to support the clinical use of the questionnaire.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guides used for focus group discussions with health care professionals and patients.
[PDF File (Adobe PDF File), 124 KB - diabetes_v7i2e34561_app1.pdf]

References

1. Borg S, Eeg-Olofsson K, Palaszewski B, Svedbo Engström M, Gerdtham UG, Gudbjörnsdottir S. Patient-reported outcome and experience measures for diabetes: development of scale models, differences between patient groups and relationships with cardiovascular and diabetes complication risk factors, in a combined registry and survey study in Sweden. BMJ Open 2019 Jan 04;9(1):e025033 [FREE Full text] [doi: 10.1136/bmjopen-2018-025033] [Medline: 30612113]

2. Svedbo Engström M. Patient Perspectives brought to the Fore for Diabetes Care: Descriptions as well as Development and Testing of the Diabetes Questionnaire. Gothenburg University Library. 2019 Nov 7. URL: http://hdl.handle.net/2077/60798 [accessed 2022-05-12]

3. Svedbo Engström M, Leksell J, Johansson UB, Eeg-Olofsson K, Borg S, Palaszewski B, et al. A disease-specific questionnaire for measuring patient-reported outcomes and experiences in the Swedish National Diabetes Register: Development and evaluation of content validity, face validity, and test-retest reliability. Patient Educ Couns 2018 Jan;101(1):139-146. [doi: 10.1016/j.pec.2017.07.016] [Medline: 28736071]

4. Svedbo Engström M, Leksell J, Johansson UB, Borg S, Palaszewski B, Franzén S, et al. New Diabetes Questionnaire to add patients' perspectives to diabetes care for adults with type 1 and type 2 diabetes: nationwide cross-sectional study of construct validity assessing associations with generic health-related quality of life and clinical variables. BMJ Open 2020 Nov 17;10(11):e038966 [FREE Full text] [doi: 10.1136/bmjopen-2020-038966] [Medline: 33203629]

5. Svedbo Engström M, Leksell J, Johansson U, Gudbjörnsdottir S. What is important for you? A qualitative interview study of living with diabetes and experiences of diabetes care to establish a basis for a tailored Patient-Reported Outcome Measure for the Swedish National Diabetes Register. BMJ Open 2016 Mar 24;6(3):e010249 [FREE Full text] [doi: 10.1136/bmjopen-2015-010249] [Medline: 27013595]

6. National guidelines for diabetes care. National Board of Health and Welfare (Socialstyrelsen). 2018 Oct 25. URL: https://www.socialstyrelsen.se/regler-och-riktlinjer/nationella-riktlinjer/slutliga-riktlinjer/diabetes/ [accessed 2021-09-22]

7. Young-Hyman D, de Groot M, Hill-Briggs F, Gonzalez JS, Hood K, Peyrot M. Psychosocial care for people with diabetes: a position statement of the American Diabetes Association. Diabetes Care 2016 Dec;39(12):2126-2140 [FREE Full text] [doi: 10.2337/dc16-2053] [Medline: 27879358]

8. Davies MJ, D'Alessio DA, Fradkin J, Kernan WN, Mathieu C, Mingrone G, et al. Management of hyperglycaemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetologia 2018 Dec;61(12):2461-2498. [doi: 10.1007/s00125-018-4729-5] [Medline: 30288571]

9. American Diabetes Association. 4. Comprehensive medical evaluation and assessment of comorbidities: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S40-S52. [doi: 10.2337/dc21-S004] [Medline: 33298415]

10. American Diabetes Association. 10. Cardiovascular disease and risk management: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S125-S150. [doi: 10.2337/dc21-S010] [Medline: 33298421]

11. American Diabetes Association. 11. Microvascular complications and foot care: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S151-S167. [doi: 10.2337/dc21-S011] [Medline: 33298422]

12. American Diabetes Association. 5. Facilitating behavior change and well-being to improve health outcomes: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S53-S72. [doi: 10.2337/dc21-S005] [Medline: 33298416]

13. American Diabetes Association. 6. Glycemic targets: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S73-S84. [doi: 10.2337/dc21-S006] [Medline: 33298417]

14. American Diabetes Association. 7. Diabetes technology: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S85-S99. [doi: 10.2337/dc21-S007] [Medline: 33298418]

15. American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: standards of medical care in diabetes-2021. Diabetes Care 2021 Jan;44(Suppl 1):S111-S124. [doi: 10.2337/dc21-S009] [Medline: 33298420]

16. Patient Act. Government Offices of Sweden, Ministry of Health and Social Affairs. URL: https://www.government.se/government-of-sweden/ministry-of-health-and-social-affairs/ [accessed 2022-05-04]

17. Polonsky WH. Emotional and quality-of-life aspects of diabetes management. Curr Diab Rep 2002 Apr;2(2):153-159. [doi: 10.1007/s11892-002-0075-5] [Medline: 12643134]

18. Glasgow RE, Peeples M, Skovlund SE. Where is the patient in diabetes performance measures? The case for including patient-centered and self-management measures. Diabetes Care 2008 May;31(5):1046-1050 [FREE Full text] [doi: 10.2337/dc07-1845] [Medline: 18445728]

19. Jones A, Vallis M, Pouwer F. If it does not significantly change HbA1c levels why should we waste time on it? A plea for the prioritization of psychological well-being in people with diabetes. Diabet Med 2015 Feb;32(2):155-163. [doi: 10.1111/dme.12620] [Medline: 25354315]

20. Skovlund SE, Lichtenberg TH, Hessler D, Ejskjaer N. Can the routine use of patient-reported outcome measures improve the delivery of person-centered diabetes care? A review of recent developments and a case study. Curr Diab Rep 2019 Aug 16;19(9):84. [doi: 10.1007/s11892-019-1190-x] [Medline: 31420754]

21. Ishaque S, Karnon J, Chen G, Nair R, Salter AB. A systematic review of randomised controlled trials evaluating the use of patient-reported outcome measures (PROMs). Qual Life Res 2019 Mar;28(3):567-592. [doi: 10.1007/s11136-018-2016-z] [Medline: 30284183]

[XSL•FO]
RenderX

22. Snyder CF, Aaronson NK, Choucair AK, Elliott TE, Greenhalgh J, Halyard MY, et al. Implementing patient-reported outcomes assessment in clinical practice: a review of the options and considerations. Qual Life Res 2012 Oct;21(8):1305-1314. [doi: 10.1007/s11136-011-0054-x] [Medline: 22048932]

23. Kotronoulas G, Kearney N, Maguire R, Harrow A, Di Domenico D, Croy S, et al. What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials. J Clin Oncol 2014 May 10;32(14):1480-1501. [doi: 10.1200/JCO.2013.53.5948] [Medline: 24711559]

24. Meirte J, Hellemans N, Anthonissen M, Denteneer L, Maertens K, Moortgat P, et al. Benefits and disadvantages of electronic patient-reported outcome measures: systematic review. JMIR Perioper Med 2020 Apr 03;3(1):e15588 [FREE Full text] [doi: 10.2196/15588] [Medline: 33393920]

25. Marrero DG, Hilliard ME, Maahs DM, McAuliffe-Fogarty AH, Hunter CM. Using patient reported outcomes in diabetes research and practice: recommendations from a national workshop. Diabetes Res Clin Pract 2019 Jul;153:23-29. [doi: 10.1016/j.diabres.2019.05.016] [Medline: 31128133]

26. McMorrow R, Hunter B, Hendrieckx C, Kwasnicka D, Cussen L, Ho FC, et al. Effect of routinely assessing and addressing depression and diabetes distress using patient-reported outcome measures in improving outcomes among adults with type 2 diabetes: a systematic review protocol. BMJ Open 2021 Mar 15;11(3):e044888 [FREE Full text] [doi: 10.1136/bmjopen-2020-044888] [Medline: 33722873]

27. Foster A, Croot L, Brazier J, Harris J, O'Cathain A. The facilitators and barriers to implementing patient reported outcome measures in organisations delivering health related services: a systematic review of reviews. J Patient Rep Outcomes 2018 Dec;2:46 [FREE Full text] [doi: 10.1186/s41687-018-0072-3] [Medline: 30363333]

28. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ 2015 Mar 19;350:h1258 [FREE Full text] [doi: 10.1136/bmj.h1258] [Medline: 25791983]

29. Eeg-Olofsson K, Johansson UB, Linder E, Leksell J. Patients' and health care professionals' perceptions of the potential of using the digital diabetes questionnaire to prepare for diabetes care meetings: qualitative focus group interview study. J Med Internet Res 2020 Aug 19;22(8):e17504 [FREE Full text] [doi: 10.2196/17504] [Medline: 32812884]

30. Krippendorff K. Content Analysis: An Introduction to Its Methodology. 3rd edition. Thousand Oaks, CA. USA: SAGE Publications; Apr 12, 2012.

31. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013 Nov 27;310(20):2191-2194. [doi: 10.1001/jama.2013.281053] [Medline: 24141714]

32. Ekman I, Swedberg K, Taft C, Lindseth A, Norberg A, Brink E, et al. Person-centered care--ready for prime time. Eur J Cardiovasc Nurs 2011 Dec;10(4):248-251. [doi: 10.1016/j.ejcnurse.2011.06.008] [Medline: 21764386]

33. Håkansson Eklund J, Holmström IK, Kumlin T, Kaminsky E, Skoglund K, Höglander J, et al. "Same same or different?" A review of reviews of person-centered and patient-centered care. Patient Educ Couns 2019 Jan;102(1):3-11. [doi: 10.1016/j.pec.2018.08.029] [Medline: 30201221]

34. Schultz AA, Wad JL, Willaing I, Nørgaard K, Persson F, Joensen LE. Achieving a useful and person-centred diabetes consultation is a shared responsibility between diabetologists and people with diabetes: a qualitative study of perspectives from people with type 1 diabetes. Diabet Med 2021 Jun;38(6):e14382. [doi: 10.1111/dme.14382] [Medline: 33245572]

35. Granström E, Wannheden C, Brommels M, Hvitfeldt H, Nyström ME. Digital tools as promoters for person-centered care practices in chronic care? Healthcare professionals' experiences from rheumatology care. BMC Health Serv Res 2020 Dec 01;20(1):1108 [FREE Full text] [doi: 10.1186/s12913-020-05945-5] [Medline: 33261602]

36. Speight J, Hendrieckx C, Pouwer F, Skinner TC, Snoek FJ. Back to the future: 25 years of 'Guidelines for encouraging psychological well-being' among people affected by diabetes. Diabet Med 2020 Aug;37(8):1225-1229. [doi: 10.1111/dme.14165] [Medline: 31661183]

37. Litterbach E, Holmes-Truscott E, Pouwer F, Speight J, Hendrieckx C. 'I wish my health professionals understood that it's not just all about your HbA!'. Qualitative responses from the second Diabetes MILES - Australia (MILES-2) study. Diabet Med 2020 Jun;37(6):971-981. [doi: 10.1111/dme.14199] [Medline: 31802530]

38. Husdal R, Thors Adolfsson ET, Leksell J, Nordgren L. Diabetes care provided by national standards can improve patients' self-management skills: a qualitative study of how people with type 2 diabetes perceive primary diabetes care. Health Expect 2021 Jun;24(3):1000-1008 [FREE Full text] [doi: 10.1111/hex.13247] [Medline: 33774899]

39. Öberg U, Isaksson U, Jutterström L, Orre C, Hörnsten Å. Person-centered interactive self-management support in primary health care for people with type 2 diabetes: protocol for a randomized controlled trial. JMIR Res Protoc 2019 Apr 08;8(4):e10250 [FREE Full text] [doi: 10.2196/10250] [Medline: 30958279]

40. Hernar I, Graue M, Richards DA, Strandberg RB, Nilsen RM, Rekdal M, et al. Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: the DiaPROM randomised controlled pilot trial. BMJ Open 2021 Apr 14;11(4):e042353 [FREE Full text] [doi: 10.1136/bmjopen-2020-042353] [Medline: 33853796]

41. Haugstvedt A, Hernar I, Strandberg RB, Richards DA, Nilsen RM, Tell GS, et al. Use of patient-reported outcome measures (PROMs) in clinical diabetes consultations: study protocol for the DiaPROM randomised controlled trial pilot study. BMJ Open 2019 Jan 17;9(1):e024008 [FREE Full text] [doi: 10.1136/bmjopen-2018-024008] [Medline: 30782722]

42. Hernar I, Graue M, Strandberg RB, Lie SS, Sigurdardottir AK, Richards DA, et al. Young adults with type 1 diabetes and their experiences with diabetes follow-up and participation in the DiaPROM pilot trial: a qualitative study. Diabet Med 2021 Jun;38(6):e14535. [doi: 10.1111/dme.14535] [Medline: 33547702]

43. Haugstvedt A, Hernar I, Graue M, Strandberg RB, Stangeland Lie S, Sigurdardottir AK, et al. Nurses' and physicians' experiences with diabetes consultations and the use of dialogue tools in the DiaPROM pilot trial: a qualitative study. Diabet Med 2021 Jun;38(6):e14419. [doi: 10.1111/dme.14419] [Medline: 33035378]

44. Dickinson JK, Guzman SJ, Maryniuk MD, O'Brian CA, Kadohiro JK, Jackson RA, et al. The use of language in diabetes care and education. Diabetes Care 2017 Dec;40(12):1790-1799. [doi: 10.2337/dci17-0041] [Medline: 29042412]

45. Position Statement: a new language for diabetes: improving communications with and about people with diabetes. Diabetes Australia. 2011 Jul 7. URL: https://www.diabetesaustralia.com.au/wp-content/uploads/Language-position-statement-2016.pdf [accessed 2021-09-22]

46. Language philosophy. International Diabetes Federation (IDF). 2014. URL: https://diabetesmadrid.org/wp-content/uploads/2015/02/IDF-Language-philosophy-2.pdf [accessed 2021-09-22]

47. Speight J, Conn J, Dunning T, Skinner T, Diabetes Australia. Diabetes Australia position statement. A new language for diabetes: improving communications with and about people with diabetes. Diabetes Res Clin Pract 2012 Sep;97(3):425-431. [doi: 10.1016/j.diabres.2012.03.015] [Medline: 22513346]

48. Speight J, Skinner TC, Dunning T, Black T, Kilov G, Lee C, et al. Our language matters: improving communication with and about people with diabetes. A position statement by Diabetes Australia. Diabetes Res Clin Pract 2021 Mar;173:108655. [doi: 10.1016/j.diabres.2021.108655] [Medline: 33422586]

49. Skovlund SE, Nicolucci A, Balk-Møller N, Berthelsen DB, Glümer C, Perrild H, et al. Perceived benefits, barriers, and facilitators of a digital patient-reported outcomes tool for routine diabetes care: protocol for a national, multicenter, mixed methods implementation study. JMIR Res Protoc 2021 Sep 03;10(9):e28391 [FREE Full text] [doi: 10.2196/28391] [Medline: 34477563]

50. Stover AM, Haverman L, van Oers HA, Greenhalgh J, Potter CM, ISOQOL PROMs/PREMs in Clinical Practice Implementation Science Work Group. Using an implementation science approach to implement and evaluate patient-reported outcome measures (PROM) initiatives in routine care settings. Qual Life Res 2021 Nov;30(11):3015-3033 [FREE Full text] [doi: 10.1007/s11136-020-02564-9] [Medline: 32651805]

51. Nilsen P, Bernhardsson S. Context matters in implementation science: a scoping review of determinant frameworks that describe contextual determinants for implementation outcomes. BMC Health Serv Res 2019 Mar 25;19(1):189 [FREE Full text] [doi: 10.1186/s12913-019-4015-3] [Medline: 30909897]

52. Graneheim UH, Lindgren BM, Lundman B. Methodological challenges in qualitative content analysis: a discussion paper. Nurse Educ Today 2017 Sep;56:29-34. [doi: 10.1016/j.nedt.2017.06.002] [Medline: 28651100]

53. Polit D, Beck C. Nursing Research: Generating and Assessing Evidence for Nursing Practice. 10th edition. Philadelphia, PA, USA: Lippincott Williams and Wilkins; Dec 1, 2015.

54. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurse Educ Today 2004 Feb;24(2):105-112. [doi: 10.1016/j.nedt.2003.10.001] [Medline: 14769454]

55. Millward L. Focus groups. In: Breakwell GM, Hamond S, Fife-Schaw C, Smith JA, editors. Research Methods in Psychology. Thousand Oaks, CA, USA: SAGE Publications; 1995:274-292.

56. May C. Towards a general theory of implementation. Implement Sci 2013 Feb 13;8:18 [FREE Full text] [doi: 10.1186/1748-5908-8-18] [Medline: 23406398]

57. May CR, Mair F, Finch T, MacFarlane A, Dowrick C, Treweek S, et al. Development of a theory of implementation and integration: Normalization Process Theory. Implement Sci 2009 May 21;4:29 [FREE Full text] [doi: 10.1186/1748-5908-4-29] [Medline: 19460163]

58. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Med 2010 Oct 20;8:63 [FREE Full text] [doi: 10.1186/1741-7015-8-63] [Medline: 20961442]

59. McEvoy R, Ballini L, Maltoni S, O'Donnell CA, Mair FS, Macfarlane A. A qualitative systematic review of studies using the normalization process theory to research implementation processes. Implement Sci 2014 Jan 02;9:2 [FREE Full text] [doi: 10.1186/1748-5908-9-2] [Medline: 24383661]

60. Chen YT, Tan YZ, Cheen M, Wee HL. Patient-reported outcome measures in registry-based studies of type 2 diabetes mellitus: a systematic review. Curr Diab Rep 2019 Nov 20;19(11):135. [doi: 10.1007/s11892-019-1265-8] [Medline: 31748944]

61. Bak JC, Serné EH, Kramer MH, Nieuwdorp M, Verheugt CL. National diabetes registries: do they make a difference? Acta Diabetol 2021 Mar;58(3):267-278 [FREE Full text] [doi: 10.1007/s00592-020-01576-8] [Medline: 32770407]

Abbreviations

HCP: health care professional
NDR: National Diabetes Register

PAID: Problem Areas In Diabetes
PREM: patient-reported experience measure
PROM: patient-reported outcome measure

XSL•FO
RenderX

<u>Original Paper</u>

GoFundMe as a Medical Plan: Ecological Study of Crowdfunding Insulin Success

Julia E Blanchette[1], PhD; MJ Tran[1], BSN, MBA; Ernest G Grigorian[1], BS; Eli Iacob[1], PhD; Linda S Edelman[1], PhD; Tamara K Oser[2], MD; Michelle L Litchman[1], PhD

[1]College of Nursing, University of Utah, Salt Lake City, UT, United States

[2]Department of Family Medicine, University of Colorado School of Medicine, Aurora, CO, United States

Corresponding Author:
Michelle L Litchman, PhD
College of Nursing
University of Utah
10 2000 E
Salt Lake City, UT, 84112
United States
Phone: 1 801 585 9612
Email: Michelle.Litchman@nurs.utah.edu

Abstract

Background: Individuals in need of medical care turn to crowdfunding websites to engage a "crowd" or group for financial support. In the last decade, access to insulin has decreased considerably for several reasons, including the rising cost of insulin, increasing popularity of high-deductible insurance plans, and increasing insurance premiums. Many people with diabetes are forced to ration or go without insulin, and they turn to crowdfunding websites to seek financial donations to purchase insulin needed to reduce health risks and mortality, and sustain quality of life.

Objective: This study aimed to explore crowdfunding campaign requests to purchase insulin in the United States.

Methods: In this retrospective, quantitative, and qualitative study, we coded the text of GoFundMe online crowdfunding campaigns and viral measures (shares, hearts, and comments) from February 25 to April 15, 2019. We described campaigns (N=205) and explored the factors associated with campaign success using correlations and qualitative thematic analysis.

Results: The majority of campaigns were initiated by middle-aged adults (age 26-64 years; 77/205, 37.6%), those with type 1 diabetes (94/205, 45.9%), and those needing funds owing to insurance coverage issues (125/205, 61.0%). The factors associated with campaign success included requests for ≤US $500 (*P*=.007) and higher viral measures (shares, *P*=.007; hearts, *P*<.001; comments, *P*=.002). The following 4 themes emerged from the campaign text: (1) desire for self-management and survival, (2) diabetes management untenable given insulin access, (3) aftermath of insulin unaffordability, and (4) privacy issues with crowdfunding. Campaign comments were both supportive (tangible, informational, and emotional) and unsupportive (questioned the need for the campaign and deemed crowdfunding inappropriate).

Conclusions: Despite crowdfunding websites being used to support the purchase of insulin, campaigns raised only a fraction of the money requested. Therefore, GoFundMe campaigns are not a reliable solution to obtain funds for insulin in the United States. Applying quantitative and qualitative methods is adequate to analyze online crowdfunding for costs of medications such as insulin. However, it is critical for people with diabetes to use resources other than online crowdfunding to access and obtain insulin owing to low success rates. Clinicians should routinely assess difficulty accessing or affording insulin, and federal health care policies should support lowering the cost of insulin.

(JMIR Diabetes 2022;7(2):e33205)   doi:10.2196/33205

XSL•FO
RenderX

Introduction

All people living with type 1 diabetes and many with type 2 diabetes require insulin to sustain life. People with diabetes are at higher risk for diabetes-related complications and death if they cannot access insulin, even for short intervals. In the last decade, access to insulin has declined considerably due to a myriad of causes, including the rising cost of insulin, increasing health insurance premiums, and increasing popularity of high-deductible insurance plans [1,2].

The price of insulin per unit doubled between 2012 and 2016 [2]. Additionally, close to 9% of the US population was without health insurance in 2017 [3]. Despite Medicaid expansion, which has greatly increased insurance access for lower income adults under the age of 65 years, other insurance barriers hinder insulin affordability. Due to the high cost of insulin, it is difficult for people with diabetes without insurance or with private high-deductible insurance plans to pay for insulin. Cost-related insulin rationing occurs in 1 in 4 people with diabetes and has been associated with detrimental impacts on glycemic outcomes [4]. In addition to health consequences, difficulty affording insulin can contribute to significant financial stress and medical bankruptcy [5].

Insulin access and affordability are critical barriers to preventing acute and long-term diabetes complications, yet people with diabetes report lack of support and resources from health care providers, pharmaceutical companies, insurance companies, hospital systems, and pharmacies [6]. Consequently, some people with diabetes are turning to social media crowdfunding as an attempt to relieve financial stress and obtain insulin. Crowdfunding campaigns aim to raise money for medical care and avoid bankruptcy through websites shared via social networks [7,8]. GoFundMe represents the largest charitable crowdfunding platform and dominates the global medical crowdfunding market [9].

About 8 million Americans have turned to online crowdfunding for medical expenses, and 50 million have reported donating to such campaigns, most commonly in states without Medicaid expansion [10,11]. Much of the current research focuses on the spread of misinformation on crowdfunding sites [12] and campaigns for experimental cures for certain types of cancers [13]. The factors related to successful campaigns for the medical costs of organ transplants include campaigns led by family members or friends rather than the individual in need, longer campaign length, higher funding goals, and greater "hearts" and shares on social media [14]. However, campaigns for people from historically marginalized racial and gender groups are associated with poorer fundraising outcomes [15]. Overall, as few as 8% of campaigns successfully fund the goal amount requested [11,16,17]. Despite low success rates, GoFundMe campaigns remain a popular platform for Americans with various medical needs and costs.

Online crowdfunding has not been well studied in people with diabetes despite its prevalence and the high cost of insulin [18]. More research is necessary to understand the specific rationales for seeking crowdfunding for diabetes care, such as insulin therapy, and to understand if crowdfunding is a successful solution for increasing insulin access [18]. In light of the dramatic rise in insulin cost, this study aims to explore GoFundMe crowdfunding requests for insulin.

Methods

Data Sources

The data sources for this ecological study included (1) GoFundMe Campaigns (campaigns), a US-based website for crowdfunding, (2) Face++, a facial recognition (FR) software [19], and (3) the 2017 United States Census. Face++ data were used when age and/or gender were not stated in the campaign. Ideally, we would have collected race from the Face++ software, but race detection was recently removed as a software feature. Data were collected between February 25, 2019, and April 15, 2019. All campaigns included were closed and no longer accepting donations at the time of data collection.

To be included in this study, GoFundMe campaigns had to focus on crowdfunding to purchase insulin for humans, be initiated in the United States given the differences in insurance access, and be written in English. Each campaign website specifies the location, including the country of origin. Campaigns were excluded if they primarily focused on noninsulin diabetes medications, glucometers, glucometer test strips, insulin pumps, or continuous glucose monitors without mentioning insulin, or requested funds for an animal with diabetes. Several search terms were analyzed to determine the search strategy. Given the focus on access to insulin, the term "insulin" and brand names of insulin, including misspellings (ie, Lantus and Lantis) were included in the initial search.

Ethics Approval

The University of Utah Institutional Review Board acknowledged this study as nonhuman research (#00105240).

Data Collection Measures

We used Research Electronic Data Capture (REDCap), a web-based study management system [20], to build an online survey for the researchers to extract quantitative and qualitative data about each campaign meeting the study criteria.

Age

"Actual age" was extracted from the campaign, when available, and photos were uploaded to the Face++ software if values were missing ("FR age"). It is important to note that not every campaign had a facial photograph of the recipient (eg, landscape and flower). Age was categorized as pediatric (≤17 years), young adult (18-25 years), adult (26-64 years), and older adult (≥65 years). Correlation (r) between actual age and FR age was 0.395 (P=.003). Face++ detected the age group for 87 of the 139 missing data cases or 42.4% of the total sample. Overall, 52 (25%) campaigns had missing photos or undetectable age by Face++.

Gender

"Actual gender" was extracted from the campaign by coding pronouns. Campaigns were coded as male if the individual requiring insulin was referenced as he, him, his, dad, brother, uncle, or grandfather. Campaigns were coded as female if the

individual requiring insulin was referenced as she, her, hers, mom, sister, aunt, or grandmother. Campaigns were coded as nonbinary if the individual requiring insulin was referenced as they or them. Face++ facial detection software was used to code campaign photos as male or female ("FR gender") when gender was not available in the text. The correlation (r) between actual gender and FR gender was 0.926 ($P<.001$). Face++ detected gender for 31 of the 68 missing data cases or 15% of the total sample. Overall, 37 (18%) campaigns had missing photos or undetectable gender by Face++.

Flesch-Kincaid Education

A Flesch-Kincaid score was identified to understand the education level in which the campaign was written. Scores were analyzed as a continuous variable (grade 0 to ≥13).

Income

Based on the city and state where the campaign originated, the city- and state-level median income and percentage of residents at the poverty level were extracted from the 2017 US Census.

Geographic Designation

Based on the city where the campaign originated, city population size was extracted from the 2017 US Census. County of residence was determined for each campaign and assigned a Rural-Urban Continuum Code (RUCC), and the codes were then collapsed into metro (RUCC codes 1-3), urban (RUCC codes 4-7), and rural (RUCC codes 8-9) categories [21].

Insurance Status

Based on the state where the campaign originated, state Medicaid expansion status (yes/no) and the percentage of the state uninsured population were extracted from the 2017 US Census.

Financial Information

The amount of funds requested, amount of funds raised, time (months) the account was active, and number of funders were extracted from the campaigns.

Viral Information

The number of shares on Facebook and Twitter combined and number of hearts on the GoFundMe website were extracted from the campaigns.

Campaign Initiator

Information about the campaign requestor was extracted from the campaign, including the relationship to the people with diabetes requiring insulin (self, friend or family, and other) and geographic location (city and state).

Rationale for Request

The campaigns were coded for the following rationales: uninsured or inadequate insurance, change in personal finance, personal emergency, general fundraising, or other. Multiple categories could be selected. The brand name of insulin, when mentioned, was coded.

Qualitative Data

The entire text of the campaign and the associated comments were extracted separately.

Statistical Analysis

Data were exported into SPSS (IBM Corp) for analysis. Since multiple search terms were used to identify the campaigns, duplicate campaigns were removed before analysis. A total of 44 duplicate campaigns were removed before data analysis. One outlier for the number of funds requested (US $1,000,000.00) was removed due to the extreme amount.

Descriptive statistics, including frequencies, were tabulated. Missing data were handled pairwise. The following research questions (RQs) guided the analysis: (1) Who started the campaign? (2) What was the purpose of the campaign? (3) What was the success of the campaign? (4) What factors were associated with campaign success?

A qualitative content analysis of campaign posts and comments was conducted for RQ1 and RQ2. Two independent researchers read textual data, line by line, and coded the data using an open code approach [22,23]. Codes were used to organize similar data to identify the rationale for the campaign and commenter responses [22]. A matrix of the types of support offered by commenters was developed. A third author facilitated consensus to establish credibility. Given the sensitivity of the topic and the fact that campaign requestors developed some campaigns without the knowledge of people with diabetes, no direct quotes were used in this manuscript to protect possible identification. Student t tests and Fisher exact tests were used for RQ3 and RQ4 to describe the factors associated with campaign success rates. Fisher exact tests were used for associations due to categorical data and small frequencies in the fully funded categories.

Results

Sample

A total of 1623 campaigns were reviewed, and 249 met the inclusion criteria. After removing 44 duplicates, a total of 205 GoFundMe campaigns were included in the final analysis.

The Face++ software could not predict age and gender when the photograph quality was poor or when the campaign did not include a photograph. Age and gender predictions from Face++ software were highly correlated with age ($r=0.395$; $P=.003$) and gender ($r=0.926$; $P<.001$) stated in the campaigns, when available.

Campaigns for people residing in the southern United States (100/205, 48.8%) and in metro geographic locations (176/205, 85.9%) were the most frequent. Table 1 provides demographic characteristics, and Table 2 provides diabetes-specific and campaign characteristics. Figure 1 provides a geographic heatmap of campaigns.

Table 1. Sample demographic characteristics with the Fisher exact test to examine contributors to the funding status (N=205, unless otherwise specified).

Variable	Fully funded (n=22), n (%)	Not funded (n=183), n (%)	Total (N=205), n (%)	P (Fisher exact test)
Requestor				N/A[a,b]
Self	9 (41)	105 (57)	114 (56)	
Family or friend	10 (46)	62 (34)	72 (35)	
Other	3 (14)	16 (9)	19 (9)	
Gender[c]				N/A
Male	13 (59)	63 (34)	76 (37)	
Female	5 (23)	87 (48)	92 (45)	
Unable to determine (no photo/poor quality photo)	4 (18)	33 (18)	37 (18)	
Age group[c]				N/A
Pediatric (<18 years)	0 (0)	12 (7)	12 (6)	
Emerging adult (18-25 years)	1 (5)	35 (19)	36 (18)	
Middle adult (26-64 years)	9 (41)	68 (37)	77 (38)	
Older adult (≥65 years)	6 (27)	22 (12)	28 (14)	
Unable to determine (no photo/poor quality photo)	6 (27)	46 (25)	52 (25)	
US region				N/A
West	5 (23)	30 (16)	35 (17)	
Midwest	7 (32)	45 (25)	52 (25)	
Northeast	2 (9)	16 (9)	18 (9)	
South	8 (36)	92 (50)	100 (49)	
Medicaid expansion state				.82
Yes	13 (59)	101 (55)	114 (56)	
No	9 (41)	82 (45)	91 (44)	
Flesch-Kincaid education score				.82
≤8	13 (59)	113 (62)	126 (62)	
9+	9 (41)	70 (38)	79 (39)	

[a]N/A: not applicable.

[b]Did not analyze the data with the Fisher exact test owing to more than 20% missing data.

[c]Face++ facial recognition software was used to determine the approximate age and gender of GoFundMe recipients when age and gender were not available.

Table 2. Campaign and diabetes-specific characteristics with the Fisher exact test to examine contributors to the funding status (N=205, unless otherwise specified).

Variable	Fully funded (n=22), n (%)	Not funded (n=183), n (%)	Total (N=205), n (%)	P (Fisher exact test)
Type of diabetes				N/A[a,b]
Type 1 or latent autoimmune diabetes in adults	10 (46)	84 (46)	94 (46)	
Type 2	2 (9)	17 (9)	19 (9)	
Gestational	0 (0)	2 (1)	2 (0)	
Unknown	10 (46)	80 (44)	90 (44)	
Reason for request				N/A
Insurance/system issue (uninsured, underinsured)	12 (55)	113 (62)	125 (61)	
Personal issue (loss of job, emergency)	1 (5)	10 (6)	11 (5)	
General fundraiser	8 (26)	41 (22)	49 (24)	
Insurance/system and personal issue	1 (5)	19 (10)	20 (10)	
Insulin type[c]				N/A[c]
Fast-acting (Apidra, Admelog, Fiasp, Afrezza)	2 (9)	50 (23)	52 (21)	
Long-acting (Lantus, Levemir, Basaglar, Toujeo, Tresiba)	2 (9)	39 (18)	41 (17)	
Intermediate/mixed/regular (neutral protamine hagedorn insulin [NPH], insulin regular human [R])	0 (0)	15 (7)	15 (6)	
Concentrated (Humalog U200, U500)	1 (4)	3 (1)	4 (2)	
Other	0 (0)	1 (1)	1 (0)	
Unknown	18 (78)	114 (51)	132 (54)	
Insulin requests				N/A
One or more types requested	4 (18)	69 (38)	73 (36)	
Unknown	18 (81)	114 (62)	132 (64)	
Medicare donut				.74
Yes	3 (14)	22 (12)	25 (12)	
No or not mentioned	19 (86)	161 (88)	180 (88)	
Disability status				>.99
Yes	2 (9)	16 (9)	18 (9)	
No or not mentioned	20 (91)	167 (91)	187 (91)	
Pharma support[d]				N/A
Requested and rejected	1 (5)	9 (5)	10 (5)	
Not mentioned (unknown)	21 (96)	174 (95)	19 (95)	
Request amount				.007
≤US $500	9 (41)	28 (15)	22 (11)	
>US $500	13 (59)	155 (85)	183 (89)	
Funding length				.82
<3 months	7 (32)	68 (37)	75 (37)	
≥3 months	15 (68)	116 (63)	130 (63)	

[a]N/A: not applicable.

[b]Did not analyze with the Fisher exact test owing to more than 20% missing data.

[c]For this variable, the N values for fully funded, not funded, and total were 23, 222, and 245, respectively.

[d]N is >205, as some requests were more than one.

Figure 1. Geographic heat map of GoFundMe campaigns.
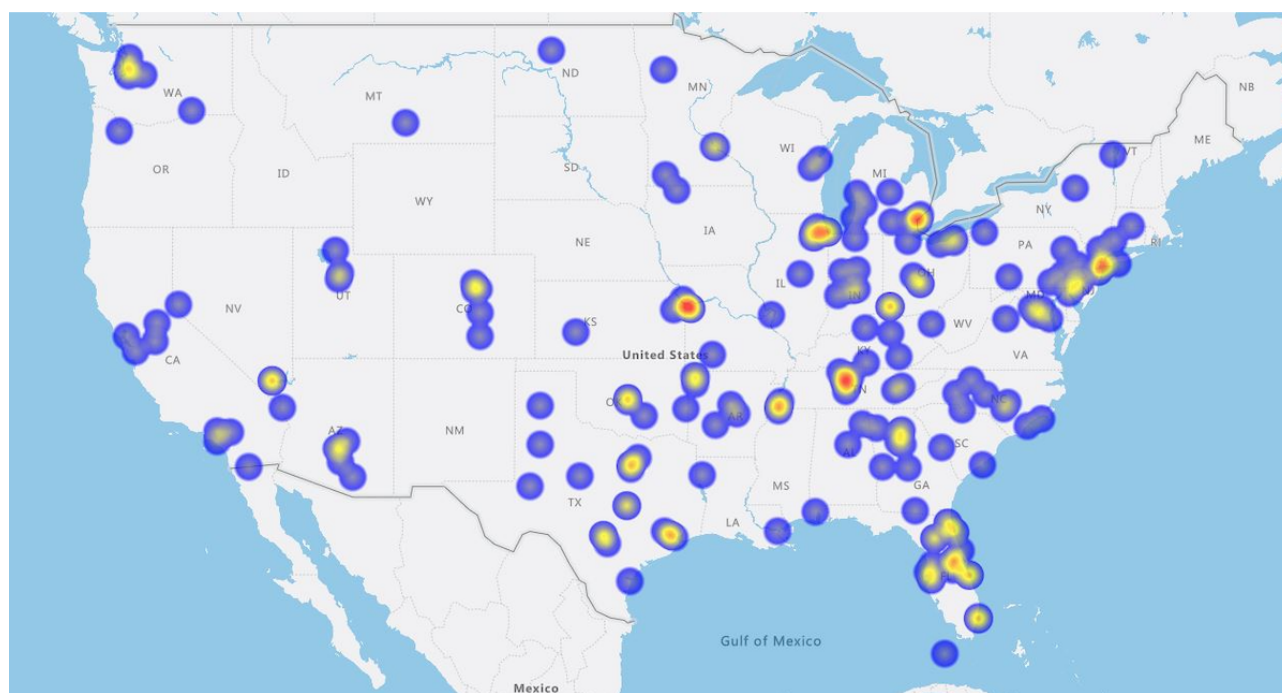
Income Descriptive

Campaign requestors originated from cities and states with median poverty levels of 17.36% (range 0.70%-47.20%) and 14.99% (range 9.70%-21.50%), respectively, based on the 2019 United States Census. The median household incomes in the cities and states of the requestors were US $52,639.86 (range US $27,838-$124,922) and US $55,537.48 (range US $42,009-$78,916), respectively, which were below the 2019 national average income of US $68,703.

Viral Measures

Campaigns received support through several donors (median 9, range 0-116) and shares (median 9, range 0-742). However, campaigns had a median of 0 (range 0-20) comments and a median of 2 (range 0-70) hearts.

RQ1: Who Started the Campaign?

The campaign requestor was commonly the person with diabetes in need of funds (114/205, 55.6%), followed by family members (46/205, 22.4%). Friends (26/205, 12.7%) less commonly requested funds. Requests were most frequently for people in the age group of 26-64 years (80/205, 39.0%), with the majority who specified diabetes type (n=115) having type 1 diabetes (94/115, 81.7%).

RQ2: What Was the Purpose of the Campaign?

About half of the campaigns (99/205, 48.3%) described how long the funds would last. Of those, 29% (29/99) needed quick funds to cover cost needs for <3 months, while 71% (70/99) needed funds that would last ≥3 months.

The most common campaign purpose was to fund insulin for people with diabetes having no insurance or inadequate insurance coverage, or an insurance system issue (125/205, 61.0%), followed by general fundraising (49/205, 23.9%), personal and insurance issues (20/205, 9.8%), and personal issues (loss of job or emergency) (11/205, 5.4%).

Just under half of the requestors lived in non-Medicaid expansion states (91/205, 44.4%). Cost issues related to the Medicare gap were reported in 12.2% (25/205) of campaigns.

A total of 245 insulin requests were made as some people with diabetes used 2 types of insulin. Fast-acting insulin (Novolog, Humalog U100, Apidra, Admelog, Fiasp, and Afrezza) was the most commonly requested (52/245, 21.2%), followed by long-acting insulin (Lantus, Levemir, Basaglar, Toujeo, and Tresiba) (41/245, 16.7%). The remaining types of insulin requested were intermediate-acting, mixed, or regular insulin (15/245, 6.1%), or concentrated insulin (4/245, 1.6%). Most insulin types (132/245, 53.9%) were not specified.

RQ3: What Was the Success of the Campaign?

Campaign goals ranged from US $50 to US $200,000 (median US $1100), while the amount raised ranged from US $0 to US $6920 (median US $65). Over one-third (77/205, 37.6%) of campaigns raised US $0, while just over 10% (22/205, 10.7%) of campaigns were fully funded. The top quartile of campaigns raised only 33.4% of the requested funds, although the range of funding was 0% to 583% (median 4%).

RQ4: What Factors Were Associated With Campaign Success?

The amount of money raised correlated with all viral measures, including the number of shares (median 9, range 0-742; $U=1319.50$; $P=.007$), number of hearts (median 2, range 0-70; $U=614.50$; $P<.001$), and number of comments (median 0, range

0-20; *U*=1061; *P*=.002). Factors, including Medicaid expansion state, Flesch-Kincaid education, Medicare donut hole status, disability status, and funding length, were not significantly associated with success in raising funds. Requests ≤US $500 were more likely to receive funding (Fisher exact *P*=.007). See Tables 1 and 2 for more information.

Qualitative Analysis of Campaign Posts

Campaign requestors described a myriad of issues surrounding the cost of insulin and privacy issues related to crowdfunding in general.

Desire for Self-management and Survival

Campaigns were often started because people with diabetes actively wanted to participate in diabetes self-management, yet lacked the funds. Themes included wanting to manage diabetes to be healthy enough to care for young children and contributing to society by continuing effective diabetes self-management that is critical to being a productive employee.

Campaign requestors emphasized that obtaining funds to afford insulin was the key to avoiding hospitalization and described how an emergency room visit or inpatient hospital stay would only exacerbate costs for those already struggling to afford insulin.

Alongside avoiding hospitalization, campaign requestors emphasized their desire to live and prevent premature death. Some campaign requestors narrated who they wanted to live for (emphasizing family), why their life mattered (how they contribute to society), what they wanted to continue doing with their lives (work, hobbies, caretaking, etc), and how insulin was necessary to avoid death.

As there are different types of insulin on the market, some campaign requestors overtly rationalized their need for brand-name insulin. Examples of needing brand-name insulin most often focused on a better biophysical response to brand-name insulin than generic insulin. Not all campaigns rationalized why brand-name insulin was desired.

Lack of Insulin Access Makes Diabetes Management Untenable

Insulin access issues were described regardless of insurance status. Some people with diabetes were waiting for new insurance to initiate. Others had recently lost a job and insurance benefits, aged out of Medicaid and were without parent insurance coverage before the age of 26 years, or were disabled and waiting for disability insurance to initiate. Those who described being underinsured included those experiencing the Medicare gap coverage ("donut hole") or a coverage gap in which there is a temporary limit on what the insurance plan covers after a certain amount of medication costs have already been paid for in a given year. Some with coverage described "fighting" or "going to battle" with insurance about insulin costs without success. Campaign requestors described applying for various discount or financial assistance programs and being denied or not given enough money.

Some campaign requestors described a new diabetes diagnosis after hospitalization. In few cases, the campaigns were developed before the people with diabetes were discharged from the hospital. The sudden expense of hospitalization, in addition to a new or ongoing insulin expense, was overwhelming and financially challenging. The people with diabetes were discharged without a way to cover insulin costs and were fearful they would be readmitted to the hospital.

At times, campaign requestors mentioned that insulin competed with other financial interests, such as addressing personal emergencies (flood in the basement of their home, broken down car, etc) and basic expenses (rent, food, and utilities). In few instances, family member health expenses for conditions, such as cancer, drained family finances and left no money for insulin. Additionally, some people with diabetes in single-income households reported decreased access to resources in general.

Some people with diabetes reported that a specific brand of insulin was more effective, yet insurance only covered an alternative brand. Other people with diabetes described difficulty managing blood glucose when using generic insulin (regular and neutral protamine hagedorn) compared with brand-name insulin. Conversely, some individuals used generic insulin but still could not afford it.

The Aftermath of Insulin Unaffordability

When people with diabetes could not afford insulin, the campaign requestors described rationing insulin doses and/or food to avoid diabetic ketoacidosis and fear of dying. Some people with diabetes reported feeling too sickly to attend work or school due to hyperglycemia from insulin rationing.

Some people with diabetes who could not afford insulin went to the emergency room to treat hyperglycemia as a quick solution, leading to additional health care expenses, despite obtaining no-cost insulin coupons or insulin from that visit. Other people with diabetes described alternative ways to access insulin, such as engaging in online insulin trading and seeking insulin donations. In one case, a person with diabetes described having an "insulin dealer" who provided insulin at a cheaper cost than when using insurance.

Privacy Issues With Crowdfunding

Many people with diabetes described feeling embarrassed and desperate for resorting to GoFundMe to support their health costs. Campaign requestors who were family members or friends expressed feeling self-conscious or awkward about putting their loved ones with diabetes in the spotlight to get assistance for them.

Qualitative Analysis of Comments

The majority of campaigns (125/205, 61.0%) had 0 comments, followed by 1-3 comments (58/205, 28.3%) and ≥4 comments (22/205, 10.7%). There were 191 comments across campaigns that were supportive and unsupportive. Supportive comments provided tangible, informational, or emotional support. Unsupportive comments questioned the need for the campaign or stated that the campaign was inappropriate. Table 3 provides examples of comments.

Table 3. Types of comments provided by commenters.

Comment type	Examples of comments provided by commenters
Supportive	
Tangible support	• Described how much financial support they contributed to the campaign • Offered to donate insulin vials/pens via mail or meeting with the people with diabetes • Described how they knew the campaign requestor and suggested that others within their social network donate as well
Informational support	• Provided information about where nonanalog generic insulin could be purchased (ie, Walmart for approximately US $25/vial) • Provided links to websites with insulin assistance options (ie, coupons or patient assistance programs) • Recommended that people with diabetes reach out to health care providers for insulin samples
Emotional support	• Provided well wishes for campaign success • Offered prayers for the people with diabetes • Described they were people with diabetes and understood what people with diabetes in need were going through
Unsupportive	
Questioned need	• Questioned the financial need for a campaign noting that the people with diabetes could afford insulin • Raised concern that the campaign was a "scam" (note that in some instances, the campaign requestor would reply with a photo of the diabetes supplies to indicate there was an actual need)
Crowdfunding is inappropriate	• Described GoFundMe as an inappropriate avenue for financial support for diabetes self-management needs

Discussion

Principal Findings

To our knowledge, this is the first study to examine crowdfunding requests for insulin. The high cost of insulin places a significant burden on people with diabetes and their supporters, who seek crowdfunding as a solution to raise funds to purchase insulin. We found that the overwhelming majority of campaigns were not fully funded.

About half of the campaigns originated from the southern United States in our study. While it is possible that crowdfunding is more prevalent in southern states, 44.4% of campaigns were started in states without Medicaid expansion. Though there is evidence that the cost of insulin affects all age groups [4], we found that over half of the campaigns were developed for individuals in middle adulthood. Middle adulthood is a time of the greatest financial stability, yet living with diabetes can greatly impact finances, marriage/divorce, raising and launching children, living with bad credit, employment, or medical insurance coverage, or result in exiting the workforce [6,24]. Additionally, those in middle adulthood are less likely to qualify for federal or state insurance programs compared with children and older adults.

Many people with diabetes are desperately trying to identify alternative ways to access insulin owing to its current cost. As identified by other researchers [6], our findings highlight the desire for engaging in diabetes self-management and emphasize the need to avoid hospitalization and prevent additional health care debt. The few fully funded campaigns were associated with requesting ≤US $500. These findings differ from those of previous studies showing that higher funding amounts resulted in greater campaign success. However, previous studies highlighted campaigns for major medical procedures, such as organ transplantation, or costly cancer treatments. As insulin is a life-long and ongoing cost, smaller requests ≤US $500 were likely for 1 month or less of insulin supply. In the context of the total cost of insulin, these small funds may only serve as a "band-aid" to the exorbitant costs endured by insulin users.

The majority of requests were for brand-name insulin. While it was clear some people with diabetes in this study knew they would not respond well to generic insulin, others may have been unaware of the generic insulin option. Some commenters offered informational support about the cost of generic insulin and tangible support via insulin donations. Recent research indicates that some people with diabetes engage in the underground exchange of diabetes medications and supplies with online strangers, including insulin donations [6,25].

Our findings indicate that viral measures correlated with money raised by the campaign. Others have found that successful crowdfunding campaigns leverage collective endorsements through close online networks [6,26], though strangers also donate [27]. Close networks may feel social pressure to donate, even when in a position where they cannot afford to contribute [27]. Individuals without close online networks or those who are digitally and/or linguistically illiterate contribute to a rise in health care disparities [11]. Importantly, campaign requestors and donors may not understand that fees from donations are deducted or understand the validation process required to receive funds.

XSL•FO

RenderX

Though crowdfunding can temporarily increase access to insulin, ethical issues related to crowdfunding for diabetes care exist [28-30]. For example, crowdfunding websites encourage photos, videos, and ongoing updates, resulting in loss of privacy. Although recent evidence suggests that some campaign requestors weigh the need for financial support over the need for privacy [31], we found that nearly one-fourth of campaign requestors were family members or friends. As such, people with diabetes may not be aware of or control what information is shared about them. There is also the possibility of phony crowdfunding accounts to solicit funds.

Limitations

This study must be interpreted in the context of its limitations. Due to the public nature of the content, some data were limited. We were unable to gather specific clinical characteristics, such as HbA_{1c} and hospitalizations. We were also unable to code insulin pump status, which could influence the number of insulins requested. We also encountered some missing data, such as age and gender. While we could impute age and gender when missing among those with facial photographs using FR software, there were limitations to imputing age. The correlation between provided age and Face++ recognition was only moderate, and due to missing information, we used Face++ age

for about 40% of the sample. As insurance coverage and financial stressors vary by age group, it was essential for us to provide age group. However, age group was provided for descriptive purposes only and not used in further statistical analysis. Another limitation of Face++ imputation was the inability to identify race and ethnicity. Finally, we were only able to analyze active campaigns and therefore were unaware if individuals repeatedly started new campaigns.

Conclusions

Applying quantitative and qualitative methods to analyze online GoFundMe campaigns is effective for understanding success in online crowdfunding for health care and medication costs such as insulin. As purchasing insulin is untenable to many people with diabetes owing to its high cost, crowdfunding through websites, such as GoFundMe, may raise a small amount of money to work as a temporary solution for purchasing insulin, but may not be considered a reliable resource to purchase insulin in the long term. Clinicians must ask people with diabetes if they have difficulty accessing or affording insulin and provide resources at appointments. Additionally, it is essential to focus on solutions, such as health care reform and health care policies, that support lowering the cost of insulin, particularly at the federal level. Hence, all people with diabetes who use insulin should have access to their life-sustaining medication.

Authors' Contributions

MLL conceived the study with support from LSE and TKO. JEB, MJT, and EGG performed data collection. Quantitative analysis was performed by JEB and MLL with oversight by EI. Qualitative analysis was conducted by MLL and MJT. All authors contributed to writing the manuscript and the final edit.

References

1. Luo J, Avorn J, Kesselheim AS. Trends in Medicaid Reimbursements for Insulin From 1991 Through 2014. JAMA Intern Med 2015 Oct 01;175(10):1681-1686. [doi: 10.1001/jamainternmed.2015.4338] [Medline: 26301721]
2. Peter P, Lipska K. The rising cost of diabetes care in the USA. The Lancet Diabetes & Endocrinology 2016 Jun;4(6):479-480 [FREE Full text] [doi: 10.1016/S2213-8587(15)00519-7] [Medline: 27156052]
3. Berchick ER, Hood E, Barnett JC. Health Insurance Coverage in the United States: 2017. U.S. Census Bureau. Washington, DC: U.S. Government Printing Office; 2018. URL: https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-264.pdf [accessed 2022-04-05]
4. Herkert D, Vijayakumar P, Luo J, Schwartz JI, Rabin TL, DeFilippo E, et al. Cost-Related Insulin Underuse Among Patients With Diabetes. JAMA Intern Med 2019 Jan 01;179(1):112-114 [FREE Full text] [doi: 10.1001/jamainternmed.2018.5008] [Medline: 30508012]
5. Dickman SL, Himmelstein DU, Woolhandler S. Inequality and the health-care system in the USA. The Lancet 2017 Apr;389(10077):1431-1441. [doi: 10.1016/s0140-6736(17)30398-7]
6. Willner S, Whittemore R, Keene D. "Life or death": Experiences of insulin insecurity among adults with type 1 diabetes in the United States. SSM Popul Health 2020 Aug;11:100624 [FREE Full text] [doi: 10.1016/j.ssmph.2020.100624] [Medline: 32676533]
7. Bassani G, Marinelli N, Vismara S. Crowdfunding in healthcare. J Technol Transf 2018 Apr 20;44(4):1290-1310. [doi: 10.1007/s10961-018-9663-7]

XSL•FO

RenderX

8. Burtch G, Chan J. Reducing medical bankruptcy through crowdfunding: Evidence from GiveForward. 2014 Presented at: 35th International Conference on Information Systems "Building a Better World Through Information Systems", ICIS 2014; December 14-17, 2014; Auckland, New Zealand URL: https://experts.umn.edu/en/publications/reducing-medical-bankruptcy-through-crowdfunding-evidence-from-gi-2

9. Pol SJ, Snyder J, Anthony SJ. "Tremendous financial burden": Crowdfunding for organ transplantation costs in Canada. PLoS ONE 2019 Dec 20;14(12):e0226686. [doi: 10.1371/journal.pone.0226686]

10. Millions of Americans Donate through Crowdfunding Sites to Help Others Pay for Medical Bills. NORC at the University of Chicago. URL: https://www.norc.org/NewsEventsPublications/PressReleases/Pages/millions-of-americans-donate-through-crowdfunding-sites-to-help-others-pay-for-medical-bills.aspx [accessed 2022-04-05]

11. Berliner LS, Kenworthy NJ. Producing a worthy illness: Personal crowdfunding amidst financial crisis. Soc Sci Med 2017 Aug;187:233-242. [doi: 10.1016/j.socscimed.2017.02.008] [Medline: 28274601]

12. Zenone M, Snyder J, Caulfield T. Crowdfunding Cannabidiol (CBD) for Cancer: Hype and Misinformation on GoFundMe. Am J Public Health 2020 Oct;110(S3):S294-S299. [doi: 10.2105/ajph.2020.305768]

13. Loeb S, Taneja S, Walter D, Zweifach S, Byrne N. Crowdfunding for prostate cancer and breast cancer. BJU Int 2018 Nov 13;122(5):723-725. [doi: 10.1111/bju.14408] [Medline: 29786946]

14. Durand WM, Peters JL, Eltorai AEM, Kalagara S, Osband AJ, Daniels AH. Medical crowdfunding for organ transplantation. Clin Transplant 2018 Jun 15;32(6):e13267. [doi: 10.1111/ctr.13267] [Medline: 29683220]

15. Kenworthy N, Dong Z, Montgomery A, Fuller E, Berliner L. A cross-sectional study of social inequities in medical crowdfunding campaigns in the United States. PLoS One 2020 Mar 5;15(3):e0229760 [FREE Full text] [doi: 10.1371/journal.pone.0229760] [Medline: 32134984]

16. Thomas HS, Lee AW, Nabavizadeh B, Namiri NK, Hakam N, Martin-Tuite P, et al. Characterizing online crowdfunding campaigns for patients with kidney cancer. Cancer Med 2021 Jul 08;10(13):4564-4574 [FREE Full text] [doi: 10.1002/cam4.3974] [Medline: 34102000]

17. Joseph Mattingly T, Li K, Ng A, Ton-Nu T, Owens J. Exploring Patient-Reported Costs Related to Hepatitis C on the Medical Crowdfunding Page GoFundMe®. Pharmacoecon Open 2021 Jun 30;5(2):245-250 [FREE Full text] [doi: 10.1007/s41669-020-00232-9] [Medline: 32997279]

18. Snyder J, Mathers A, Crooks VA. Fund my treatment!: A call for ethics-focused social science research into the use of crowdfunding for medical care. Soc Sci Med 2016 Nov;169:27-30. [doi: 10.1016/j.socscimed.2016.09.024] [Medline: 27665200]

19. Face Detection. Face Plus Plus. URL: https://www.faceplusplus.com/face-detection/ [accessed 2022-04-05]

20. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]

21. Rural-Urban Continuum Codes. Economic Research Service U.S. Department of Agriculture. URL: https://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx [accessed 2022-04-05]

22. Morgan DL. Qualitative content analysis: a guide to paths not taken. Qual Health Res 1993 Feb 01;3(1):112-121. [doi: 10.1177/104973239300300107] [Medline: 8457790]

23. Sandelowski M. Whatever happened to qualitative description? Res. Nurs. Health 2000 Aug;23(4):334-340. [doi: 10.1002/1098-240x(200008)23:4<334::aid-nur9>3.0.co;2-g]

24. Kayser K, Smith L, Washington A, Harris LM, Head B. Living with the financial consequences of cancer: A life course perspective. Journal of Psychosocial Oncology 2020 Sep 02;39(1):17-34. [doi: 10.1080/07347332.2020.1814933]

25. Litchman ML, Oser TK, Wawrzynski SE, Walker HR, Oser S. The Underground Exchange of Diabetes Medications and Supplies: Donating, Trading, and Borrowing, Oh My!. J Diabetes Sci Technol 2020 Nov 04;14(6):1000-1009 [FREE Full text] [doi: 10.1177/1932296819888215] [Medline: 31801370]

26. Kim ES, Kawachi I, Chen Y, Kubzansky LD. Association Between Purpose in Life and Objective Measures of Physical Function in Older Adults. JAMA Psychiatry 2017 Oct 01;74(10):1039-1045 [FREE Full text] [doi: 10.1001/jamapsychiatry.2017.2145] [Medline: 28813554]

27. Kim JG, Vaccaro K, Karahalios K, Hong H. "Not by Money Alone": Social Support Opportunities in Medical Crowdfunding Campaigns. In: CSCW '17: Proceedings of the 2017 ACM Conference on Computer Supported Cooperative Work and Social Computing. 2017 Presented at: ACM Conference on Computer Supported Cooperative Work and Social Computing; February 25, 2017-March 1, 2017; Portland, OR, USA p. 1997-2009. [doi: 10.1145/2998181.2998245]

28. Snyder J, Chow-White P, Crooks VA, Mathers A. Widening the gap: additional concerns with crowdfunding in health care. The Lancet Oncology 2017 May;18(5):e240. [doi: 10.1016/s1470-2045(17)30259-0]

29. Snyder J. Crowdfunding FOR MEDICAL CARE: Ethical Issues in an Emerging Health Care Funding Practice. Hastings Cent Rep 2016 Nov 22;46(6):36-42. [doi: 10.1002/hast.645] [Medline: 27875643]

30. Young MJ, Scheinberg E. The Rise of Crowdfunding for Medical Care: Promises and Perils. JAMA 2017 Apr 25;317(16):1623-1624. [doi: 10.1001/jama.2017.3078] [Medline: 28334321]

31.   Gonzales AL, Kwon EY, Lynch T, Fritz N. "Better everyone should know our business than we lose our house": Costs and benefits of medical crowdfunding for support, privacy, and identity. New Media & Society 2016 Sep 07;20(2):641-658. [doi: 10.1177/1461444816667723]

Abbreviations

FR: facial recognition
RQ: research question
RUCC: Rural-Urban Continuum Code

[XSL•FO]

RenderX

Review

Identifying Patients With Hypoglycemia Using Natural Language Processing: Systematic Literature Review

Yaguang Zheng[1], PhD; Victoria Vaughan Dickson[1], PhD; Saul Blecker[2], MHS, MD; Jason M Ng[3], MD; Brynne Campbell Rice[4], MA, MSLIS, MS; Gail D'Eramo Melkus[1], EdD; Liat Shenkar[5], BS; Marie Claire R Mortejo[1], BSN; Stephen B Johnson[2], PhD

[1]Rory Meyers College of Nursing, New York University, New York, NY, United States

[2]Department of Population Health, Grossman School of Medicine, New York University, New York, NY, United States

[3]Division of Endocrinology and Metabolism, Department of Medicine, University of Pittsburgh, Pittsburgh, PA, United States

[4]Division of Libraries, New York University, New York, NY, United States

[5]Lehigh Valley Health Network, Lehigh Valley Reilly Children's Hospital, Allentown, PA, United States

Corresponding Author:
Yaguang Zheng, PhD
Rory Meyers College of Nursing
New York University
433 1st Avenue
New York, NY, 10010
United States
Phone: 1 212 998 5170
Email: yaguang.zheng@nyu.edu

Abstract

Background: Accurately identifying patients with hypoglycemia is key to preventing adverse events and mortality. Natural language processing (NLP), a form of artificial intelligence, uses computational algorithms to extract information from text data. NLP is a scalable, efficient, and quick method to extract hypoglycemia-related information when using electronic health record data sources from a large population.

Objective: The objective of this systematic review was to synthesize the literature on the application of NLP to extract hypoglycemia from electronic health record clinical notes.

Methods: Literature searches were conducted electronically in PubMed, Web of Science Core Collection, CINAHL (EBSCO), PsycINFO (Ovid), IEEE Xplore, Google Scholar, and ACL Anthology. Keywords included *hypoglycemia*, *low blood glucose*, *NLP*, and *machine learning*. Inclusion criteria included studies that applied NLP to identify hypoglycemia, reported the outcomes related to hypoglycemia, and were published in English as full papers.

Results: This review (n=8 studies) revealed heterogeneity of the reported results related to hypoglycemia. Of the 8 included studies, 4 (50%) reported that the prevalence rate of any level of hypoglycemia was 3.4% to 46.2%. The use of NLP to analyze clinical notes improved the capture of undocumented or missed hypoglycemic events using International Classification of Diseases, Ninth Revision (ICD-9), and International Classification of Diseases, Tenth Revision (ICD-10), and laboratory testing. The combination of NLP and ICD-9 or ICD-10 codes significantly increased the identification of hypoglycemic events compared with individual methods; for example, the prevalence rates of hypoglycemia were 12.4% for International Classification of Diseases codes, 25.1% for an NLP algorithm, and 32.2% for combined algorithms. All the reviewed studies applied rule-based NLP algorithms to identify hypoglycemia.

Conclusions: The findings provided evidence that the application of NLP to analyze clinical notes improved the capture of hypoglycemic events, particularly when combined with the ICD-9 or ICD-10 codes and laboratory testing.

Introduction

Background

Approximately 34 million (13%) US adults have diabetes [1]. Worldwide, 387 million persons have diabetes, a number that is expected to rise to 592 million by 2035 [2]. In 2017, direct and indirect costs attributed to diabetes in the United States were estimated to be US $327 billion [3]. Optimal glycemic control (glycated hemoglobin [HbA_{1c}] <7%) can be achieved with comprehensive antidiabetic treatment; however, the risk of hypoglycemia increases. In patients with type 2 diabetes (T2D), after experiencing hypoglycemia, the 3-year incidence of cardiovascular events was 35.1%, and mortality 28.3% to 31.9% [4,5].

The incidence of hypoglycemia has been reported to vary widely for patients with diabetes. An earlier systematic review and meta-analysis of 46 studies found that 45% of the patients with T2D had mild or moderate hypoglycemia and 6% had severe hypoglycemia; the prevalence was even higher among those treated with insulin, with 50% having mild or moderate hypoglycemia events and 21% having severe events [6]. A subsequent review study showed that the rates of severe hypoglycemia in T2D were between 0.7 and 12 per 100 person-years in randomized controlled trials and between 0.2 (without treatment with insulin or sulfonylureas) and 2 (with treatment with insulin or sulfonylureas) per 100 person-years [7]. The most recent systematic review and meta-analysis of 72 studies indicated that the incidence rate of hypoglycemia was 14.5 to 42,890 episodes per 1000 person-years in type 1 diabetes (T1D) and 0.072 to 16,360 episodes per 1000 person-years in T2D [8].

The reported rates of hypoglycemia vary largely because of the marked heterogeneity in the way that hypoglycemia is defined, measured, and reported. Accurately identifying patients with hypoglycemia is key to preventing adverse events and mortality. There are several methods to identify hypoglycemia events and severity in large populations, including patient questionnaires and International Classification of Diseases, Ninth Revision (ICD-9), or International Classification of Diseases, Tenth Revision (ICD-10), and electronic health records (EHRs). Studies have found that using questionnaires [9] or International Classification of Diseases (ICD) codes [10] is often insensitive, leads to underestimation of hypoglycemia events, and is nonspecific in detecting hypoglycemia events.

EHRs have been widely adopted by health care systems, resulting in large amounts of data, including unstructured text in clinical notes [11,12]. The amount of unstructured text is vast and continues to grow at a breakneck pace. Clinical notes enable health care providers to not only identify patients at risk of hypoglycemia but also to obtain details on hypoglycemia; for example, symptomatic or asymptomatic hypoglycemia [13]. Once the patients at risk of hypoglycemia are identified, their treatment can be personalized, which helps to prevent future hypoglycemia and the resulting serious adverse effects. Traditional methods such as manual chart review can extract information related to hypoglycemia from EHR clinical notes [14]; however, such methods are time-consuming, labor intensive, and not scalable, which makes them impractical for use in large populations [15].

By contrast, novel data science approaches, including using natural language processing (NLP), have been applied to overcome the aforementioned difficulties [16]. NLP, a form of artificial intelligence, uses computational algorithms to process human language content for a variety of purposes [17]. The application of NLP algorithms is a scalable, efficient, and quick method to extract unstructured data from a large population [18,19]. Applications of NLP in the health domain can be categorized into 2 groups: rule-based methods and machine learning methods [20]. Rule-based NLP techniques are based on a predefined clinical vocabulary, which identifies a set of core concepts for target extraction (eg, hypoglycemia), and may also use pattern matching (such as regular expressions) and filters [21,22]. Rule-based systems are time-consuming to set up, but they are easy to understand and modify and often require fewer amounts of data than machine learning approaches [21,23,24]. Machine learning systems leverage the same feature sets as those used in rule-based systems but do the work to discover the rules needed for a solution; however, this comes at a price: the resulting systems often function as a *black box*, which is difficult for humans to understand and trust [20]. In addition, machine learning systems typically require very large sample sizes for development [23]. Deep learning approaches (neural networks) are a form of machine learning used in recent years [25,26], which can achieve performances comparable with, or better than, those of domain experts in identifying clinical information [16]. However, deep learning–based models require large amounts of training data to achieve high accuracy, hindering the adoption of deep learning–based models in scenarios with limited amounts of training data [27]. As a result, state-of-the-art deep learning methods of NLP (eg, transformer models and transfer learning) were developed to address these issues, and they have been proven to be extremely effective in the NLP domain [27,28].

Objectives

Currently, little is known about what types of NLP algorithms were applied to identify hypoglycemia and how differences in hypoglycemia incidence identified from unstructured data using NLP compare with hypoglycemia incidence identified from structured data (eg, ICD codes) across studies. It was reported in 1 study that a higher number of hypoglycemia events could be identified in clinical notes by using NLP than by using ICD codes (65% vs 20%, respectively) [29]. Thus, in this systematic review, we aimed to synthesize the literature on the application of NLP to extract hypoglycemia from EHR clinical notes and compare the differences between hypoglycemia incidence identified from unstructured data using NLP and hypoglycemia incidence identified from structured data (eg, ICD codes) across studies.

Methods

Search Strategies

Literature searches for a comprehensive review were conducted in 7 electronic databases: PubMed, Web of Science Core Collection, CINAHL (EBSCO), PsycINFO (Ovid), IEEE

Xplore, Google Scholar, and ACL Anthology. The search strategies were developed in consultation with a health sciences librarian (BCR). The searches were conducted before February 22, 2022. Database-specific subject headings (eg, Medical Subject Headings) and relevant keywords were identified to describe hypoglycemia and these terms were searched in combination with terms related to NLP. As few articles related to hypoglycemia and NLP were located, the searches were widened to include broader terms such as *blood sugar* or *blood glucose*, and *machine learning* or *artificial intelligence*. No date, language, or publication filters were applied within the databases. Appropriate Boolean operators were used to structure the search queries and both unqualified free-text searching and field tags were used; the detailed search queries for each database are presented in Textbox 1.

Textbox 1. Search strategies for hypoglycemia and natural language processing.

PubMed

- ((*Hypoglycemia* [MeSH]) OR *Blood Glucose* [MeSH] OR *hypoglycemi** [TW] OR *blood sugar** [TW] OR *blood glucose* [TW]) AND ((((Natural Language Processing [MeSH]) OR *Machine Learning* [MeSH]) OR *Artificial Intelligence* [MeSH]) OR *Data Mining* [MeSH:noexp] OR *NLP* [TW] OR *natural language processing* [TW] OR *machine learning* [TW] OR *artificial intelligence* [TW] OR *text mine* [TW] OR *text analys** [TW] OR *text processing* [TW] OR *text classif** [TW] OR *information extraction* [TW] OR ((electronic health record* [TW]) AND (*diagnos** [TW])))

Web of Science

- TS=(*hypoglycemi** OR (*blood NEAR/3 sugar*) OR (*blood NEAR/3 glucose*)) AND TS=((*"Natural Language Processing"* OR *NLP* OR *"Machine Learning"* OR *"Artificial Intelligence"* OR (*"text mining"* OR *"text mine"* OR *"text analys*"* OR *"text* analyst"* OR *"text* processing"* OR *"text classif*"* OR *"information extraction"*) OR ((*electronic health record** OR *electronic medical record** OR *electronic patient record**) AND *diagnos**)))

- Document type: article

- Language: English

CINAHL

- ((MH "*Hypoglycemia*") OR (MH "*Blood Glucose*") OR (*hypoglycemi** OR *"blood glucose"* OR *"blood sugar"*)) AND (((MH "*Natural Language Processing*") OR *"natural language processing"* OR (MH "*Artificial Intelligence*+") OR (MH "*Data Mining*") OR (MH "*Machine Learning*+") OR *"text mining"* OR *"text analysis"* OR *"text processing"* OR *text classif** OR *"information extraction"*) OR ((("*electronic health record*" OR "*electronic medical record*" OR "*electronic patient record*" OR "*electronic health records*" OR "*electronic medical records*" OR "*electronic patient records*" OR *EHR* OR *EMR*) N3 *diagnos**)))

- Language: English

PsycINFO (Ovid)

- (*hypoglycemi*.mp.* or *exp Hypoglycemia/* or *blood sugar.mp.* or *exp Blood Sugar/* or *blood glucose.mp.*) AND (*natural language processing.mp.* or *exp Natural Language Processing/* or *machine learning.mp.* or *exp Machine Learning/* or *artificial intelligence.mp.* or *exp Artificial Intelligence/* or *text mining.mp.* or *text processing.mp.* or *text classif*.mp.* or *information extraction.mp.* or ((*exp Electronic Health Records/* or *electronic health record.mp.* or *electronic medical record.mp.* or *electronic patient record.mp.*) and (*exp Diagnosis/* or *diagnos*.mp.)))*

ACL Anthology

- *hypoglycemia* OR *blood glucose* OR *blood sugar* OR *hypoglycemic*

Google Scholar

- *natural language processing* AND *hypoglycemia* AND *electronic health records*

IEEE Xplore

- (*All Metadata:blood sugar* OR *All Metadata:blood glucose* OR *All Metadata:hypoglycemia* OR *All Metadata:hypoglycemic)* AND (*All Metadata:natural language processing* OR *All Metadata:NLP* OR *All Metadata:"machine learning"* OR *All Metadata:"artificial intelligence"* OR *All Metadata:"text mining"* OR *All Metadata:"text analysis"* OR *All Metadata:"text analyses"* OR *All Metadata:"text analytics"* OR *All Metadata:"text processing"*)

- Filters applied: journals

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: studies that (1) were restricted to participants aged ≥18 years; (2) reported a sample with a diagnosis of diabetes; (3) applied NLP to identify hypoglycemia; (4) reported the number or percentage of participants who had experienced at least one hypoglycemic episode, the incidence of hypoglycemic episodes experienced, or data to allow the calculation of one of these measures; (5) used EHR data; (6) were published as full papers in peer-reviewed journals; (7) were published in English. No restrictions were applied regarding the definition or

measurement of hypoglycemia. No restrictions were applied to country or origin of the studies. Studies were excluded if (1) they did not report outcomes related to hypoglycemia, (2) they were pharmacological trials or the intervention focused on treatment or care, (3) the participants were all pregnant or children, and (4) they reported only conference papers or proceedings.

Data Extraction

We first developed and tested a data extraction form, with adaptations made accordingly. The titles, abstracts, and full-text articles were screened by 2 independent reviewers (MCRM, LS, Emily M Pan, or Yi Lan Zhang). Once conflicts were identified, agreement was reached after discussion with the third reviewer (YZ). The results related to the identification of eligible studies were summarized according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Figure 1). The searches yielded 2070 citations, and after removing duplicates, 1705 (82.37%) titles and abstracts were screened for eligibility. After full-text retrieval of 334 potentially relevant papers, 326 (97.6%) were subsequently excluded, leaving 8 (2.4%) papers that applied NLP to identify hypoglycemia and reported the rates of hypoglycemia that were eligible for inclusion in the analyses. The reference sections of the relevant articles were searched manually, but no further relevant articles were found. Studies were summarized based on the following categories: authors and country, sample size and characteristics, medical conditions, antihyperglycemic medication, study design, data source, definition of hypoglycemia, method used to identify hypoglycemia, NLP algorithm (eg, rule-based or machine learning), NLP algorithm validation, and outcomes (Tables 1 and 2).

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart. In the case of Google Scholar, the first 100 results based on relevancy ranking is suggested to identify additional articles, and in the case of ACL Anthology, all the citations found were added to the irrelevant set (excluded based on title and abstract) [30]. NLP: natural language processing.
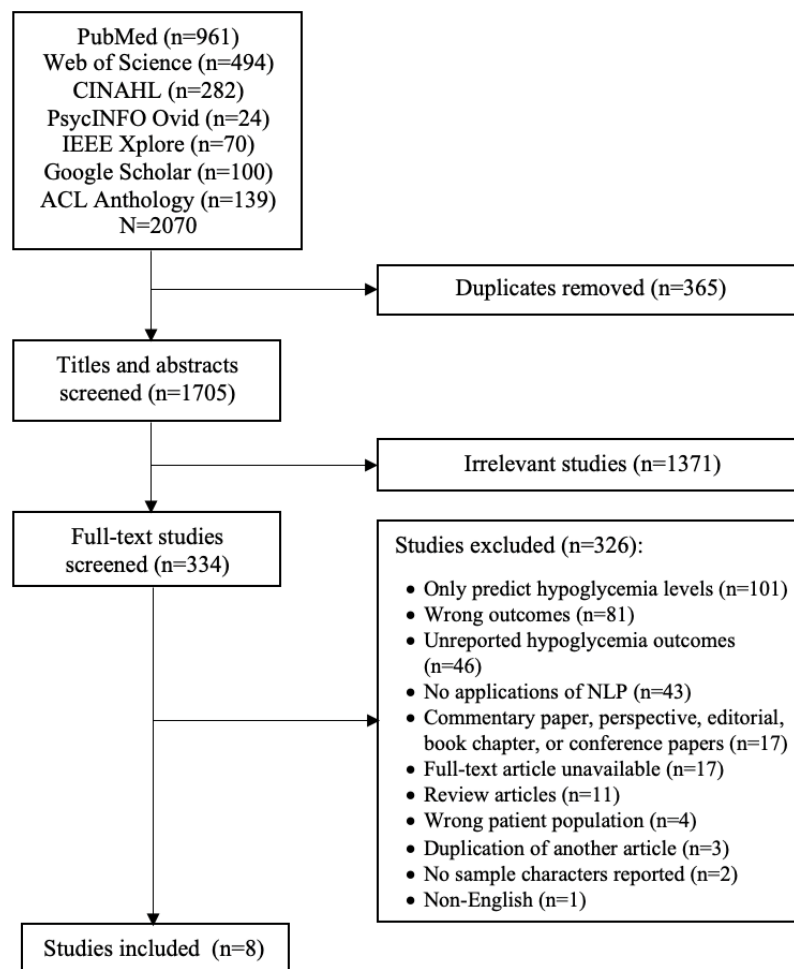
Table 1. Summary of studies on natural language processing (NLP) and hypoglycemia.

Author, year, country	Sample characteristics	Medical conditions	Antihyperglycemic medication	Study design
Nunes et al, 2016 [31], United States	N=844,683; age (years; n [%]): <30: 10,138 (1.20), 30 to 39: 38,491 (4.56), 40 to 49: 105,476 (12.49), 50 to 59: 196,494 (23.26), 60 to 69: 232,885 (27.57), >69: 261,199 (30.92); female (n [%]): 433,322 (51.30); White (n [%]): 655,474 (77.60); T2D[a] (n [%]): 844,683 (100); baseline measures, mean (SD): BMI (kg/m^2): 31.8 (10.2), HbA$_{1c}$[b] (%): 7.0 (1.9), blood glucose level (mg/dL): 139.0 (82)	Atrial fibrillation (n [%]): 60,773 (7.19); hypertension (n [%]): 555,482 (65.76); hyperlipidemia (n [%]): 510,944 (60.49); cerebrovascular disease (n [%]): 54,336 (6.43); chronic kidney disease: retinopathy (n [%]): 10,356 (1.23), neuropathy (n [%]): 44,352 (5.25), nephropathy (n [%]): 26,498 (3.14); ischemic heart disease (n [%]): 154,049 (18.24); congestive heart failure (n [%]): 59,438 (7.04)	Not specified	Retrospective cohort study
Nunes et al 2017 [29], United States	N=143,635; age (years; n [%]): <30: 1333 (0.93), 30 to 39: 5420 (3.77), 40 to 49: 15,645 (10.89), 50 to 59: 32,796 (22.83), 60 to 69: 39,852 (27.75), >69: 48,491 (33.76); female (n [%]): 69,879 (48.65); White (n [%]): 116,701 (81.25); T2D (n [%]): 143,635 (100); baseline measures (median [IQR]): BMI (kg/m^2): 32.3 (28.1-37.6), HbA$_{1c}$ (%): 7.1 (6.5-8.1), blood glucose level (mg/dL): 146.0 (116.0-191.0)	N=143,635; cerebrovascular disease (n [%]): 11,903 (8.29); retinopathy (n [%]): 3091 (2.15); neuropathy (n [%]): 12,961 (9.02); nephropathy (n [%]): 8338 (5.80); ischemic heart disease (n [%]): 33,570 (23.37)	N=143,635; sulfonylureas (n [%]): 143,635 (100)	Retrospective cohort study
Loughlin et al, 2018 [32], United States	N=6024; EQW[c] cohort (n [%]): 2008 (33.33%); age (years): —[d]; female (n [%]): 1004 (50); White (n [%]): 1630 (81.17); T2D (n [%]): 2008 (100); baseline measures: —; BI[e] cohort (n [%]): 4016 (66.67%); age (years): —; female (n [%]): 2036 (50.70); White (n [%]): 3277 (81.60); T2D (n [%]): 4016 (100); baseline measures: —	—	N=6024; insulin (n [%]): 6024 (100)	Retrospective cohort study
Pettus et al, 2019 [33], United States	N=831,456; BI switchers (n=3920 to 19,256); age (years): range 58.2-60.1; female (%): range 49.8-52.0; White (%): —; T2D: (831,456, 100%); baseline measures: BMI (kg/m^2): range 33.8-35.0; HbA$_{1c}$ (%): range 8.91-9.02; blood glucose level (mg/dL): —; smoking (%): —. Insulin naïve (n=2279 to 47,085); age (years): range 58.8-60.4; female (%): range 48.6-52.1; White (%): —; T2D (n [%]): (100); baseline measures: BMI (kg/m^2): range 34.0-34.6; HbA$_{1c}$ (%): range 9.39-9.64; blood glucose level (mg/dL): —; smoking (%): —	BI switchers: hypertension: 63.4-73.4, hyperlipidemia: 68.1-77.8, microvascular complication: 44.7-55.7, macrovascular complication: 44.2-63.5. Insulin naïve: hypertension: 56.8-74.2; hyperlipidemia: 61.5-77.8, microvascular complication: 25.3-34.6, macrovascular complication: 32.7-63.5	BI switchers: sulfonylureas: 24.5-28.3; any OAD[f]: 63.6-75.2. Insulin naïve: sulfonylureas: 47.6-56.6;	Retrospective cohort study

Author, year, country	Sample characteristics	Medical conditions	Antihyperglycemic medication	Study design
Li et al, 2019 [34], United States	N=38,780; age (years), mean: 57.0; female (n [%]): 21,716 (56); White (%): 18,226 (47); T2D (%): —; baseline measures: BMI (kg/m^2), mean (SD): 35.7 (9.8); HbA$_{1c}$ (n [%]): ≤6.5%: 5321 (13.72), >6.5% to <7%: 1840 (4.74), ≥7% to <8%: 3155 (8.14), ≥8% to <9%: 1773 (4.57), ≥9%: 3977 (10.26), missing: 22,714 (58.57)	N=38,780; coronary artery disease (n [%]): 2021 (5.21); chronic heart failure (n [%]): 1582 (4.08); diabetic neuropathy (n [%]): 1414 (3.65)	N=38,780; long-acting insulin (LAI^g): 615 (1.59); sulfonylureas: 8727 (22.50)	Retrospective cohort study
Misra-Hebert et al, 2020 [35], United States	N=204,517; the values provided herein are from a subsample: (n=46,302); age (years): 61.48; female (%):22,633 (48.90); White (%):34,004 (73.40); T2D (n [%]):46,302 (100); baseline measures: BMI (kg/m^2): 32.2; HbA$_{1c}$ (%): 6.6; blood glucose level (mg/dL): —	n=46,302; cardiovascular disease (n [%]): 13,372 (28.9); congestive heart failure (n [%]): 2195 (4.7); chronic kidney disease (n [%]): 2460 (5.3)	n=46,302; insulin (n [%]): 8050 (17.4); glucagon-like peptide-1 receptor agonist (n [%]): 1781 (3.8); dipeptidyl peptidase 4: 4437 (9.6); sodium-glucose cotransporter-2 inhibitor (n [%]): 791 (1.7); metformin: 28,851 (62.3); sulfonylureas (n [%]): 10,098 (21.8); alpha-glucosidase inhibitor (n [%]): 107 (0.2)	Retrospective cohort study
Uzoigw et al 2020 [36], United States	N=359,087; T2D (n [%]): 317,399 (88.39); age (years), median (IQR): 68.0 (18); female (n [%]): 154,512 (48.68); White (%):121,468 (38.27); baseline measures: BMI (kg/m^2): —; HbA$_{1c}$ (%): —; blood glucose level (mg/dL): —; smoking (n [%]):106,760 (33.63). T1D^h: (n [%]): 41,688 (11.61); age (years): median (IQR) 55.0 (30); female (n [%]): 21,034 (50.46); White (n [%]): 16,072 (38.55); baseline measures: BMI (kg/m^2): —; HbA$_{1c}$ (%): —; blood glucose level (mg/dL): —; smoking (n [%]): 9174 (22)	T2D: N=317,399; hypertension (n [%]): 257,093 (81); hyperlipidemia (n [%]): 193,616 (61); cardiovascular disease (n [%]): 158,699 (50). T1D: N=41,688; high blood sugar level or diabetic ketoacidosis (n [%]): 14,067 (33.74); cancer (n [%]): 6752 (16.20); stroke (n [%]): 7377 (17.70); substance use or abuse (n [%]): 4917 (11.79)	T2D: N=317,399; insulin (n [%]): 174,569 (55); sulfonylureas (n [%]): 55,710 (17.55); metformin (n [%]): 114,263(36). T1D: N=41,688; insulin (n [%]): 37,279 (89.42); sulfonylureas (n [%]): 1846 (4.43); metformin (n [%]): 5059 (12.14)	Retrospective cohort study
Ganz et al 2014 [37], United States	N=7235; HbA$_{1c}$ (%): —; blood glucose level (mg/dL): —; smoking (%): —; T2D (n [%]): 7235 (100); age (years), mean (SD): 60.82 (11.65); female (n [%]): 3668 (50.70); White (n [%]): 4576 (63.25); baseline measures: BMI (kg/m^2): —; HbA$_{1c}$ (%): —; blood glucose level (mg/dL): —; smoking (%): —	T2D (n [%]): 7235 (100)	Insulin: glargine (%): 77.24; neutral protamine Hagedorn insulin (%): 5.86; detemir (%): 16.90. Sulfonylureas (%): 38.06; metformin (%): 36.66; other OADs (%): 25.82	Retrospective cohort study

[a]T2D: type 2 diabetes.

[b]HbA$_{1c}$: glycated hemoglobin.

[c]EQW: exenatide once weekly.

[d]Not available.

[e]BI: basal insulin.

[f]OAD: oral antidiabetic drug.

[g]LAI: long-acting insulin.

[h]T1D: type 1 diabetes.

Table 2. Summary of studies on natural language processing (NLP) and hypoglycemia.

Author, year, country	Data source	Definition of hypoglycemia	Method used to identify hypoglycemia	NLP algorithm: rule-based or machine learning	NLP algorithm validation	Outcomes
Nunes et al, 2016 [31], United States	Optum Humedica EHR[a] database, which incorporates EHRs from 35 large medical provider organizations (including >195 hospitals), >25,000 physicians, and >25 million patients, making up the largest EHR database within the United States (January 2009 to March 2014)	Serious: ICD-9[b] identified events were characterized as serious or nonserious if the diagnosis was identified within a problem list; NLP-identified categories included serious (eg, serious, acute, severe, and profound); mild to moderate: NLP-identified categories included mild to moderate (eg, mild, moderate, slight, and minor)	ICD-9 algorithm (structured diagnostic codes only); NLP algorithm (NLP of clinical notes); combined algorithm (either ICD-9 diagnostic codes or NLP of clinical notes)	Rule-based	The final algorithm was validated by manual review: precision (PPV[c])=0.77, recall (sensitivity)=0.67	Period prevalence (%): any conditions: ICD-9: 12.37, NLP: 25.11, combined: 32.19; serious: ICD-9: 11.93, NLP: 10.71, combined: 18.72; mild to moderate: ICD-9: 0.00, NLP: 0.76, combined: 0.78. Incidence rate (per 100 person-years): any conditions: ICD-9: 2.25, NLP: 4.78, combined: 6.28. Serious: ICD-9: 2.12, NLP: 1.72, combined: 3.19; mild to moderate: ICD-9: 0.00, NLP: 0.09, combined: 0.08. Event rate (per 100 person-years): any conditions: ICD-9: 6.92, NLP: 10.03, combined: 16.12; serious: ICD-9: 6.63, NLP: 3.06, combined: 8.90; mild to moderate: ICD-9: 0.00, NLP: 0.20, combined: 0.19
Nunes et al, 2017 [29], United States	Optum EHR database (January 2009 to December 2014)	Serious: ICD[d] and CPT[e] evidence of medical intervention or abstracted descriptors suggestive of serious event; nonserious, mild to moderate: No ICD or CPT evidence of medical intervention but with abstracted descriptors suggestive of mild to moderate event; nonserious, unspecified: no ICD or CPT evidence of medical intervention and no descriptors of event seriousness	ICD codes and NLP	Rule-based	The final algorithm was validated by manual review: precision (PPV)=0.77, recall (sensitivity)=0.67	Incidence rate (per 100 person-years; 95% CI): any conditions: overall: 11.76 (11.49-12.04), sulfonylureas use: 12.77 (12.40-13.15), sulfonylureas nonuse: 10.39 (10.00-10.79). Serious: overall: 5.06 (4.88-5.24), sulfonylureas use: 5.77 (5.52-6.03), sulfonylureas nonuse: 4.09 (3.84-4.34). Nonserious, mild to moderate: overall: 0.14 (0.11-0.17), sulfonylureas use: 0.17 (0.13-0.22), sulfonylureas nonuse: 0.09 (0.06-0.13). Nonserious, unspecified: overall: 6.57 (6.37-6.78), sulfonylureas use: 6.83 (6.56-7.11), sulfonylureas nonuse: 6.21 (5.91-6.52)

Author, year, country	Data source	Definition of hypoglycemia	Method used to identify hypoglycemia	NLP algorithm: rule-based or machine learning	NLP algorithm validation	Outcomes
Loughlin et al, 2018 [32], United States	Optum EHR database (January 2012 to January 2015)	Documented blood glucose level <3.9 mmol/L or emergency physician–charted diagnosis of hypoglycemia	Hypoglycemia and gastrointestinal symptoms (vomiting, nausea, diarrhea, or constipation) were identified by using both ICD-9 Clinical Modification diagnostic codes within structured fields and NLP clinical notes; hypoglycemia was identified using an algorithm developed by Optum, incorporated diagnostic codes, and NLP of clinical notes	Rule-based	The final algorithm was validated by manual review: precision (PPV)=0.77, recall (sensitivity)=0.67	Incidence rate (per 1000 person-years; 95% CI): EQW[f] cohort: 52.5 (44.4-61.6), BI[g] cohort: 65.7 (59.1-72.7). Any gastrointestinal symptoms: EQW cohort: 225.5 (206.8-245.5), BI cohort: 191.0 (179.1-203.6). Participants with at least one event (n/N [%]): EQW cohort: 149/2008 (7.42), BI cohort: 368/4016 (9.16). Any gastrointestinal symptoms (n/N [%]): EQW cohort: 534/2008 (26.60), BI cohort: 946/4016 (23.56)
Pettus et al, 2019 [33], United States	Optum Humedica EHR database (January 1, 2007, to March 31, 2017)	Hypoglycemia: ICD-9 and ICD-10[h] codes for hypoglycemia; plasma glucose level measures ≤70 mg/dL; IM[i] glucagon administration; NLP: mention of hypoglycemia; severe hypoglycemia: ICD-9 and ICD-10 codes for hypoglycemia that is severe by default or ICD-9 and ICD-10 codes for hypoglycemia and hypoglycemia is reason for care on discharge or admission or hypoglycemia index date on same day as emergency department visit or inpatient diagnosis on admission (all related to hypoglycemic coma); plasma glucose level measures <54 mg/dL; IM glucagon administration; NLP: mention of hypoglycemia with either a descriptor of hypoglycemia severity, including severity terms (eg, severe) and attributes (eg, emergency), or emergency department visit or inpatient admission on same day as medical record was written	ICD-9 and ICD-10 codes; plasma glucose measures ≤70 mg/dL; IM glucagon administration; NLP	Rule-based	The final algorithm was validated by manual review: precision (PPV)=0.77, recall (sensitivity)=0.67	Any hypoglycemia (%): BI switchers: 42.2-46.2. Insulin naïve: 22.8-28.8. Severe hypoglycemia: BI switchers: 8.2-17.4, insulin naïve: 2.7-8.6

[XSL•FO]
RenderX

Author, year, country	Data source	Definition of hypoglycemia	Method used to identify hypoglycemia	NLP algorithm: rule-based or machine learning	NLP algorithm validation	Outcomes
Li et al, 2019 [34], United States	Regenstrief Medical Record System, which is an urban safety-net medical institution in Indianapolis, Indiana, United States. In 2012, Eskenazi Health had 1081 physicians on staff and serviced 950,592 outpatient visits, including 234,637 community health center visits (January 1, 2004, to December 31, 2013)	Plasma or point-of-care glucose value of at least 5 mg/dL and <70 mg/dL, documented in the medical record; ICD-9 code: 251.1 or 251.2; ICD code 250.8 without any of the following codes: 259.8, 272.7, 681.xx, 682.x, 686.9, 707.1x, 707.2x, 707.8, 707.9, 709.3, 730.0x, 730.1x, 730.2x, 731.8; text note indicating hypoglycemia, including a blood glucose value	Laboratory tests; diagnostic codes; NLP	Rule-based	—	A 1-year window for prior episodes of hypoglycemia: overall prevalence (n/N [%]): 8182/38,780 (21); non-LAI[j] and sulfonylureas within 90 days (%): 42.92; sulfonylureas without insulin (%): 23.82; no insulin, no sulfonylureas (%): 17.85%; blood glucose value between 5 mg/dL and 70 mg/dL (n/N [%]): 7070/38,780 (18.23); blood glucose value<54 mg/dL (n/N [%]): 4784/38,780 (12.34); NLP (n/N [%]): 3751/38,780 (9.67), with 539/38,780 (1.39), identified only by NLP
Misra-Hebert et al, 2020 [35], United States	Cleveland Clinic Health System patient records (2005 to 2017)	Hypoglycemia: blood glucose level <70 mg/dL; severe hypoglycemia: patients with T2D[k] require hospitalization or emergency department visit; nonsevere hypoglycemia: does not require assistance for recovery	NLP; ICD-9 codes: 251.0, 251.1, 251.2; ICD-10 codes: E08.641, E11.641, E11.649, E13.64, E13.641, E13.649, E16.0, E16.1, E15, E16.2	Rule-based	Compared with clinician chart review manually, PPV=93%	Prevalence: among 204,517 patients with no codes for nonsevere hypoglycemia, evidence of nonsevere hypoglycemia was found in 7035 (3.4%) using NLP. Number of nonsevere hypoglycemia events: ICD codes (n/N [%]): 10,205/204,517 (4.99), NLP: 14,763/204,517 (7.22), with overlap of only 5 events. Incidence proportion of patients from 2005 to 2017 ICD codes (%): severe hypoglycemia: 0.3 to 1.7, nonsevere hypoglycemia: 0.4 to 1.3; NLP+ICD (%): nonsevere hypoglycemia: 0.8 to 2.6
Uzoigw et al, 2020 [36], United States	Amplity Insights database, unstructured health records, generated from provider notes as transcribed from verbal to written form (January 1, 2016, to April 30, 2018)	Nonsymptom-based: mention of hypoglycemia, low blood glucose level or blood glucose value≤70 mg/dL; symptom-based: keywords identified by endocrinologists, used by patients to describe hypoglycemia	ICD codes; NLP	Rule-based	—	Prevalence during 2 years (%): T2D: ICD: 52 (<0.1); combined symptom and nonsymptom-based: 11.4; nonsymptom-based: 7.59; symptom-based: irritable or anxious: 14.50; cognitive issues: 12.14; elevated or irregular heart rate: 10.21. T1D[l]: ICD codes: 30 (0.1); combined symptom and nonsymptom-based: 20.4; nonsymptom-based: 18.12; symptom-based: irritable or anxious: 16.00; cognitive issues: 8.17; elevated or irregular heart rate: 8.17

Author, year, country	Data source	Definition of hypoglycemia	Method used to identify hypoglycemia	NLP algorithm: rule-based or machine learning	NLP algorithm validation	Outcomes
Ganz et al, 2014 [37], United States	Humedica real-time longitudinal clinical data patient-level EHR database (January 2008 to December 2011)	Severe hypoglycemia: blood glucose level≤40 mg/dL	ICD-9 codes 251.0x, 251.1x, 251.2x, or 250.3x on different days; NLP	Rule-based	The final algorithm was validated by manual review: precision (PPV)=0.77, recall (sensitivity)=0.67	Posttitration follow-up period (1.8 years): incidence rate (per 100 patient-years; 95% CI)=4.63 (4.59-4.67); total severe hypoglycemia rate (per 100 patient-years)=9.69 (9.64-9.75). Incidence rate for patients with history of severe hypoglycemia events (95% CI)=5.91 (5.76-6.06). Total severe hypoglycemia rate for patients with history of severe hypoglycemia events (95% CI)=9.00 (8.87-9.12)

[a]EHR: electronic health record.

[b]ICD-9: International Classification of Diseases, Ninth Revision.

[c]PPV: positive predictive value.

[d]ICD: International Classification of Diseases.

[e]CPT: Current Procedures Terminology.

[f]EQW: exenatide once weekly.

[g]BI: basal insulin.

[h]ICD-10: International Classification of Diseases, Tenth Revision.

[i]IM: intramuscular.

[j]LAI: long-acting insulin.

[k]T2D: type 2 diabetes.

[l]T1D: type 1 diabetes.

Results

Description of Included Studies

All included studies (n=8) were conducted in the United States [29,31-37]. The sample sizes were large, ranging from 6024 to 844,683. Of the 8 studies, 6 (75%) included only T2D [29,31-33,35,37], 1 (13%) included both T1D and T2D [36], and 1 (13%) did not specify the type of diabetes [34]. The participants varied in age from 57 to 68 years, and 48.7% to 56% were women. Among the studies (7/8, 88%) that reported on ethnicity, the percentage of non-White participants ranged from 18.8% to 62%. Mean BMI ranged from 31.8 (SD 10.2) to 35.7 (SD 9.8) kg/m^2, and mean HbA$_{1c}$ ranged from 6.6% to 9.64%. Varied comorbidities were reported; for example, hypertension, hyperlipidemia, ischemic heart disease, and heart failure. Of the 8 studies, 4 (50%) provided diabetes-related complications, including retinopathy, neuropathy, and nephropathy [29,31,33,34]; 6 (75%) reported that 1.6% to 100% of the participants injected insulin [32-37]; and 6 (75%) reported 4.4% to 100% sulfonylureas use [29,33-37].

All the included studies (n=8) were retrospective cohort study designs, with the observational durations of the cohort ranging from 2 to 12 years. Population samples were obtained from varied EHR databases such as Optum Humedica [29,31-33,37], Regenstrief [34], Cleveland Clinic Health System patient records [35], and Amplity Insights [36].

Methods of Identifying Hypoglycemia

All included studies used a combination of ICD codes and NLP to identify hypoglycemia; other methods were applied, including laboratory tests for plasma glucose measures ≤70 or <54 mg/dL [33,34] and glucagon administration [33]. ICD-9 and ICD-10 codes used to identify hypoglycemia were described in detail by Misra-Hebert et al [35]. Of the 8 studies, 3 (38%) reported both serious (level 3) and mild or moderate hypoglycemia (levels 1 and 2) [29,31,35], 1 (13%) reported both overall unspecified and severe hypoglycemia [33], and 3 (38%) reported data on unspecified hypoglycemia [32,34,36], whereas 2 (25%) studies also reported symptom-based and nonsymptom-based hypoglycemia [32,36].

NLP Algorithms Applied to Identify Hypoglycemia

All included studies applied rule-based algorithms (Table 3). The study by Misra-Hebert et al [35] described in detail the NLP steps, including splitting clinical notes into sentences and phrases, filtering sentences and phrases to those containing references to a hypoglycemia-related Unified Medical Language System [38] concept, identifying temporal phrases (identifying when the event occurred), and clarifying polarity (assertion or negation) into no, nonsevere, or severe event using both

XSL•FO

RenderX

rule-based algorithms. Li et al [34] identified hypoglycemia using a formally defined pattern (*regular expression*) [39] such as a *blood sugar word,* followed within 5 words by what could be a low blood sugar value represented by a number ranging from 10 to 69. Uzoigwe et al [36] identified keywords or concepts of interest related to both symptom-based and nonsymptom-based hypoglycemic events. The remaining studies (5/8, 63%) applied the same NLP algorithms to identify [29,31-33,37] (1) terms or concepts (eg, hypoglycemia), including alternative or incorrect spellings and abbreviations; (2) descriptive attributes of the hypoglycemia mention (eg,

seriousness, duration, and frequency); (3) sentiment of the mention (eg, denial, affirmation, and discussion); and (4) other contextual information (eg, note section headers and neighboring text).

Manual review of clinical notes was used as the gold standard to validate the NLP algorithms in 63% (5/8) of the studies. Of the 8 studies, 2 (25%) did not report validation of the algorithm, whereas in the 6 (75%) reporting studies, the precision (positive predictive value) for the hypoglycemia algorithm was 0.77% to 93% [29,31-33,35,37]. Of these 6 studies, 5 (83%) reported that the recall (sensitivity) was 0.67 [29,31-33,37].

Table 3. Natural language processing (NLP) algorithms applied in the reviewed studies.

Study	NLP algorithm type	Details of NLP algorithms
Ganz et al, 2014 [37]; Nunes et al, 2016 [31]; Nunes et al, 2017 [29]; Loughlin et al, 2018 [32]; Pettus et al, 2019 [33]	Rule-based	• Identify terms consistent with hypoglycemia (including alternative or incorrect spellings and abbreviations) • Identify descriptive attributes of the hypoglycemia mention (eg, seriousness, duration, and frequency) • Identify sentiment of the mention (eg, denial and affirmation, including "has," "diagnosed," and "present") • Identify contextual information (eg, note section headers and neighboring text). Sections such as "history of present illness," "assessment," "hospital course," "reason," "review of symptoms," and "chief complaint" generally reflected occurrence of hypoglycemia
Li et al, 2019 [34]	Rule-based	• A formally defined pattern (regular expression), which identified clinical reports mentioning a "blood sugar word" followed within 5 words by what could be a low blood sugar value represented by a number ranging from 10 to 69
Misra-Hebert et al, 2020 [35]	Rule-based	• Split clinical notes into sentences and phrases • Filter sentences and phrases to those containing a hypoglycemia-related Unified Medical Language System concept • Identify temporal phrases (when the event occurred) • Classify polarity (assertion or negation) into no, nonsevere, and severe event
Uzoigwe et al, 2020 [36]	Rule-based	• Identify keywords or concepts of interest: symptom-based and nonsymptom-based hypoglycemic events • Symptom-based terms: neuroglycopenic and adrenergic symptomology associated with hypoglycemia. • Adrenergic symptomology: elevated or irregular heart rate, sweating, tremor, trembling, tingling, or shaking, and vision impairment • Neuroglycopenic symptomology: cognitive issues, irritable or anxious, mood or behavior change+NOT substance abuse or alcohol, slurred speech+NOT stroke+NOT substance abuse or alcohol • Nonsymptom-based definition: • Mention of "hypoglycemia" • Relevant medical ontology such as "low glucose" • A blood glucose laboratory value ≤70 mg/dL documented

Prevalence or Incidence of Hypoglycemia

The prevalence or the incidence of hypoglycemia largely varied across studies. All studies used a combination of NLP and other approaches (eg, ICD codes) to identify hypoglycemia. Overall, the prevalence rate of any condition of hypoglycemia was 3.4% to 46.2%, as reported by 50% (4/8) of the studies [31,33,34,36], and the incidence rate was 6.28% to 65.7%, as reported by 38% (3/8) of the studies [29,31,32]. The prevalence rate of nonsevere hypoglycemia was 0.1% to 3.4% [29,31,35] and that of severe hypoglycemia was 5.1% to 18.7% [29,31,33,37]. Of the 8 studies, 4 (50%) compared the prevalence or incidence of

hypoglycemia identified by NLP and ICD codes. In the study by Nunes et al (2016) [31], the prevalence rates of any hypoglycemia within the study period were 12.4%, 25.1%, and 32.2% for the ICD-9, NLP algorithm, and combined algorithm, respectively. Similarly, Misra-Hebert et al [35] found that NLP identified higher nonserious hypoglycemia events than ICD codes (14,763 vs 10,205 events) during the study period from 2005 to 2017; among 204,517 patients with no ICD codes for nonsevere hypoglycemia, evidence of nonsevere hypoglycemia was found in 7035 (3.44%) using NLP. Li et al [34] also showed that hypoglycemia was identified in 21% of the participants, with 9.67% identified only by NLP algorithms. In addition,

Uzoigwe et al [36] found that the prevalence rates of hypoglycemia were 11.4% and <0.1% using NLP algorithms and ICD codes, respectively, in T2D; the prevalence rates were 20.4% and 0.1%, respectively, in T1D.

Using the combination of NLP and other approaches (eg, ICD codes) identified the highest prevalence or incidence of hypoglycemia compared with either method alone. Nunes et al [31] found that the prevalence rates of hypoglycemia were 12.4% for ICD codes, 25.1% for NLP algorithm, and 32.2% for combined algorithms; the incidence rates per 100 person-years were 2.3%, 4.8%, and 6.3% using ICD codes, NLP, and combined algorithms, respectively. Similarly, Misra-Hebert et al [35] identified that the incidence proportions of patients in the period from 2005 to 2017 were 0.4% and 1.3% for nonsevere hypoglycemia when using only ICD codes, whereas when NLP was added, the incidence proportions increased to 0.8% and 2.6%.

Discussion

Principal Findings

This systematic review aimed to synthesize the literature on the application of NLP to extract hypoglycemia from EHR clinical notes. Of the 8 studies, 4 (50%) reported that the prevalence rate of any level of hypoglycemia was 3.4% to 46.2%. Overall, the use of NLP to analyze clinical notes improved the capture of hypoglycemic events that may have been undocumented or missed using laboratory testing or ICD-9 and ICD-10 codes. The combination of NLP and other approaches significantly increased the identification of hypoglycemic events compared with individual methods. All reviewed studies applied rule-based NLP methods to identify hypoglycemia.

Previous reviews of the prevalence and incidence of hypoglycemia using NLP are limited. Our study found that the prevalence rate of any condition of hypoglycemia was 3.4% to 46.2%, whereas a previous review study reported that the prevalence rate of any condition of hypoglycemia ranged from 1% to 19% for studies using EHR as a data source [8]. In addition, 13% (1/8) of the studies in our review reported that symptom-based hypoglycemia—the estimated prevalence rate of hypoglycemia using combined symptom-based and nonsymptom-based definitions—was 20.4% (T1D) and 11.4% (T2D) [36], which is more prevalent than previous analyses without applying NLP for data extraction [40,41].

All included studies (n=8) applied rule-based NLP to identify hypoglycemia. The main aim of our paper focused on the application of NLP algorithms to identify hypoglycemia and not on the method for developing algorithms. Published articles have reported developing machine learning or deep learning algorithms to identify hypoglycemia, but they did not report the incidence of hypoglycemia; therefore, we did not include such papers in our review. For example, Chen et al [42] incorporated 3 machine learning algorithms to detect hypoglycemia, including logistic regression, linear support vector machines, and random forest. The result showed that single cross-validation logistic regression with cost-sensitive learning achieved the best performance with sensitivity of 0.693 and specificity of 0.974. In addition, Jin et al [43] developed and evaluated deep learning–based NLP systems to automatically detect hypoglycemia events from EHR narratives; they found that the convolutional neural network model yielded a promising performance with precision of 0.96 and recall of 0.86 in a 10-fold cross-validation setting. Furthermore, none of our reviewed studies applied the currently dominant method (eg, transformer models and transfer learning) in NLP research to identify hypoglycemia from EHR data. Our review indicated that the applications of NLP to identify hypoglycemia mainly use the rule-based system. Although machine learning– and deep learning–based algorithms have been developed, they have not been applied in clinical research.

A limitation of this review is the heterogeneity of the reported results. This heterogeneity prevents the estimation of the pooled incidence and prevalence of hypoglycemia in diabetes using NLP algorithms. In addition, excluding conference proceedings reduced the number of papers included. However, medical literature does not take conference proceedings into much consideration when making clinical decisions; therefore, conference proceedings are usually not included in a review paper in medical literature. However, in terms of clinical impacts, findings from the excluded conference proceedings would have more impact regarding the clinical decision of using NLP as a clinical algorithm, which can help patients or physicians to better identify high-risk hypoglycemia. To the best of our knowledge, this is the first systematic review to synthesize the prevalence and incidence of hypoglycemia using NLP in individuals with diabetes. All reviewed studies applied the combination of NLP with ICD codes and laboratory testing and identified higher incidence of hypoglycemia when using EHR data sources. This has significant clinical implications for the prevention and management of hypoglycemia; with the widespread use of EHRs, leveraging clinical notes significantly improves the identification of individuals with hypoglycemia. The preferred strategy is to use structured data (ICD codes), followed by using NLP to synthesize the unstructured data to pinpoint those at highest risk for hypoglycemia.

Conclusions

In conclusion, our findings provided evidence that the application of NLP to analyze clinical notes improved the capture of hypoglycemic events, particularly when combined with ICD-9 and ICD-10 codes and laboratory testing. Identifying such patients with diabetes is important and necessary for characterizing treatment and unmet needs, thus preventing the adverse events and mortality associated with hypoglycemia. The current application of NLP in the identification of hypoglycemia still relies on the traditional rule-based methods; although machine learning– and deep learning–based algorithms have been developed, they have not been applied in clinical research. Future research should explore comparison of the rule-based systems, machine learning approaches, and deep learning–based NLP methods (eg, transformer models and transfer learning) to improve NLP efficiency.

Acknowledgments

Conflicts of Interest

None declared.

References

1. Centers for Disease Control and Prevention. National Diabetes Statistics Report. Centers for Disease Control and Prevention. Atlanta, GA, USA: U.S. Dept of Health and Human Services; 2020. URL: https://www.cdc.gov/diabetes/data/statistics-report/index.html [accessed 2022-04-21]

2. Ogurtsova K, da Rocha Fernandes JD, Huang Y, Linnenkamp U, Guariguata L, Cho NH, et al. IDF Diabetes Atlas: global estimates for the prevalence of diabetes for 2015 and 2040. Diabetes Res Clin Pract 2017 Jun;128:40-50. [doi: 10.1016/j.diabres.2017.03.024] [Medline: 28437734]

3. American Diabetes Association. Economic costs of diabetes in the U.S. in 2017. Diabetes Care 2018 May;41(5):917-928 [FREE Full text] [doi: 10.2337/dci18-0007] [Medline: 29567642]

4. Lee AK, Warren B, Lee CJ, McEvoy JW, Matsushita K, Huang ES, et al. The association of severe hypoglycemia with incident cardiovascular events and mortality in adults with type 2 diabetes. Diabetes Care 2018 Jan;41(1):104-111 [FREE Full text] [doi: 10.2337/dc17-1669] [Medline: 29127240]

5. Akirov A, Grossman A, Shochat T, Shimon I. Mortality among hospitalized patients with hypoglycemia: insulin related and noninsulin related. J Clin Endocrinol Metab 2017 Feb 01;102(2):416-424. [doi: 10.1210/jc.2016-2653] [Medline: 27854553]

6. Edridge CL, Dunkley AJ, Bodicoat DH, Rose TC, Gray LJ, Davies MJ, et al. Prevalence and incidence of hypoglycaemia in 532,542 people with type 2 diabetes on oral therapies and insulin: a systematic review and meta-analysis of population based studies. PLoS One 2015 Jun 10;10(6):e0126427 [FREE Full text] [doi: 10.1371/journal.pone.0126427] [Medline: 26061690]

7. Silbert R, Salcido-Montenegro A, Rodriguez-Gutierrez R, Katabi A, McCoy RG. Hypoglycemia among patients with type 2 diabetes: epidemiology, risk factors, and prevention strategies. Curr Diab Rep 2018 Jun 21;18(8):53 [FREE Full text] [doi: 10.1007/s11892-018-1018-0] [Medline: 29931579]

8. Alwafi H, Alsharif AA, Wei L, Langan D, Naser AY, Mongkhon P, et al. Incidence and prevalence of hypoglycaemia in type 1 and type 2 diabetes individuals: a systematic review and meta-analysis. Diabetes Res Clin Pract 2020 Dec;170:108522. [doi: 10.1016/j.diabres.2020.108522] [Medline: 33096187]

9. Han K, Yun JS, Park YM, Ahn YB, Cho JH, Cha SA, et al. Development and validation of a risk prediction model for severe hypoglycemia in adult patients with type 2 diabetes: a nationwide population-based cohort study. Clin Epidemiol 2018 Oct 23;10:1545-1559 [FREE Full text] [doi: 10.2147/CLEP.S169835] [Medline: 30425585]

10. Karter AJ, Moffet HH, Liu JY, Lipska KJ. Surveillance of hypoglycemia-limitations of emergency department and hospital utilization data. JAMA Intern Med 2018 Jul 01;178(7):987-988 [FREE Full text] [doi: 10.1001/jamainternmed.2018.1014] [Medline: 29710182]

11. Yu KH, Beam AL, Kohane IS. Artificial intelligence in healthcare. Nat Biomed Eng 2018 Oct;2(10):719-731. [doi: 10.1038/s41551-018-0305-z] [Medline: 31015651]

12. MIT Critical Data. Secondary Analysis of Electronic Health Records. Cham, Switzerland: Springer; 2016.

13. Zhou L, Siddiqui T, Seliger SL, Blumenthal JB, Kang Y, Doerfler R, et al. Text preprocessing for improving hypoglycemia detection from clinical notes - a case study of patients with diabetes. Int J Med Inform 2019 Sep;129:374-380. [doi: 10.1016/j.ijmedinf.2019.06.020] [Medline: 31445280]

14. Murdoch TB, Detsky AS. The inevitable application of big data to health care. JAMA 2013 Apr 03;309(13):1351-1352. [doi: 10.1001/jama.2013.393] [Medline: 23549579]

15. Zheng Y, Siminerio LM, Krall J, Anton BB, Hodges JC, Bednarz L, et al. Applying real-world data to inform continuous glucose monitoring use in clinical practice. J Diabetes Sci Technol 2021 Jul;15(4):968-969 [FREE Full text] [doi: 10.1177/1932296821997403] [Medline: 33703933]

16. Elbattah M, Arnaud É, Gignon M, Dequen G. The role of text analytics in healthcare: a review of recent developments and applications. In: Proceedings of the 14th International Joint Conference on Biomedical Engineering Systems and Technologies. 2021 Presented at: BIOSTEC '21; February 11-13, 2021; Virtual p. 825-832. [doi: 10.5220/0010414508250832]

17. Hirschberg J, Manning CD. Advances in natural language processing. Science 2015 Jul 17;349(6245):261-266. [doi: 10.1126/science.aaa8685] [Medline: 26185244]

18. Pivovarov R, Elhadad N. Automated methods for the summarization of electronic health records. J Am Med Inform Assoc 2015 Sep;22(5):938-947 [FREE Full text] [doi: 10.1093/jamia/ocv032] [Medline: 25882031]

XSL•FO
RenderX

19. Chen L, Guo U, Illipparambil LC, Netherton MD, Sheshadri B, Karu E, et al. Racing against the clock: internal medicine residents' time spent on electronic health records. J Grad Med Educ 2016 Feb;8(1):39-44 [FREE Full text] [doi: 10.4300/JGME-D-15-00240.1] [Medline: 26913101]

20. Olthof AW, Shouche P, Fennema EM, IJpma FF, Koolstra RH, Stirler VM, et al. Machine learning based natural language processing of radiology reports in orthopaedic trauma. Comput Methods Programs Biomed 2021 Sep;208:106304 [FREE Full text] [doi: 10.1016/j.cmpb.2021.106304] [Medline: 34333208]

21. Johnson SB, Adekkanattu P, Campion Jr TR, Flory J, Pathak J, Patterson OV, et al. From sour grapes to low-hanging fruit: a case study demonstrating a practical strategy for natural language processing portability. AMIA Jt Summits Transl Sci Proc 2018 May 18;2017:104-112 [FREE Full text] [Medline: 29888051]

22. Sholle ET, Pinheiro LC, Adekkanattu P, Davila MA, Johnson SB, Pathak J, et al. Underserved populations with missing race ethnicity data differ significantly from those with structured race/ethnicity documentation. J Am Med Inform Assoc 2019 Aug 01;26(8-9):722-729 [FREE Full text] [doi: 10.1093/jamia/ocz040] [Medline: 31329882]

23. Tan WK, Hassanpour S, Heagerty PJ, Rundell SD, Suri P, Huhdanpaa HT, et al. Comparison of natural language processing rules-based and machine-learning systems to identify lumbar spine imaging findings related to low back pain. Acad Radiol 2018 Nov;25(11):1422-1432 [FREE Full text] [doi: 10.1016/j.acra.2018.03.008] [Medline: 29605561]

24. Chen L, Gu Y, Ji X, Lou C, Sun Z, Li H, et al. Clinical trial cohort selection based on multi-level rule-based natural language processing system. J Am Med Inform Assoc 2019 Nov 01;26(11):1218-1226 [FREE Full text] [doi: 10.1093/jamia/ocz109] [Medline: 31300825]

25. Sulieman L, Gilmore D, French C, Cronin RM, Jackson GP, Russell M, et al. Classifying patient portal messages using Convolutional Neural Networks. J Biomed Inform 2017 Oct;74:59-70 [FREE Full text] [doi: 10.1016/j.jbi.2017.08.014] [Medline: 28864104]

26. Wu S, Roberts K, Datta S, Du J, Ji Z, Si Y, et al. Deep learning in clinical natural language processing: a methodical review. J Am Med Inform Assoc 2020 Mar 01;27(3):457-470 [FREE Full text] [doi: 10.1093/jamia/ocz200] [Medline: 31794016]

27. Rasmy L, Xiang Y, Xie Z, Tao C, Zhi D. Med-BERT: pretrained contextualized embeddings on large-scale structured electronic health records for disease prediction. NPJ Digit Med 2021 May 20;4(1):86 [FREE Full text] [doi: 10.1038/s41746-021-00455-y] [Medline: 34017034]

28. Devlin J, Chang MW, Lee K, Toutanova K. BERT: pre-training of deep bidirectional transformers for language understanding. In: Proceedings of the 2019 Conference of the North American Chapter of the Association for Computational Linguistics: Human Language Technologies. 2019 Presented at: NAACL '19; June 2-7, 2019; Minneapolis, MN, USA p. 4171-4186 URL: https://aclanthology.org/N19-1423.pdf [doi: 10.18653/v1/N19-1423]

29. Nunes AP, Iglay K, Radican L, Engel SS, Yang J, Doherty MC, et al. Hypoglycaemia seriousness and weight gain as determinants of cardiovascular disease outcomes among sulfonylurea users. Diabetes Obes Metab 2017 Oct;19(10):1425-1435. [doi: 10.1111/dom.13000] [Medline: 28497592]

30. Bramer WM. Serving Evidence Syntheses: improving literature retrieval in systematic reviews. Erasmus University Rotterdam. 2019 Oct 29. URL: https://repub.eur.nl/pub/120107 [accessed 2022-05-06]

31. Nunes AP, Yang J, Radican L, Engel SS, Kurtyka K, Tunceli K, et al. Assessing occurrence of hypoglycemia and its severity from electronic health records of patients with type 2 diabetes mellitus. Diabetes Res Clin Pract 2016 Nov;121:192-203. [doi: 10.1016/j.diabres.2016.09.012] [Medline: 27744128]

32. Loughlin AM, Qiao Q, Nunes AP, Ezzy SM, Yochum L, Clifford CR, et al. Effectiveness and tolerability of therapy with once-weekly exenatide versus basal insulin among injectable-naive patients with type 2 diabetes in a real-world setting in the United States. Diabetes Spectr 2018 May;31(2):129-137 [FREE Full text] [doi: 10.2337/ds16-0081] [Medline: 29773932]

33. Pettus J, Roussel R, Liz Zhou F, Bosnyak Z, Westerbacka J, Berria R, et al. Rates of hypoglycemia predicted in patients with type 2 diabetes on insulin Glargine 300 U/ml versus first- and second-generation basal insulin analogs: the real-world LIGHTNING study. Diabetes Ther 2019 Apr;10(2):617-633 [FREE Full text] [doi: 10.1007/s13300-019-0568-8] [Medline: 30767173]

34. Li X, Yu S, Zhang Z, Radican L, Cummins J, Engel SS, et al. Predictive modeling of hypoglycemia for clinical decision support in evaluating outpatients with diabetes mellitus. Curr Med Res Opin 2019 Nov;35(11):1885-1891. [doi: 10.1080/03007995.2019.1636016] [Medline: 31234649]

35. Misra-Hebert AD, Milinovich A, Zajichek A, Ji X, Hobbs TD, Weng W, et al. Natural language processing improves detection of nonsevere hypoglycemia in medical records versus coding alone in patients with type 2 diabetes but does not improve prediction of severe hypoglycemia events: an analysis using the electronic medical record in a large health system. Diabetes Care 2020 Aug;43(8):1937-1940 [FREE Full text] [doi: 10.2337/dc19-1791] [Medline: 32414887]

36. Uzoigwe C, Hamersky CM, Arbit DI, Weng W, Radin MS. Assessing prevalence of hypoglycemia in a medical transcription database. Diabetes Metab Syndr Obes 2020 Jun 24;13:2209-2216 [FREE Full text] [doi: 10.2147/DMSO.S235298] [Medline: 32612376]

37. Ganz ML, Wintfeld NS, Li Q, Lee YC, Gatt E, Huang JC. Severe hypoglycemia rates and associated costs among type 2 diabetics starting basal insulin therapy in the United States. Curr Med Res Opin 2014 Oct;30(10):1991-2000. [doi: 10.1185/03007995.2014.936930] [Medline: 24945720]

38.   Humphreys BL, Lindberg DA, Hole WT. Assessing and enhancing the value of the UMLS Knowledge Sources. Proc Annu Symp Comput Appl Med Care 1991:78-82 [FREE Full text] [Medline: 1807711]

39.   Ye X, Chen Q, Wang X, Dillig I, Durrett G. Sketch-driven regular expression generation from natural language and examples. Trans Assoc Comput Linguist 2020 Dec;8:679-694 [FREE Full text] [doi: 10.1162/tacl_a_00339]

40.   Liu J, Wang R, Ganz ML, Paprocki Y, Schneider D, Weatherall J. The burden of severe hypoglycemia in type 1 diabetes. Curr Med Res Opin 2018 Jan;34(1):171-177. [doi: 10.1080/03007995.2017.1391079] [Medline: 29019269]

41.   Liu J, Wang R, Ganz ML, Paprocki Y, Schneider D, Weatherall J. The burden of severe hypoglycemia in type 2 diabetes. Curr Med Res Opin 2018 Jan;34(1):179-186. [doi: 10.1080/03007995.2017.1391080] [Medline: 29017368]

42.   Chen J, Lalor J, Liu W, Druhl E, Granillo E, Vimalananda VG, et al. Detecting hypoglycemia incidents reported in patients' secure messages: using cost-sensitive learning and oversampling to reduce data imbalance. J Med Internet Res 2019 Mar 11;21(3):e11990 [FREE Full text] [doi: 10.2196/11990] [Medline: 30855231]

43.   Jin Y, Li F, Yu H. HYPE: a high performing NLP system for automatically detecting hypoglycemia events from electronic health record notes. arXiv (forthcoming) 2018 Nov 28 [FREE Full text]

Abbreviations

EHR: electronic health record

HbA$_{1c}$: glycated hemoglobin

ICD: International Classification of Diseases

ICD-10: International Classification of Diseases, Tenth Revision

ICD-9: International Classification of Diseases, Ninth Revision

NLP: natural language processing

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

T1D: type 1 diabetes

T2D: type 2 diabetes

XSL•FO
RenderX

<u>Review</u>

Smartphone Apps for Diabetes Medication Adherence: Systematic Review

Sheikh Mohammed Shariful Islam[1], MBBS, MPH, PhD; Vinaytosh Mishra[2], PhD; Muhammad Umer Siddiqui[3], MD, MS; Jeban Chandir Moses[4], MSc; Sasan Adibi[4], PhD; Lemai Nguyen[4], PhD; Nilmini Wickramasinghe[5], PhD

[1]Institute for Physical Activity and Nutrition, School of Exercise and Nutrition Sciences, Faculty of Health, Deakin University, Melbourne, Australia

[2]College of Healthcare Management and Economics, Gulf Medical University, Ajman, United Arab Emirates

[3]Department of Internal Medicine, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA, United States

[4]School of Information Technology, Deakin University, Burwood, Australia

[5]Iverson Health Innovation Research Institute, Swinburne University of Technology, Melbourne, Australia

Corresponding Author:
Sheikh Mohammed Shariful Islam, MBBS, MPH, PhD
Institute for Physical Activity and Nutrition
School of Exercise and Nutrition Sciences, Faculty of Health
Deakin University
221 Burwood Highway
Burwood
Melbourne, 3125
Australia
Phone: 61 0392468393
Email: shariful@deakin.edu.au

Abstract

Background: Diabetes is one of the leading noncommunicable chronic diseases globally. In people with diabetes, blood glucose levels need to be monitored regularly and managed adequately through healthy lifestyles and medications. However, various factors contribute to poor medication adherence. Smartphone apps can improve medication adherence in people with diabetes, but it is not clear which app features are most beneficial.

Objective: This study aims to systematically review and evaluate high-quality apps for diabetes medication adherence, which are freely available to the public in Android and Apple app stores and present the technical features of the apps.

Methods: We systematically searched Apple App Store and Google Play for apps that assist in diabetes medication adherence, using predefined selection criteria. We assessed apps using the Mobile App Rating Scale (MARS) and calculated the mean app-specific score (MASS) by taking the average of app-specific scores on 6 dimensions, namely, awareness, knowledge, attitudes, intention to change, help-seeking, and behavior change rated on a 5-point scale (1=strongly disagree and 5=strongly agree). We used the mean of the app's performance on these 6 dimensions to calculate the MASS. Apps that achieved a total MASS mean quality score greater than 4 out of 5 were considered to be of high quality in our study. We formulated a task-technology fit matrix to evaluate the apps for diabetes medication adherence.

Results: We identified 8 high-quality apps (MASS score≥4) and presented the findings under 3 main categories: characteristics of the included apps, app features, and diabetes medication adherence. Our framework to evaluate smartphone apps in promoting diabetes medication adherence considered physiological factors influencing diabetes and app features. On evaluation, we observed that 25% of the apps promoted high adherence and another 25% of the apps promoted moderate adherence. Finally, we found that 50% of the apps provided low adherence to diabetes medication.

Conclusions: Our findings show that almost half of the high-quality apps publicly available for free did not achieve high to moderate medication adherence. Our framework could have positive implications for the future design and development of apps for patients with diabetes. Additionally, apps need to be evaluated using a standardized framework, and only those promoting higher medication adherence should be prescribed for better health outcomes.

XSL•FO
RenderX

Introduction

Diabetes is one of the leading noncommunicable chronic diseases globally and poses a significant challenge to individuals' physical and mental health and quality of life [1,2]. According to the International Diabetes Federation, in 2019, approximately 463 million adults (9.3% of the global adult population) aged 20-79 years lived with diabetes [3,4]. By 2045, the number of people with diabetes is projected to surge to 700 million [3,4]. People with diabetes face long-term disease burden and financial costs [5], and an estimated 79% of adults with diabetes live in transitional countries [3]. In addition, more than 1.1 million children and adolescents are living with type 1 diabetes mellitus (T1DM) [3], involving autoimmune destruction of pancreatic β-cells, resulting in insulin deficiency [6]. Aging, urbanization, and lifestyle factors are causative factors of type 2 diabetes mellitus (T2DM) [4], which is a chronic metabolic disorder characterized by insulin insensitivity as a result of insulin resistance, declining insulin production, and eventual pancreatic β-cell failure [7]. Further, deaths due to diabetes have reached an alarming 4.2 million annually [3].

In patients with diabetes, blood glucose (BG) levels need to be monitored regularly and managed adequately to maintain health and well-being [8]. Nevertheless, almost half of the people with diabetes remain nonadherent to their prescribed medications [9-11], leading to uncontrolled diabetes, poor outcomes, and lower quality of life [10,12-14]. Nonadherence to medical therapy also results in increased absenteeism, hospitalization risk, and need for health care, which have an enormous economic impact on individuals and society [15,16]. Several factors contribute to poor adherence to medication, including complex dosing regimens, clinical inertia, safety concerns, socioeconomic issues, costs of medication, ethnicity, patient education and beliefs, social support, and polypharmacy [13,17-19]. The Prospective Urban Rural Epidemiology (PURE) study showed that 26.9% and 63.0% of households in low-income countries could not afford metformin and insulin, respectively [20]. High adherence to diabetes treatment has a beneficial impact on BMI, lipid and glycemic control, and emotional and physical performance [21]. Younger age, higher numbers of medications, and higher hemoglobin A_{1c} levels have been associated with lower medication adherence among patients with T2DM [22].

The widespread applications of information and communication technologies (ICTs) in the health sector have resulted in significant improvements in the health care delivery system, such as promoting patient-centered health care, improving quality of care, and educating health professionals and patients [23]. ICTs, including web-based, mobile phone–based, and digital technologies for electronic capture, storage, processing, and information exchange, have been used to prevent and manage chronic disease and improve medication adherence [5,24-27]. Several studies have shown mobile health as an effective and cost-effective approach for improving diabetes care [5,28-30]. The Global Observatory for eHealth, World Health Organization, defines mobile health (mHealth) as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices." mHealth capitalizes on mobile phones' core utility of voice and SMS as well as more complex functionalities and applications, including general packet radio service, mobile telecommunications, a global positioning system, and Bluetooth technology [31].

Smartphone apps on diabetes management and self-management are available for the public to download from major app stores, including Google Play and Apple App Store [32,33]. Further, several apps are available, which can collect health data, providing clinical decision support systems and assisting with medication adherence [34]. mHealth interventions are promising for the treatment and management of diabetes [35]. Further, there is strong evidence for the efficacy of apps for lifestyle modification in patients with T2DM [36] and self-managed tasks in improving health outcomes [37]. Apps have been effective in increasing treatment adherence among patients with various conditions, such as asthma, heart failure, hypertension, and HIV [38]; medication adherence among patients with depression, cardiovascular disease, Parkinson disease, hypertension, and multimorbidity [39]; older adults with coronary heart disease [40]; and essential hypertension [41]. Although a few recent reviews evaluated medication adherence among individuals with diabetes [42-44], to our knowledge, no systematic reviews have been undertaken to identify high-quality apps and evaluate their features for diabetes medication adherence. Hence, this study systematically reviews and evaluates apps available for diabetes medication adherence and presents the technical features of high-quality apps freely available to the public in Google Play and Apple App Store.

Methods

Design

This study adopted the principles of a systematic review process to identify and select apps, including using an app quality assessment tool, a search strategy, predefined inclusion criteria to screen apps, app rating and selection, and data extraction for qualitative analysis.

App Selection and Assessment

Search Strategy

Globally, the dominating operating systems in the smartphone market are Android and iOS [45]. Hence, we searched Google Play (Android) and Apple App Store (iOS) in May 2020 for apps used for diabetes medication adherence without country-specific restrictions. The key search terms used "Diabetes OR Diabetic OR Diabetics OR blood glucose OR blood sugar" AND "medication OR medicine OR drugs OR medication adherence OR medication support." The search produced a list of apps for screening. Figure 1 illustrates the process of app selection from the respective app stores.

Figure 1. App selection steps followed for Google Play and Apple App Store. MARS: Mobile App Rating Scale, T2DM: type 2 diabetes mellitus.
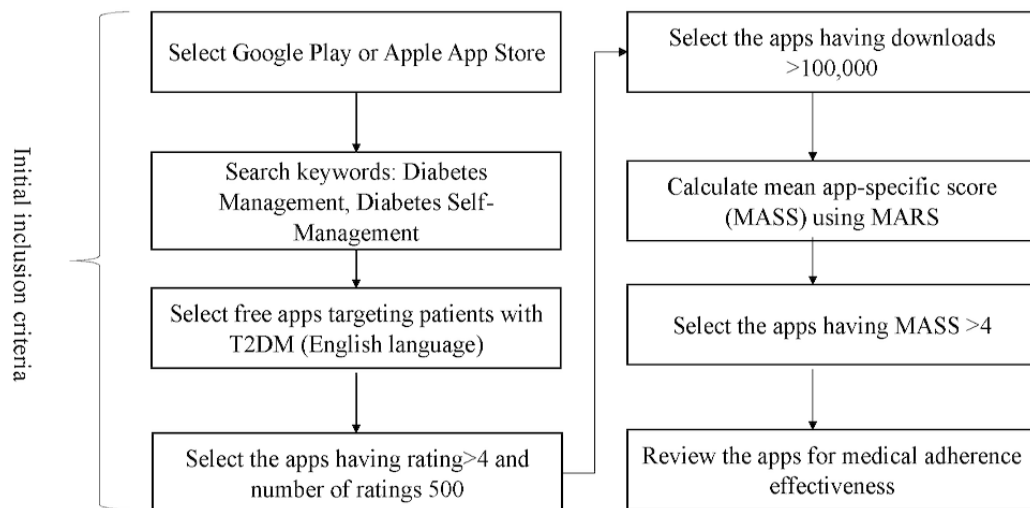
App Screening

Two researchers (VM and MS) screened the app titles and descriptions from the app stores, using the inclusion and exclusion criteria as shown in Textbox 1. In cases of disagreement, the third reviewer (SMSI) intervened to evaluate the situation and reach a consensus. We considered apps available on both the Apple and Google platforms as single apps. Further, we included apps with more than 100,000 downloads to identify the most common apps used in diabetes medication adherence, following the approach of a similar study to assess the quality of apps and perform a content analysis of apps targeting medical adherence [46]. We evaluated high-quality apps using the Mobile App Rating Scale (MARS)

[47]. Apps achieving a total mean quality score greater than 4 out of 5 in our study were considered to be of high quality [48]. MARS is a validated tool that measures app quality across 5 multidimensional layers to assess the quality of apps: (1) engagement, (2) functionality, (3) aesthetics, (4) information, and (5) app subjective quality [47]. The MARS scale gives equal weightage to all 5 dimensions and uses a 5-point rating scale from 1 to 5 with 1=inadequate and 5=excellent. The maximum score for each dimension is 25 for engagement, 20 for functionality, 15 for aesthetics, 35 for information, and 20 for app subjective quality. We calculated the total mean score by determining the mean of the average score for the 5 dimensions [47].

Textbox 1. App selection criteria.

Inclusion criteria:

- Apps for adults with type 2 diabetes
- Apps with functionality supporting medication adherence or self-management features
- Apps in the English language
- Apps available for free and not requiring a paid subscription
- Apps with >500 user ratings

Exclusion criteria:

- Apps intended only for use by health care professionals and not general public
- Apps not updated since January 1, 2018
- Apps providing only diabetes education or suggestions for medication reminders
- Apps with country restrictions
- Apps that had any technical issues such as problems with downloading, logging in, and crashing

---

App Assessment

To determine which apps to include in this study, the apps obtained after preliminary screening and application of the initial inclusion criteria were downloaded and used by the two authors (VM and MS) independently to test their functionality. After discussion, the quality assessment was reported and in case of

disagreements, input from the third author was sought. Further, we calculated the mean app-specific score (MASS) by taking the average of app-specific scores on 6 dimensions, namely, awareness, knowledge, attitudes, intention to change, help-seeking, and behavior change. These are also rated on a 5-point scale with 1=strongly disagree and 5=strongly agree. We used the mean of the app's performance on these 6

dimensions to calculate the MASS [47]. We further assessed the perceived impact of the app on the users' knowledge, attitudes, intentions to change, and the likelihood of actual change on the target health behavior (diabetes medication adherence in our case). Multimedia Appendix 1 presents an app-specific evaluation and the MASS for the considered apps.

App Rating and Selection

We considered apps with a MASS greater than 4 to identify high-quality apps for diabetes medication adherence.

Data Extraction

Two reviewers performed the data extraction. One reviewer evaluated Apple App Store's apps, and the other reviewer evaluated Google Play apps. Before reviewing the apps, the reviewers conferred and decided to include all the critical features that the apps provide. We specifically focused on medication reminders and the adherence features that the apps offer. The reviewers extracted information on the app features using a predetermined Excel (Microsoft Inc) sheet. The Excel sheet was developed on the basis of a pilot app assessment exercise with 5 apps with extensive features; the Excel sheet was refined for this study. We excluded apps that could not be assessed owing to country-specific or other restrictions. We included additional features of free apps that were available upon subscription only.

Data Analysis

We grouped the apps on the basis of the operating system (ie, Android and iOS), presented the mean MARS rating, and summarized the main features. We also presented the MASS and app-specific rating for medication adherence based on awareness, knowledge, attitude, intention to change, help-seeking, and behavior change.

Results

Overview

We identified 249 apps in Google Play and 209 apps in the Apple App Store. The initial inclusion criteria resulted in 63 and 39 Apps for Google Play and Apple App Store, respectively. Finally, 8 apps with a MARS greater than 4 were included. The mean MASS for the included apps was 4.2, and the average app rating by users was 4.7. Figure 2 depicts the app selection methodology followed for both Apple App Store and Google Play for selecting the relevant apps that satisfy the selection criteria.

Figure 2. Summary of app selection for review. MASS: mean app-specific score.
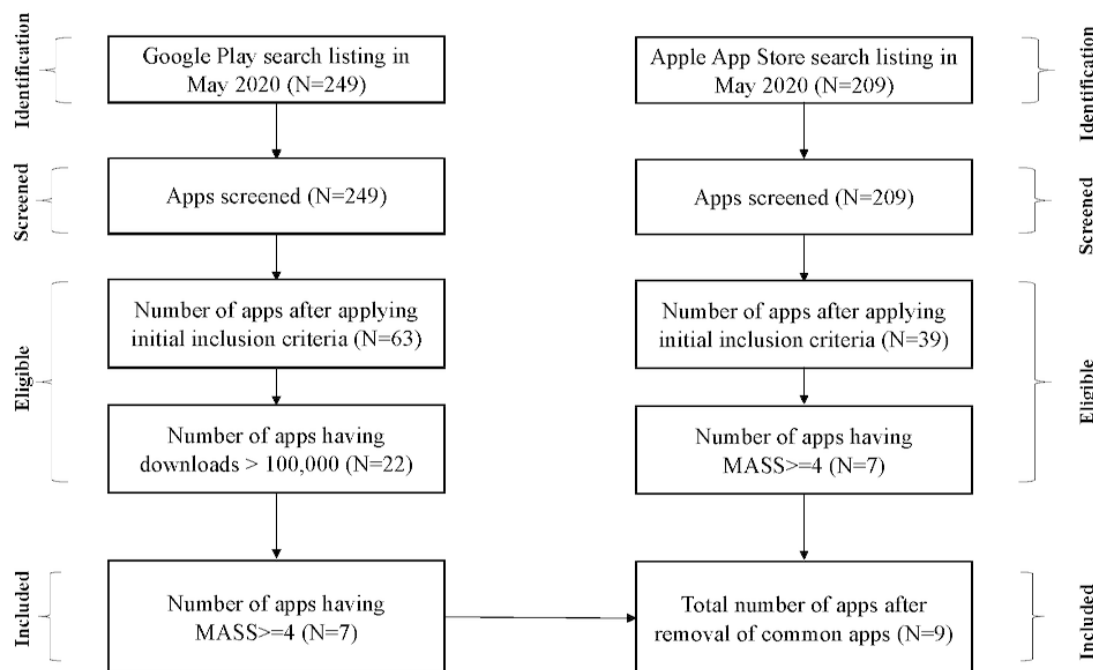
Characteristics of the Included Apps

All 8 apps were available in the Apple Store [49-56], 7 were available in Google Play [49-55], and one app had the option to be accessed through a web application and Amazon Alexa

[56]. Given that all the apps were available in the Apple App Store, we extracted information for the apps from the App Store. Table 1 presents an overview of the apps. In contrast, Multimedia Appendix 2 presents detailed information for each app.

Table 1. Overview of the apps.

Apps	Operating system	Category	Available languages, n	Data privacy		Seller	In-app purchases
				Identified	Deidentified		
Diabetes:M [49]	Android and iOS	Medical	8	Yes	Yes	Chronic disease software development company	Yes
mySugr - Diabetes Tracker Log [52]	Android and iOS	Medical	24	Yes	No	Digital health company	Yes
Health2Sync [51]	Android and iOS	Medical	4	Yes	No	Digital health company	Yes
MyTherapy Pill Reminder [53]	Android and iOS	Medical	30	No	Yes	Health, wellness, and fitness	No
One Drop: Transform Your Life [54]	Android and iOS	Health and fitness	11	Yes	Yes	Software and Technology services	Yes
Glucose Buddy Diabetes Tracker [50]	Android and iOS	Medical	31	Yes	Yes	Individual	Yes
OneTouch Reveal [55]	Android and iOS	Medical	14	Yes	Yes	Diagnostic systems manufacturer	No
Sugarmate [56]	iOS	Medical	5	Required to provide with the next app update	Required to provide with the next app update	Software company	No

The Apple App Store apps were categorized as medical [49-53,55,56] and health and fitness [54] apps. Including English language, the apps were available in around 5 [51,56], 10 [49,54,55], 20 [52], and 30 languages [50,53]. Additionally, all the apps had family sharing options (ie, the app could be shared with and used by 6 family members) [49-56]. Apart from one app [56], the apps defined their privacy policy explicitly, defining the identified [49-52,54,55] and deidentified data [49,50,53-55], although it differed between the apps. For example, data such as health and fitness information, contact information, identifiers, diagnostics, location, user content, and usage data were considered "identified" data by one app [52]. In contrast, the same data were considered "deidentified" data by another app [53]. Further, the apps were sold by software companies [54,56], digital health companies [49,51,52,55], health and fitness companies [53], and individuals [50]. Finally, although all the apps were free [49-56], they had an in-app

purchase option [49-52,54]; that is, users had the option to pay a prescribed amount to access additional features, such as premium subscription features [49-52] and access to a coach [54].

The compatible operating system (OS) version for the apps varied drastically between the apps. For the apps to run smoothly, 9.0 [49], 10.3 [56], 11.0 [51], 12.0 [50], 13.0 [53-55], 13.2 [52] or later versions of the OS were required.

App Features

Overview

In this section, we discuss the salient features of the apps evaluated against standard parameters. However, we have considered the free app features for this analysis (and we have not considered the in-app features). Figure 3 illustrates the apps and their corresponding features.

Figure 3. Apps and their corresponding features. CGM: continuous glucose monitoring, DM: diabetes mellitus, T1DM: type 1 diabetes mellitus, T2DM: type 2 diabetes mellitus.
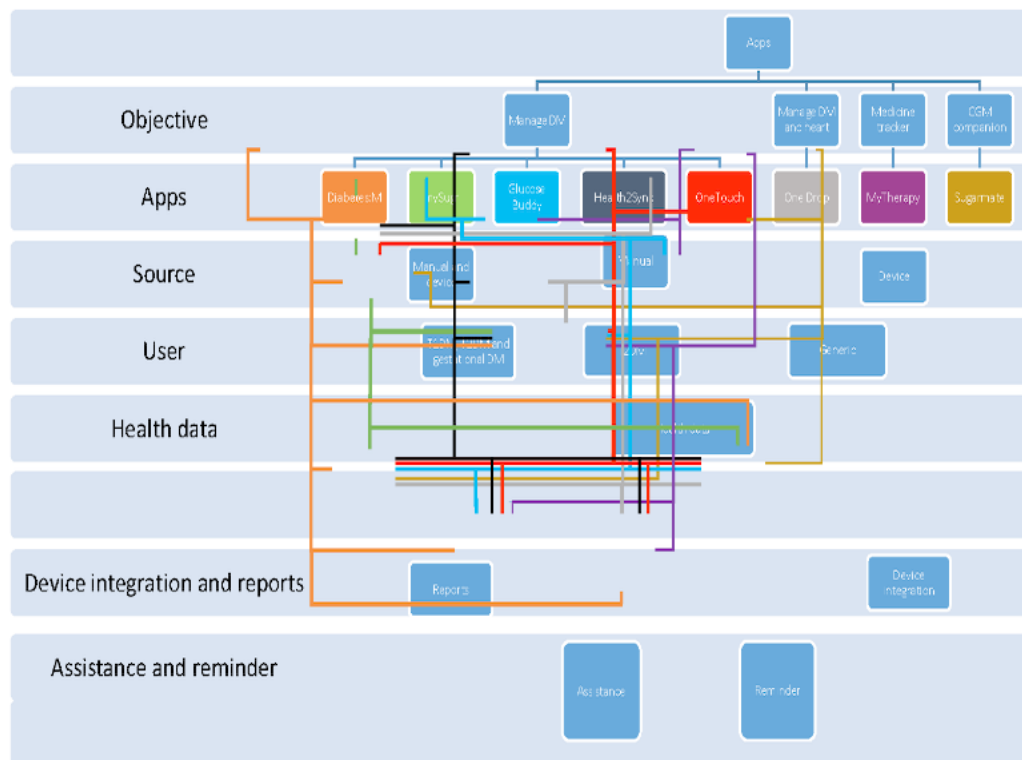
Device Objective and Target Population

The primary objective of the apps was to manage diabetes [49-52,55], manage diabetes and heart health [54], assist in medication tracking [53], and function as a companion to a continuous glucose monitoring (CGM) device [56]. Although a few apps have been developed for the general population irrespective of their medical condition [50,53,56], a few other apps aimed to address the needs of patients with T2DM [51,54]. In contrast, other apps had functionalities to address the health and well-being needs of patients with T1DM, T2DM, or gestational diabetes mellitus [49,52,55]. The apps had age ratings of 4+ [50-54,56] and 17+ [49,55].

BG Reading

The apps had different methodologies and used varying technologies to capture the BG recordings. For example, some apps could log in to the recordings manually [50,53]. In contrast, a few other apps could capture CGM recordings from the integrated BG monitoring (BGM) devices [55,56]. Nevertheless, some other apps could manually log in the BG recordings and CGM recordings from the integrated BGM devices [49,51,52,54].

Health Data

In addition to recording BG readings, the apps had the option to capture other health-related data, including food consumed [49,50,52,54-56], blood pressure [50-54], weight [50-54], daily activity and steps walked [52,54-56], and medication [49,50,52,54]. Further, regarding food consumption, the apps specifically considered the intake of carbohydrates [49,50,52,55,56], protein [49], fats [49], and calories [49].

Device Integration

There are various BGM or CGM devices available in the market, and some apps could integrate and function with multiple devices, such as Dexcom, OneTouch, and Accu-Chek [49,51,54]. In contrast, other apps functioned exclusively with a device, such as Accu-Chek [52] and Dexcom [49,50,54]. Moreover, an app developed by the seller of the OneTouch device aimed to capture CGM recordings to perform analysis tasks integrating other health parameters [55]. In contrast, a seller not related to the Dexcom device developed an app to capture the CGM readings in real time and perform other tasks [56].

Reports

The apps had features to generate reports on BG levels, taking into consideration other factors including food consumed [49,50,52,54-56], physical activity [49,54,55], medication [49,50,52,54], and other vital recordings [50,51,53,54,56]. From the reports generated, the apps provided an overview of short durations of captured data such as whenever the app is launched [51]; hourly [50], daily [49,52,54,56], weekly [49,52,54], and fortnightly [55]; and longer durations such as monthly [49,52,54] and yearly [49]. Moreover, a few apps could alert individuals when their BG levels dropped below or increased past threshold values through notifications [49,55], SMS text messaging [51,56], or phone calls [56].

Reminders

Forgetting to take medication is a significant cause of medication nonadherence among patients [57]; hence, apps with reminders could improve adherence. The apps had reminders to check

glucose levels [49], take meals [49,54,55], medications [53,54], exercise [53,54], and address other personalized medical needs [51,55].

Adherence Motivation

To continuously support individuals in their journey of diabetes medication adherence, apps have provided options to invite clinicians, nutritionists, family, friends, and loved ones to view their progress and accordingly assist them [51,53,54]; have patient information for further support [49], providing personalized tips [51,53,55]; and deliver an education plan featuring 5-minute lessons [50]. In addition, a few apps had gamification features (ie, elements of game-playing), such as point-scoring, competition with others, and challenges to encourage engagement [52,54-56].

Diabetes Medication Adherence

Among people with diabetes, optimum glycemic control is essential, and good adherence is associated with a lower risk of all-cause mortality and hospitalization [58]. Many models have been studied to explore the acceptance and use of technologies. One such model is task-technology fit (TTF). TTF states that a technology should be effective in completing the assigned task, which will lead to an increase in user performance and adoption [59]. TTF rates the task characteristics and technology characteristics of apps, which affects the effectiveness and adoption of the apps by the user. Accordingly, in this section, we used the TTF and quantified the effectiveness of apps in diabetes adherence to evaluate whether the apps promote adherence to diabetes medication [60,61]. A recent study used TTF to evaluate the effectiveness of the mHealth app in delivering health care services [62].

Primary prevention and mitigating the severity of diabetes revolve around regular BG checks, food consumed, physical activity, other vital readings, and adherence to medication [63]. Hence, they are the primary factors considered in this study. Although apps have been found to improve awareness of medication adherence and reduce self-reported barriers to medication adherence among medication-nonadherent patients with diabetes [64], a study observed that a large proportion of diabetes self-management apps lacked features for enhancing medication adherence and safety [65]. Consequently, among the app features, we considered the overview (report generated and graphically presented for a period), reminders (customized alerts to perform tasks), notifications (alerts when BG shoots up or drops below the threshold), assistance (additional support provided by various stakeholders), and motivation (assistance from loved ones and challenges through gamification) as the imperative app features needed to support an individual in diabetes medication adherence.

Table 2 presents a TTF matrix for diabetes medication adherence to evaluate the apps against the defined primary factors and app features. In the matrix, we have marked "yes" when factors and features are available. We then totaled the score for primary factors and app features separately. We defined a score of 5 in both primary factors and app features as apps assisting in very high adherence, 4 and above in either primary factors or app features as apps assisting in high adherence, and a score of 3 and above in either primary factors or app features as apps assisting in moderate adherence. We further defined a low adherence app as apps scoring 2 and above in either primary factors or app features and any score below 2 for primary factors or app features as apps resulting in poor adherence.

Table 2. The task-technology fit matrix for diabetes medication adherence.

App	Primary factors						App features					
	Blood glucose	Food	Physical Activity	Medication	Vital signs	Score	Overview	Reminder	Notification	Assistance	Motivation	Score
Diabetes:M [49]	Yes	Yes	Yes	Yes	No	4	Yes	Yes	Yes	Yes	No	4
mySugr - Diabetes Tracker Log [52]	Yes	Yes	No	Yes	No	3	Yes	No	No	No	Yes	2
Health2Sync [51]	Yes	No	No	No	Yes	2	Yes	Yes	Yes	Yes	Yes	5
MyTherapy Pill Reminder [53]	Yes	No	No	No	Yes	2		Yes	No	Yes	Yes	3
One Drop: Transform Your Life [54]	Yes	Yes	Yes	Yes	Yes	5	Yes	Yes	No	No	Yes	3
Glucose Buddy Diabetes Tracker [50]	Yes	No	No	Yes	Yes	3	Yes	No	No	Yes	No	2
OneTouch Reveal [55]	Yes	Yes	Yes	Yes	No	4	Yes	Yes	Yes	Yes	Yes	5
Sugarmate [56]	Yes	Yes	No	Yes	Yes	4	Yes	No	Yes	No	Yes	3

According to our evaluation, none of the apps assists in very high adherence, and there are no poor-adherence apps. In addition, we found that 3 apps each assisted in high adherence (25%) [49,55] and moderate adherence to diabetes medication (25%) [54,56]. In contrast, 4 other apps were in the low adherence category in assisting with diabetes medication adherence (50%) [50-53].

Discussion

Principal Findings

In this systematic review, we identified 8 high-quality apps publicly available in the Apple App Store and Google Play free of charge. The mean MASS of the apps was 4.2, while the average user ratings was 4.7. Only 2 apps showed high adherence and 2 apps showed moderate adherence, while half of the apps showed low adherence. However, since the global market is poised for rapid growth and could have widespread implications in delivering personalized health care [66], interoperable mHealth solutions available in the Apple App Store and Google Play are generally designed and developed for widespread adaptability. Our systematic review suggests evaluating apps using a standardized framework before prescribing them to patients with diabetes, and using behavioral theories for improving medication adherence.

All the apps were available in English and more than 5 other languages [49-56]. Moreover, bilingual English-speaking patients expressed the need for language translation to understand and communicate using the apps [67], and the selected apps could address this concern through the multilanguage option provided. However, globally, 79% of adults with diabetes live in transitional countries [3]. An increase in mobile phone subscriptions over the years, including in transitional countries [68], and the constant technological advancements in mobile phones [69] promote mHealth as effective for use in transitional countries having barriers, such as lack of infrastructure and equipment and technology gaps [70]. Hence, if the selected apps have languages that predominate in transitional countries with a higher prevalence of diabetes, they might assist in diabetes management, reducing the burden on the health care system and curbing mortality rates.

Deidentification is essential for protecting patient privacy and removing identifiers that directly or indirectly point to a person [71]. However, there is variability in the definition of deidentification [72]. For instance, among the considered apps, health and fitness, contact information, identifiers, diagnostics, location, user content, and usage data were considered identified data by one app [52]. In contrast, the same data were deemed deidentified data by another app [53]. This discrepancy could be due to differences in definitions and legal practice followed in countries where the apps have been developed [72]. Hence, health care apps developed in accordance with the guidelines of legislation, such as the US Health Insurance Portability and Accountability Act and the European General Data Protection Regulation, could have uniformity in defining identified and deidentified data [72]. Accordingly, following global regulatory guidelines could bring uniformity in the use of identified and deidentified data.

In-app purchases permit the user to purchase added services from within an app, and 5 apps considered in this study had this feature [49-52,54]. Remarkably, in-app purchase options work well in promoting health apps wherein the essential functions are offered freely [73]. However, the intention to upgrade to a paid subscription is driven by the subscription features, benefits, and price value [74]. Hence, developing free health apps with in-app purchase options will be necessary to promote the app; however, the content should provide sufficient value to retain subscriptions [74].

A few apps described in this study could be used by all patients with diabetes [50,53,56]. In contrast, other apps were specifically targeted to patients with T2DM [51,54] or to those with T1DM, T2DM, or gestational DM [49,52,55]. Nevertheless, apps with specific descriptions were sought more by users compared to those with general descriptions [75]. Some apps had an age rating of ≥4 [50-54,56] and ≥17 [49,55]. T1DM affects children [3], and although some apps were indicated as suitable for patients with T1DM, the age rating was ≥17 [49,55]. Another app had an age rating of ≥4 and could be used by patients with T1DM [52]. Hence, developing apps with specific descriptions and appropriate age ratings could assist the appropriate target population.

We have considered physiological factors influencing diabetes and app features to develop and assess apps using the TTF matrix.

Limitations of the Research

This review had certain limitations. First, in this study, we included apps that had greater than 500 ratings. Therefore, we could have eliminated several new apps with fewer than 500 reviews, but that might have had a higher MASS. Second, we included only apps in the English language, possibly missing effective apps in languages other than English. Third, our search date was limited to May 2020. However, the constraints associated with the severity of the COVID-19 pandemic could have enabled the development and usage of apps that satisfied our selection criteria. Finally, we limited our search to the apps available in the major app stores: Apple App Store and Google Play. However, these stores account for 80% (4.41 million) of the global apps as of May 2020 [76].

Implications and Future Research

Our findings provide guidelines for app developers to develop an app that assists in diabetes medication adherence. Further, several apps are very likely to be developed and prescribed during the pandemic period [77,78]. Therefore, evaluating the apps using our framework could help the apps to provide high medication adherence for better health and well-being of patients with diabetes. With the advancement in smartphone technology, various health vitals could be captured and transferred in real time for analysis [79-81]. The application of machine learning and big data could provide a wealth of predictive information to the patient and to health care professionals [82-87]. Furthermore, high-quality apps coupled with evidence-based ICT programs using user-centric designs, wearable device, and machine learning approaches could be used to provide personalized interventions for people with diabetes [84,87-93].

Hence, our findings could have practical and research implications for diabetes medication adherence.

Conclusions

Our framework to evaluate smartphone apps in promoting diabetes medication adherence has considered physiological factors influencing diabetes and app features. Therefore, our findings could have positive implications for the design and development of apps for patients with diabetes. Additionally, the available apps could be evaluated in accordance with our framework, and those apps promoting higher medication adherence could be prescribed for better health outcomes.

Authors' Contributions

SMSI, VM, and MUS conceptualized the paper. VM and MUS downloaded the apps and performed screening and data extraction. SMSI, VM, and MUS wrote the first draft. All other authors provided data, developed models, reviewed results, provided guidance on methodology, or reviewed and contributed to the manuscript. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Apps Selected for the Review and MASS.
[DOCX File , 15 KB - diabetes_v7i2e33264_app1.docx]

Multimedia Appendix 2
Detailed information on all apps.
[DOCX File , 21 KB - diabetes_v7i2e33264_app2.docx]

References

1.   Islam SMS, Purnat TD, Phuong NTA, Mwingira U, Schacht K, Fröschl G. Non-communicable diseases (NCDs) in developing countries: a symposium report. Global Health 2014 Dec 11;10(1):81 [FREE Full text] [doi: 10.1186/s12992-014-0081-9] [Medline: 25498459]

2.   Sun H, Saeedi P, Karuranga S, Pinkepank M, Ogurtsova K, Duncan BB, et al. IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045. Diabetes Res Clin Pract 2022 Jan;183:109119. [doi: 10.1016/j.diabres.2021.109119] [Medline: 34879977]

3.   International Diabetes Federation. URL: https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html [accessed 2020-12-10]

4.   Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, IDF Diabetes Atlas Committee. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9 edition. Diabetes Res Clin Pract 2019 Nov;157:107843. [doi: 10.1016/j.diabres.2019.107843] [Medline: 31518657]

5.   Islam SMS, Peiffer R, Chow CK, Maddison R, Lechner A, Holle R, et al. Cost-effectiveness of a mobile-phone text messaging intervention on type 2 diabetes—A randomized-controlled trial. Health Policy and Technology 2020 Mar;9(1):79-85. [doi: 10.1016/j.hlpt.2019.12.003]

6.   Kahanovitz L, Sluss PM, Russell SJ. Type 1 Diabetes - A Clinical Perspective. Point Care 2017 Mar;16(1):37-40 [FREE Full text] [doi: 10.1097/POC.0000000000000125] [Medline: 28943810]

7.   Olokoba AB, Obateru OA, Olokoba LB. Type 2 diabetes mellitus: a review of current trends. Oman Med J 2012 Jul 16;27(4):269-273 [FREE Full text] [doi: 10.5001/omj.2012.68] [Medline: 23071876]

8.   Nguyen L, Adibi S, Wickramasinghe N. Towards a Better Life for Diabetic Patients: Developing and Integrating a Non-invasive Self-Management Support Tool Within a Smart Digital Companion. In: Delivering Superior Health and Wellness Management with IoT and Analytics. Cham: Springer; 2019:207-222.

9.   Aminde LN, Tindong M, Ngwasiri CA, Aminde JA, Njim T, Fondong AA, et al. Adherence to antidiabetic medication and factors associated with non-adherence among patients with type-2 diabetes mellitus in two regional hospitals in Cameroon. BMC Endocr Disord 2019 Apr 03;19(1):35 [FREE Full text] [doi: 10.1186/s12902-019-0360-9] [Medline: 30943969]

10. Islam SMS, Biswas T, Bhuiyan FA, Mustafa K, Islam A. Patients' perspective of disease and medication adherence for type 2 diabetes in an urban area in Bangladesh: a qualitative study. BMC Res Notes 2017 Mar 21;10(1):131 [FREE Full text] [doi: 10.1186/s13104-017-2454-7] [Medline: 28327202]

11. Polonsky W, Henry R. Poor medication adherence in type 2 diabetes: recognizing the scope of the problem and its key contributors. PPA 2016 Jul;Volume 10:1299-1307. [doi: 10.2147/ppa.s106821]

12. Islam SMS, Uddin R, Zaman SB, Biswas T, Tansi T, Chegini Z, et al. Healthcare seeking behavior and glycemic control in patients with type 2 diabetes attending a tertiary hospital. Int J Diabetes Dev Ctries 2020 Oct 08;41(2):280-287. [doi: 10.1007/s13410-020-00875-8]

13. Safita N, Islam SMS, Chow CK, Niessen L, Lechner A, Holle R, et al. The impact of type 2 diabetes on health related quality of life in Bangladesh: results from a matched study comparing treated cases with non-diabetic controls. Health Qual Life Outcomes 2016 Sep 13;14(1):129 [FREE Full text] [doi: 10.1186/s12955-016-0530-7] [Medline: 27624600]

14. Islam SMS, Rawal LB, Niessen LW. Prevalence of depression and its associated factors in patients with type 2 diabetes: A cross-sectional study in Dhaka, Bangladesh. Asian J Psychiatr 2015 Oct;17:36-41. [doi: 10.1016/j.ajp.2015.07.008] [Medline: 26259893]

15. Cutler RL, Fernandez-Llimos F, Frommer M, Benrimoj C, Garcia-Cardenas V. Economic impact of medication non-adherence by disease groups: a systematic review. BMJ Open 2018 Jan 21;8(1):e016982 [FREE Full text] [doi: 10.1136/bmjopen-2017-016982] [Medline: 29358417]

16. Shariful Islam SM, Lechner A, Ferrari U, Laxy M, Seissler J, Brown J, et al. Healthcare use and expenditure for diabetes in Bangladesh. BMJ Glob Health 2017 Jan 03;2(1):e000033 [FREE Full text] [doi: 10.1136/bmjgh-2016-000033] [Medline: 28588991]

17. Bailey C, Kodack M. Patient adherence to medication requirements for therapy of type 2 diabetes. Int J Clin Pract 2011 Mar;65(3):314-322. [doi: 10.1111/j.1742-1241.2010.02544.x] [Medline: 21314869]

18. Islam SMS, Islam MT, Uddin R, Tansi T, Talukder S, Sarker F, et al. Factors associated with low medication adherence in patients with Type 2 diabetes mellitus attending a tertiary hospital in Bangladesh. Lifestyle Medicine 2021 Sep 07;2(4). [doi: 10.1002/lim2.47]

19. Kherallah R, Al Rifai M, Kamat I, Krittanawong C, Mahtta D, Lee MT, et al. Prevalence and predictors of cost-related medication nonadherence in individuals with cardiovascular disease: Results from the Behavioral Risk Factor Surveillance System (BRFSS) survey. Prev Med 2021 Dec;153:106715 [FREE Full text] [doi: 10.1016/j.ypmed.2021.106715] [Medline: 34242664]

20. Chow CK, Ramasundarahettige C, Hu W, AlHabib KF, Avezum A, Cheng X, et al. Availability and affordability of essential medicines for diabetes across high-income, middle-income, and low-income countries: a prospective epidemiological study. Lancet Diabetes Endocrinol 2018 Oct;6(10):798-808. [doi: 10.1016/s2213-8587(18)30233-x]

21. Marinho FS, Moram CBM, Rodrigues PC, Leite NC, Salles GF, Cardoso CRL. Treatment Adherence and Its Associated Factors in Patients with Type 2 Diabetes: Results from the Rio de Janeiro Type 2 Diabetes Cohort Study. J Diabetes Res 2018 Nov 27;2018:8970196-8970198 [FREE Full text] [doi: 10.1155/2018/8970196] [Medline: 30599003]

22. Aloudah NM, Scott NW, Aljadhey HS, Araujo-Soares V, Alrubeaan KA, Watson MC. Medication adherence among patients with Type 2 diabetes: A mixed methods study. PLoS One 2018 Dec 11;13(12):e0207583 [FREE Full text] [doi: 10.1371/journal.pone.0207583] [Medline: 30533042]

23. Islam SMS, Tabassum R. Implementation of information and communication technologies for health in Bangladesh. Bull World Health Organ 2015 Aug 31;93(11):806-809. [doi: 10.2471/blt.15.153684]

24. Gutierrez MA, Moreno RA, Rebelo MS. Information and Communication Technologies and Global Health Challenges. In: Global Health Informatics: How Information Technology Can Change our Lives in a Globalized World. Cambridge, MA: Academic Press; 2017:50-93.

25. Rouleau G, Gagnon M, Côté J. Impacts of information and communication technologies on nursing care: an overview of systematic reviews (protocol). Syst Rev 2015 May 23;4(1):75 [FREE Full text] [doi: 10.1186/s13643-015-0062-y] [Medline: 26002726]

26. Shariful Islam SM, Niessen LW, Ferrari U, Ali L, Seissler J, Lechner A. Effects of Mobile Phone SMS to Improve Glycemic Control Among Patients With Type 2 Diabetes in Bangladesh: A Prospective, Parallel-Group, Randomized Controlled Trial. Diabetes Care 2015 Aug;38(8):e112-e113. [doi: 10.2337/dc15-0505] [Medline: 26207059]

27. Dening J, Islam SMS, George E, Maddison R. Web-Based Interventions for Dietary Behavior in Adults With Type 2 Diabetes: Systematic Review of Randomized Controlled Trials. J Med Internet Res 2020 Aug 28;22(8):e16437 [FREE Full text] [doi: 10.2196/16437] [Medline: 32857059]

28. Chen YR, Schulz PJ. The Effect of Information Communication Technology Interventions on Reducing Social Isolation in the Elderly: A Systematic Review. J Med Internet Res 2016 Jan 28;18(1):e18 [FREE Full text] [doi: 10.2196/jmir.4596] [Medline: 26822073]

29. Shariful Islam SM, Farmer AJ, Bobrow K, Maddison R, Whittaker R, Pfaeffli Dale LA, et al. Mobile phone text-messaging interventions aimed to prevent cardiovascular diseases (Text2PreventCVD): systematic review and individual patient data meta-analysis. Open Heart 2019 Oct 09;6(2):e001017 [FREE Full text] [doi: 10.1136/openhrt-2019-001017] [Medline: 31673381]

XSL•FO

RenderX

30. Shariful Islam SM, Lechner A, Ferrari U, Seissler J, Holle R, Niessen LW. Mobile phone use and willingness to pay for SMS for diabetes in Bangladesh. J Public Health (Oxf) 2016 Mar 16;38(1):163-169. [doi: 10.1093/pubmed/fdv009] [Medline: 25687131]

31. mHealth: new horizons for health through mobile technologies: second global survey on eHealth. World Health Organization. 2011. URL: https://www.who.int/goe/publications/goe_mhealth_web.pdf [accessed 2022-04-13]

32. Larbi D, Randine P, Årsand E, Antypas K, Bradway M, Gabarron E. Methods and Evaluation Criteria for Apps and Digital Interventions for Diabetes Self-Management: Systematic Review. J Med Internet Res 2020 Jul 06;22(7):e18480 [FREE Full text] [doi: 10.2196/18480] [Medline: 32628125]

33. Veazie S, Winchell K, Gilbert J, Paynter R, Ivlev I, Eden KB, et al. Rapid Evidence Review of Mobile Applications for Self-management of Diabetes. J Gen Intern Med 2018 Jul 8;33(7):1167-1176 [FREE Full text] [doi: 10.1007/s11606-018-4410-1] [Medline: 29740786]

34. Kubben P. Mobile apps, in Fundamentals of Clinical Data Science. In: Kubben P, Dumontier M, Dekker A, editors. Fundamentals of Clinical Data Science. Cham: Springer; 2019:171-179.

35. Wang Y, Min J, Khuri J, Xue H, Xie B, A Kaminsky L, et al. Effectiveness of Mobile Health Interventions on Diabetes and Obesity Treatment and Management: Systematic Review of Systematic Reviews. JMIR Mhealth Uhealth 2020 Apr 28;8(4):e15400 [FREE Full text] [doi: 10.2196/15400] [Medline: 32343253]

36. Wu X, Guo X, Zhang Z. The Efficacy of Mobile Phone Apps for Lifestyle Modification in Diabetes: Systematic Review and Meta-Analysis. JMIR Mhealth Uhealth 2019 Jan 15;7(1):e12297 [FREE Full text] [doi: 10.2196/12297] [Medline: 30664494]

37. Jeffrey B, Bagala M, Creighton A, Leavey T, Nicholls S, Wood C, et al. Mobile phone applications and their use in the self-management of Type 2 Diabetes Mellitus: a qualitative study among app users and non-app users. Diabetol Metab Syndr 2019 Oct 16;11(1):84 [FREE Full text] [doi: 10.1186/s13098-019-0480-4] [Medline: 31636719]

38. Pérez-Jover V, Sala-González M, Guilabert M, Mira JJ. Mobile Apps for Increasing Treatment Adherence: Systematic Review. J Med Internet Res 2019 Jun 18;21(6):e12505 [FREE Full text] [doi: 10.2196/12505] [Medline: 31215517]

39. Armitage LC, Kassavou A, Sutton S. Do mobile device apps designed to support medication adherence demonstrate efficacy? A systematic review of randomised controlled trials, with meta-analysis. BMJ Open 2020 Jan 30;10(1):e032045 [FREE Full text] [doi: 10.1136/bmjopen-2019-032045] [Medline: 32005778]

40. Park LG, Ng F, K Shim J, Elnaggar A, Villero O. Perceptions and experiences of using mobile technology for medication adherence among older adults with coronary heart disease: A qualitative study. Digit Health 2020 May 20;6:2055207620926844 [FREE Full text] [doi: 10.1177/2055207620926844] [Medline: 32489672]

41. Mohammadi Tork Abad S, Negahban Bonabi T, Heidari S. Effectiveness of smartphone-based medication reminder application on medication adherence of patients with essential hypertension: A clinical trial study. J Nurs Midwifery Sci 2020;7(4):219. [doi: 10.4103/jnms.jnms_16_20]

42. McGovern A, Tippu Z, Hinton W, Munro N, Whyte M, de Lusignan S. Systematic review of adherence rates by medication class in type 2 diabetes: a study protocol. BMJ Open 2016 Feb 29;6(2):e010469 [FREE Full text] [doi: 10.1136/bmjopen-2015-010469] [Medline: 26928029]

43. Capoccia K, Odegard PS, Letassy N. Medication Adherence With Diabetes Medication: A Systematic Review of the Literature. Diabetes Educ 2016 Feb 04;42(1):34-71. [doi: 10.1177/0145721715619038] [Medline: 26637240]

44. Anderson L, Nuckols TK, Coles C, Le MM, Schnipper JL, Shane R, Members of the PHARM-DC Group. A systematic overview of systematic reviews evaluating medication adherence interventions. Am J Health Syst Pharm 2020 Jan 08;77(2):138-147 [FREE Full text] [doi: 10.1093/ajhp/zxz284] [Medline: 31901098]

45. Chmielarz W. The Usage of Smartphone and Mobile Applications from the Point of View of Customers in Poland. Information 2020 Apr 17;11(4):220. [doi: 10.3390/info11040220]

46. Park JYE, Li J, Howren A, Tsao NW, De Vera M. Mobile Phone Apps Targeting Medication Adherence: Quality Assessment and Content Analysis of User Reviews. JMIR Mhealth Uhealth 2019 Jan 31;7(1):e11919 [FREE Full text] [doi: 10.2196/11919] [Medline: 30702435]

47. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015 Mar 11;3(1):e27 [FREE Full text] [doi: 10.2196/mhealth.3422] [Medline: 25760773]

48. LeBeau K, Huey LG, Hart M. Assessing the Quality of Mobile Apps Used by Occupational Therapists: Evaluation Using the User Version of the Mobile Application Rating Scale. JMIR Mhealth Uhealth 2019 May 01;7(5):e13019 [FREE Full text] [doi: 10.2196/13019] [Medline: 31066712]

49. Diabetes:M. Manage Diabetes Like a Pro!. Apple Inc. URL: https://apps.apple.com/au/app/diabetes-m/id1196733537 [accessed 2022-06-02]

50. Glucose Buddy Diabetes Tracker (Version 5.328). Apple Inc. URL: https://apps.apple.com/us/app/glucose-buddy-diabetes-tracker/id294754639 [accessed 2022-06-02]

51. Health2Sync (Version 2.5.2). Apple Inc. URL: https://apps.apple.com/au/app/health2sync/id806136243 [accessed 2022-06-02]

52. mySugr - Diabetes Tracker Log (Version 3.83.4). Apple Inc. URL: https://apps.apple.com/au/app/mysugr-diabetes-tracker-log/id516509211 [accessed 2022-06-02]

53.   MyTherapy Pill Reminder (Version 3.75.2). Apple Inc. URL: https://apps.apple.com/au/app/mytherapy-pill-reminder/id662170995 [accessed 2022-06-02]

54.   One Drop: Better Health Today (Version 6.17.0). Apple Inc. URL: https://apps.apple.com/us/app/one-drop-diabetes-management/id972238816 [accessed 2022-06-02]

55.   OneTouch Reveal (Version 5.3). Apple Inc. URL: https://apps.apple.com/us/app/onetouch-reveal/id651293599?shortlink=ed2241e6&pid=US%20Site [accessed 2022-06-02]

56.   Sugarmate | Diabetes Tracker (Version 2.6.23). Apple Inc. URL: https://apps.apple.com/us/app/sugarmate/id1111093108 [accessed 2022-06-02]

57.   Alshehri K, Altuwaylie TM, Alqhtani A, Albawab AA, Almalki AH. Type 2 Diabetic Patients Adherence Towards Their Medications. Cureus 2020 Feb 10;12(2):e6932 [FREE Full text] [doi: 10.7759/cureus.6932] [Medline: 32190485]

58.   Khunti N, Khunti N, Khunti K. Adherence to type 2 diabetes management. Br J Diabetes 2019 Dec 17;19(2):99-104. [doi: 10.15277/bjd.2019.223]

59.   Goodhue DL, Thompson RL. Task-Technology Fit and Individual Performance. MIS Quarterly 1995 Jun;19(2):213. [doi: 10.2307/249689]

60.   Spies R, Grobbelaar S, Botha A. A Scoping Review of the Application of the Task-Technology Fit Theory. 2020 Presented at: 19th IFIP WG 6.11 Conference on e-Business, e-Services, and e-Society, I3E 2020; April 6-8, 2020; Skukuza p. 397-408. [doi: 10.1007/978-3-030-44999-5_33]

61.   Wickramasinghe N, Schaffer JL, Seitz J, Muhammad I, Vogel D. Fit-Viability Model Examination of e-Health Solutions. In: Wickramasinghe N, Schaffer J, editors. Theories to Inform Superior Health Informatics Research and Practice. Cham: Springer; 2018:251-269.

62.   Zaidi S, Kazi AM, Riaz A, Ali A, Najmi R, Jabeen R, et al. Operability, Usefulness, and Task-Technology Fit of an mHealth App for Delivering Primary Health Care Services by Community Health Workers in Underserved Areas of Pakistan and Afghanistan: Qualitative Study. J Med Internet Res 2020 Sep 17;22(9):e18414 [FREE Full text] [doi: 10.2196/18414] [Medline: 32940612]

63.   Blaslov K, Naranđa FS, Kruljac I, Renar IP. Treatment approach to type 2 diabetes: Past, present and future. World J Diabetes 2018 Dec 15;9(12):209-219 [FREE Full text] [doi: 10.4239/wjd.v9.i12.209] [Medline: 30588282]

64.   Huang Z, Tan E, Lum E, Sloot P, Boehm BO, Car J. A Smartphone App to Improve Medication Adherence in Patients With Type 2 Diabetes in Asia: Feasibility Randomized Controlled Trial. JMIR Mhealth Uhealth 2019 Sep 12;7(9):e14914. [doi: 10.2196/14914]

65.   Huang Z, Lum E, Jimenez G, Semwal M, Sloot P, Car J. Medication management support in diabetes: a systematic assessment of diabetes self-management apps. BMC Med 2019 Jul 17;17(1):127 [FREE Full text] [doi: 10.1186/s12916-019-1362-1] [Medline: 31311573]

66.   Li D. 5G and intelligence medicine-how the next generation of wireless technology will reconstruct healthcare? Precis Clin Med 2019 Dec;2(4):205-208 [FREE Full text] [doi: 10.1093/pcmedi/pbz020] [Medline: 31886033]

67.   Albrecht U, Behrends M, Schmeer R, Matthies HK, von Jan U. Usage of multilingual mobile translation applications in clinical settings. JMIR Mhealth Uhealth 2013 Apr 23;1(1):e4 [FREE Full text] [doi: 10.2196/mhealth.2268] [Medline: 25100677]

68.   DataBank: World Development Indicators. The World Bank. URL: https://databank.worldbank.org/reports.aspx?source=2&series=IT.CEL.SETS.P2 [accessed 2022-09-20]

69.   Harris A, Cooper M. Mobile phones: Impacts, challenges, and predictions. Hum Behav & Emerg Tech 2019 Feb 18;1(1):15-17. [doi: 10.1002/hbe2.112]

70.   Kruse C, Betancourt J, Ortiz S, Valdes Luna SM, Bamrah IK, Segovia N. Barriers to the Use of Mobile Health in Improving Health Outcomes in Developing Countries: Systematic Review. J Med Internet Res 2019 Oct 09;21(10):e13263 [FREE Full text] [doi: 10.2196/13263] [Medline: 31593543]

71.   Ahmed T, Aziz MMA, Mohammed N. De-identification of electronic health record using neural network. Sci Rep 2020 Oct 29;10(1):18600 [FREE Full text] [doi: 10.1038/s41598-020-75544-1] [Medline: 33122735]

72.   Chevrier R, Foufi V, Gaudet-Blavignac C, Robert A, Lovis C. Use and Understanding of Anonymization and De-Identification in the Biomedical Literature: Scoping Review. J Med Internet Res 2019 May 31;21(5):e13484 [FREE Full text] [doi: 10.2196/13484] [Medline: 31152528]

73.   Aydin G, Silahtaroglu G. Insights into mobile health application market via a content analysis of marketplace data with machine learning. PLoS One 2021 Jan 6;16(1):e0244302 [FREE Full text] [doi: 10.1371/journal.pone.0244302] [Medline: 33406100]

74.   Mäntymäki M, Islam AN, Benbasat I. What drives subscribing to premium in freemium services? A consumer value‐based view of differences between upgrading to and staying with premium. Info Systems J 2019 Aug 16;30(2):295-333. [doi: 10.1111/isj.12262]

75.   Paglialonga A, Lugo A, Santoro E. An overview on the emerging area of identification, characterization, and assessment of health apps. J Biomed Inform 2018 Jul;83:97-102 [FREE Full text] [doi: 10.1016/j.jbi.2018.05.017] [Medline: 29852318]

76.   Almalki M, Giannicchi A. Health Apps for Combating COVID-19: Descriptive Review and Taxonomy. JMIR Mhealth Uhealth 2021 Mar 02;9(3):e24322 [FREE Full text] [doi: 10.2196/24322] [Medline: 33626017]

77. Kakhi K, Alizadehsani R, Khosravi A, Nahavandi S, Islam SMS. Challenges of Internet of Medical Things for Electronic Healthcare. 2021 Presented at: 2021 IEEE 4th International Conference and Workshop Óbuda on Electrical and Power Engineering (CANDO-EPE); November 17-18, 2021; Budapest. [doi: 10.1109/cando-epe54223.2021.9667929]

78. Moses JC, Adibi S, Shariful Islam SM, Wickramasinghe N, Nguyen L. Application of Smartphone Technologies in Disease Monitoring: A Systematic Review. Healthcare (Basel) 2021 Jul 14;9(7):889 [FREE Full text] [doi: 10.3390/healthcare9070889] [Medline: 34356267]

79. Fischer F, Kleen S. Possibilities, Problems, and Perspectives of Data Collection by Mobile Apps in Longitudinal Epidemiological Studies: Scoping Review. J Med Internet Res 2021 Jan 22;23(1):e17691 [FREE Full text] [doi: 10.2196/17691] [Medline: 33480850]

80. Mishra V, Islam SMS. Framework for the Adoption of Healthcare 4.0 – An ISM Approach. In: Bali V, Bhatnagar V, Sinha S, Johri P, editors. Disruptive Technologies for Society 5.0: Exploration of New Ideas, Techniques, and Tools. Boca Raton, FL: CRC Press; 2021.

81. Zaman SB, Khan RK, Evans RG, Thrift AG, Maddison R, Islam SMS. Exploring Barriers to and Enablers of the Adoption of Information and Communication Technology for the Care of Older Adults With Chronic Diseases: Scoping Review. JMIR Aging 2022 Jan 07;5(1):e25251 [FREE Full text] [doi: 10.2196/25251] [Medline: 34994695]

82. Khan ZF, Alotaibi SR. Applications of Artificial Intelligence and Big Data Analytics in m-Health: A Healthcare System Perspective. J Healthc Eng 2020 Sep 01;2020:8894694 [FREE Full text] [doi: 10.1155/2020/8894694] [Medline: 32952992]

83. Islam S, Talukder A, Awal MA, Siddiqui MMU, Ahamad MM, Ahammed B, et al. Machine Learning Approaches for Predicting Hypertension and Its Associated Factors Using Population-Level Data From Three South Asian Countries. Front Cardiovasc Med 2022;9:839379 [FREE Full text] [doi: 10.3389/fcvm.2022.839379] [Medline: 35433854]

84. Howlader KC, Satu MS, Awal MA, Islam MR, Islam SMS, Quinn JMW, et al. Machine learning models for classification and identification of significant attributes to detect type 2 diabetes. Health Inf Sci Syst 2022 Dec 09;10(1):2 [FREE Full text] [doi: 10.1007/s13755-021-00168-2] [Medline: 35178244]

85. Chowdhury NK, Kabir MA, Rahman MM, Islam SMS. Machine learning for detecting COVID-19 from cough sounds: An ensemble-based MCDM method. Comput Biol Med 2022 Jun;145:105405 [FREE Full text] [doi: 10.1016/j.compbiomed.2022.105405] [Medline: 35318171]

86. Abdalrada AS, Abawajy J, Al-Quraishi T, Islam SMS. Prediction of cardiac autonomic neuropathy using a machine learning model in patients with diabetes. Ther Adv Endocrinol Metab 2022 Mar 22;13:20420188221086693 [FREE Full text] [doi: 10.1177/20420188221086693] [Medline: 35341207]

87. Abdalrada AS, Abawajy J, Al-Quraishi T, Islam SMS. Machine learning models for prediction of co-occurrence of diabetes and cardiovascular diseases: a retrospective cohort study. J Diabetes Metab Disord 2022 Jan 12. [doi: 10.1007/s40200-021-00968-z]

88. Islam SMS, Ahmed S, Uddin R, Siddiqui MU, Malekahmadi M, Al Mamun A, et al. Cardiovascular diseases risk prediction in patients with diabetes: Posthoc analysis from a matched case-control study in Bangladesh. J Diabetes Metab Disord 2021 Jun 15;20(1):417-425 [FREE Full text] [doi: 10.1007/s40200-021-00761-y] [Medline: 34222069]

89. Shariful Islam SM, Chow CK, Redfern J, Kok C, Rådholm K, Stepien S, et al. Effect of text messaging on depression in patients with coronary heart disease: a substudy analysis from the TEXT ME randomised controlled trial. BMJ Open 2019 Feb 20;9(2):e022637 [FREE Full text] [doi: 10.1136/bmjopen-2018-022637] [Medline: 30787075]

90. Dening J, George ES, Ball K, Islam SMS. User-centered development of a digitally-delivered dietary intervention for adults with type 2 diabetes: The T2Diet study. Internet Interv 2022 Apr;28:100505 [FREE Full text] [doi: 10.1016/j.invent.2022.100505] [Medline: 35242592]

91. Chow CK, Ariyarathna N, Islam SMS, Thiagalingam A, Redfern J. mHealth in Cardiovascular Health Care. Heart Lung Circ 2016 Aug;25(8):802-807. [doi: 10.1016/j.hlc.2016.04.009] [Medline: 27262389]

92. Cho Y, Lee S, Islam SMS, Kim SY. Theories Applied to m-Health Interventions for Behavior Change in Low- and Middle-Income Countries: A Systematic Review. Telemed J E Health 2018 Oct;24(10):727-741 [FREE Full text] [doi: 10.1089/tmj.2017.0249] [Medline: 29437546]

93. Islam SMS, Cartledge S, Karmakar C, Rawstorn JC, Fraser SF, Chow C, et al. Validation and Acceptability of a Cuffless Wrist-Worn Wearable Blood Pressure Monitoring Device Among Users and Health Care Professionals: Mixed Methods Study. JMIR Mhealth Uhealth 2019 Sep 14;7(10):e14706 [FREE Full text] [doi: 10.2196/14706] [Medline: 31628788]

Abbreviations

BG: blood glucose
BGM: blood glucose monitoring
CGM: continuous glucose monitoring
ICT: information and communication technology
MARS: Mobile App Rating Scale
MASS: mean app-specific score
mHealth: mobile health

OS: operating system
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus
TTF: task-technology fit

XSL•FO
RenderX

XSL•FO

RenderX