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Fitterfly Diabetes CGM Digital Therapeutics Program for Glycemic Control and Weight Management in People With Type 2 Diabetes Mellitus: Real-world Effectiveness Evaluation

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Abstract

Background: Digital therapeutic platforms facilitate health care through patient-centered strategies based on multidisciplinary teams and shared decision-making. Such platforms can be used for developing a dynamic model of diabetes care delivery, which can help in improving glycemic control by promoting long-term behavior changes in people with diabetes.

Objective: This study aims to evaluate the real-world effectiveness of the Fitterfly Diabetes CGM digital therapeutics program for improving glycemic control in people with type 2 diabetes mellitus (T2DM) after the completion of 90 days in the program.

Methods: We analyzed deidentified data of 109 participants in the Fitterfly Diabetes CGM program. This program was delivered through the Fitterfly mobile app coupled with continuous glucose monitoring (CGM) technology. This program consists of 3 phases: the first phase is observation, wherein the patient's CGM readings are observed for 7 days (week 1); the second phase is the intervention; and the third phase aims at sustaining the lifestyle modification introduced during the second phase. The primary outcome of our study was the change in the participants' hemoglobin A_{1c} (HbA_{1c}) levels after program completion. We also evaluated the changes in participant weight and BMI after the program, changes in the CGM metrics in the initial 2 weeks of the program, and the effects of participant engagement in the program on improving their clinical outcomes.

Results: At the end of the 90 days of the program, the mean HbA_{1c} levels, weight, and BMI of the participants were significantly reduced by 1.2% (SD 1.6%), 2.05 (SD 2.84) kg, and 0.74 (SD 1.02) kg/m^2 from baseline values of 8.4% (SD 1.7%), 74.45 (SD 14.96) kg, and 27.44 (SD 4.69) kg/m^2 in week 1, respectively (P<.001). The average blood glucose levels and time above range

values showed a significant mean reduction by 16.44 (SD 32.05) mg/dL and 8.7% (SD 17.1%) in week 2 from week 1 baseline values of 152.90 (SD 51.63) mg/dL and 36.7% (SD 28.4%), respectively (P<.001 for both). Time in range values significantly improved by 7.1% (SD 16.7%) from a baseline value of 57.5% (SD 25%) in week 1 (P<.001). Of all the participants, 46.9% (50/109) showed HbA_{1c} reduction ≥1% and 38.5% (42/109) showed weight loss ≥4%. The average number of times the mobile app was opened by each participant during the program was 108.80 (SD 127.91) times.

Conclusions: Our study shows that participants in the Fitterfly Diabetes CGM program showed a significant improvement in their glycemic control and reduction in weight and BMI. They also showed a high level of engagement with the program. Weight reduction was significantly associated with higher participant engagement with the program. Thus, this digital therapeutic program can be considered as an effective tool for improving glycemic control in people with T2DM.

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KEYWORDS

digital therapeutics; glycemic control; continuous glucose monitoring; monitoring; glucose; diabetes; type 2 diabetes; decision-making; model; glycemic; effectiveness; mobile application; application; engagement

Introduction

Background

Diabetes mellitus affects more than 536 million adults globally, and the incidence is projected to rise to 783 million by 2045 [1]. Type 2 diabetes mellitus (T2DM) accounts for the majority of cases with diabetes, and the trend is expected to be similar in 2045. Many studies on people with T2DM have shown that the degree of hyperglycemia is associated with the risk of microvascular complications [2,3], neuropathy [4], stroke [2], myocardial infarction [5], macrovascular mortality [6], and all-cause mortality [5,7]. Glycemic variability is also associated with the development of complications in diabetes [8,9].

Diabetes care delivery is currently facing challenges such as skewed patient-to-physician ratios [10,11], inadequate diabetes self-management education and support [12], fragmented care across individual health care providers [13], inadequate resources for glucose monitoring [14], and lack of awareness about dietary management practices that often lead to poor glycemic control [15]. High-quality diabetes care depends on the adoption of comprehensible lifestyle management techniques, which include diabetes self-management education and support, nutritional therapy, physical activity, regular glucose monitoring, psychological care, and smoking cessation [16]. Patients with diabetes are challenged with a huge burden of self-care, including regular glucose monitoring, dietary management, meal tracking, and physical activity on a daily basis, which has been shown to result in lower treatment adherence and psychological burnout [17]. Regular self-care can become exhausting, and education and support from experts can help in reducing the onset and progression of diabetes complications [18]. Along with this, a personalized treatment approach can help people with diabetes reach their glycemic targets [19] and reduce the risk of T2DM-related complications [14]. Thus, there is an urgent need for a dynamic model of diabetes care delivery using patient-centered strategies based on multidisciplinary teams and shared decision-making, which can help in improving glycemic control by promoting long-term behavior changes in people with diabetes [20]. Digital therapeutic platforms provide evidence-based therapeutic interventions with the use of high-quality software to prevent, manage, or treat a medical disorder or disease [21]. Digital therapeutic platforms have been shown to provide diabetes care independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes [22].

Fitterfly Diabetes CGM is a 90-day digital therapeutics program that provides personalized lifestyle management support for people with T2DM. This program consists of the initial application of the continuous glucose monitoring (CGM) sensor on the patient and the concurrent detailed profiling of the patient's glucose readings and fitness and stress assessments by a multidisciplinary care team of experts comprising nutritionists, physiotherapists, and psychologists. In this program, CGM readings are correlated with a vast set of input data (food logs, activity logs, symptoms, medication, sleep, and stress) from the mobile app. Artificial intelligence and machine learning predictive models are used to predict the personalized glycemic response of the individuals, by assessing the impact of food, activity, medication, sleep, symptoms, and stress on blood glucose excursions.

In a previous study performed on 64 participants with T2DM enrolled in the Fitterfly Diabetes CGM program (formerly known as Diabefly-Pro; Fitterfly Healthtech Pvt Ltd), CGM data were analyzed only in the initial 14 days of the program. Participants followed their usual lifestyle in week 1 but a modified lifestyle plan in week 2. In week 2, the mean blood glucose level was significantly reduced by 17.5 mg/dL (P<.001) and the time in range (TIR) and the glucose management indicator significantly improved by 4.5% and 0.4%, respectively (P<.001), while the time above range (TAR) reduced significantly by 11% (P<.001). The changes in the CGM metrics in that study indicated that the Fitterfly Diabetes CGM program significantly improved glycemic control in a short duration [23]. However, the extent of improvement in glycemic control after the completion of the program at 90 days was not studied. Therefore, our study aims to analyze the deidentified data of 109 participants with T2DM in the Fitterfly Diabetes CGM program for assessing its real-world effectiveness in improving glycemic control in 90 days.

Objective

The Fitterfly Diabetes CGM program aims at providing personalized lifestyle management with the help of the CGM sensor (FreeStyle Libre Pro, Abbott Diabetes Care). The primary

outcome of our study was to analyze the changes in the hemoglobin A_{1c} (HbA_{1c}) levels after the completion of the program as compared to those in the baseline. We also focused on evaluating the short-term effects of a modified lifestyle plan by using the CGM metrics of the participants, changes in their weight and BMI after program completion, and the effects of participant engagement in the program on their clinical outcomes.

Methods

Study Design

This study is based on the analysis of the deidentified data of participants enrolled in the Fitterfly Diabetes CGM program. Participants were recruited through direct referrals by the treating physician or via a social media campaign offering an app-based diabetes management program. Participants were enrolled in the program only after the screening process, which was based on the following inclusion and exclusion criteria. The inclusion criteria for the participants were (1) diagnosis of T2DM with HbA_{1c} levels >6.5%, (2) age ≥18 years at the time of enrollment, (3) having a smartphone and willing to utilize the mobile app, and (4) having a minimum level of literacy to read and understand the English language. The exclusion criteria for the participants were (1) presence of any physical, cognitive, and psychiatric impairments, which can affect their ability to follow dietary regimens or physical exercise, (2) presence of severe complications (eg, end-stage chronic kidney failure, chronic liver disease), (3) history of unstable angina pectoris or stroke within the past 6 months, and (4) history of surgical procedures, which can affect the ability to follow a dietary regimen. All participants signed informed consent for the use of data for research purposes. Refusal to sign the informed consent form did not affect their participation in the program and the quality of care.

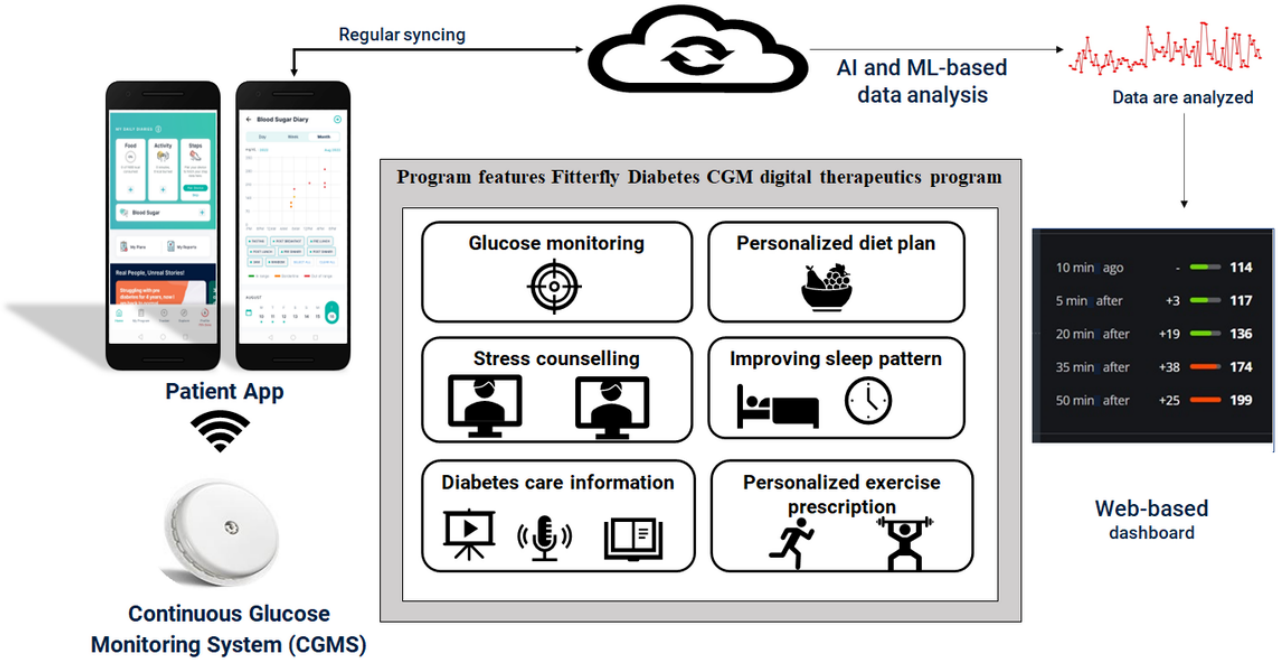
Ethical Considerations

This study involves secondary analysis of deidentified data, and no investigational product or procedures were used in this study. Thus, no ethics clearance was obtained for this study. All participants were provided care as per normal clinical standards, and there was no change in their treatment from the usual customary care. All participants signed the informed consent permitting the collection of primary data for the secondary analysis of deidentified data for research purposes and publications. Our study guarantees the protection of privacy and confidentiality of participants by ensuring that the study data are deidentified. Participants were not provided any compensation for study participation.

Program Details

Figure 1 shows the major components of the Fitterfly Diabetes CGM program. The diabetes management program was delivered through a Fitterfly mobile app coupled with CGM technology. Personalized guidance was provided based on data insights on the blood glucose levels through CGM monitoring and the data entered by participants through the mobile app, including meals items, duration and type of physical activity performed, normal lifestyle habits, diabetes distress score, anthropometric parameters, symptoms, sleep quality, medication usage, and laboratory reports. The Fitterfly Diabetes CGM program uses machine learning and artificial intelligence models to integrate and correlate the data collected from the CGM device and the mobile app to create a personalized lifestyle plan based on an individual's glycemic response.

Figure 1. Process flow of the Fitterfly diabetes CGM digital therapeutics program. AI: artificial intelligence; CGM: continuous glucose monitoring; ML: machine learning.



The key differentiating features of the Fitterfly Diabetes CGM program are as follows:

1. Mobile app software: The Fitterfly mobile app software helps in logging of anthropometric and other data (HbA_{1c} levels; meals; physical activity; anthropometric data such as height, waist circumference, and weight) along with ensuring regular access to diabetes education content (lessons, quizzes, articles, blogs) based on evidence-based guidelines. Regular reports (nutrition, physical fitness, and psychological well-being assessment) are also created and shared via the mobile app with the participants during the 90 days of the program.
2. Food database: The in-house food database access was provided through the mobile app. The food database provides dietary information such as calories, macronutrients (protein, fat, and carbohydrate), micronutrients (calcium, phosphorus, iron, sodium, potassium, zinc, magnesium), omega-3 fats, and total fiber in various meal items (17,187 recipes, 13,866 packed foods, and 152 cuisines). The food database was created from authentic sources such as the Indian Food Composition tables 2017 and the National Institute of Nutrition, India.
3. Virtual access to nutritionists: Meal logs created by the participants were reviewed by nutritionists, and a personalized diet plan was created and shared regularly with each participant based on their personalized glycemic response. The team made regular calls to assess the goals achieved by the participants and to keep them on track.
4. Virtual access to physiotherapists: Personalized exercise plans were created for participants based on a videocall-based physical fitness assessment in the initial phase of the program by trained physiotherapists. The personalized exercise prescription is based on physical fitness, pain complaints of participants, and physical activity readiness level. Regular calls by physiotherapists were provided to assess the goals achieved by participants and to keep them on track. The participants underwent videocall-based primary fitness assessments using the 6-minute walk test, 1-minute push-up test, wall sit test, 1-minute sit-up test, and V-sit and reach test for the analysis of cardiorespiratory fitness, upper body strength, lower body strength, core strength, and flexibility, respectively, under the supervision of trained physiotherapists at the beginning and end of the program.
5. Virtual access to psychologists: The main objectives of psychological care were to enhance motivation, positivity, and optimism; improve sleep quality; manage stress; and learn self-control techniques for better adherence to the program and for providing care for diabetes-related distress in participants. The participants are provided with video and activity cards via the mobile app. Regular calls were performed by the psychologists to assess the goals achieved by the participants and to keep them on track. Psychological well-being assessment was conducted using questionnaire-based scales such as Diabetes Distress Scale, Motivation and Attitude toward Changing Health, and Pittsburgh Sleep Quality Index, which were administered using the mobile app at the beginning and end of the program.
6. Remote health coaching: Remote health coaches help the participants with their queries or problems faced by participants through messages and calls.
7. Dashboard: Web-based dashboards helped in integrating all the information and ensured easy access of the data to remote health coaches and experts (nutritionists, physiotherapists, and psychologists) during the program.

The Fitterfly Diabetes CGM program consists of 3 phases. The first phase is the observation phase, wherein the CGM readings of the participants are monitored for 7 days (week 1) based on their normal lifestyles (daily activity, meals, stress, and sleep quality). The second phase is the intervention phase, during which nutritionists and physiotherapists provide every participant with a diet and exercise plan, respectively, based on their personalized glycemic response data collected from the CGM monitoring sheet. The participants were instructed to follow the modified diet and exercise plan and were monitored again for the next 7 days (week 2) through the CGM device. Feedback regarding stress management and sleep quality was also provided. The third phase of the program aims at sustaining the lifestyle modification introduced during the second phase of the program while including regular feedback and support from health coaches to build lifelong lifestyle changes for better management of diabetes.

Data Collection

The primary outcome of this study was to evaluate the change in the HbA_{1c} levels. The secondary outcomes of this study were reductions in weight and BMI, psychological well-being, and physical fitness. Before the start of the program, all the participants downloaded the Fitterfly mobile app and trained personnel applied the CGM sensor on the participant. CGM readings were collected on day 7 and day 14 of the program by trained personnel during their personal visits to participants. All the participants completed a profiling questionnaire, which helped in personalizing the participant's experience. The profiling questionnaires were administered using the mobile app.

Statistical Analysis

Statistical analysis was performed using the R software (version 4.0.3, R Core Team and the R Foundation for Statistical Computing). Continuous data were expressed as mean (SD) and median (IQR). Categorical data were represented as number (%). Shapiro-Wilk test was used for normality assessment of data. Wilcoxon signed-rank test was performed for the evaluation of outcomes before and after the program, with $P \leq .05$ considered as statistically significant. The correlation between various factors was studied using Pearson test for parametric data and Spearman rank test for nonparametric data.

Results

Baseline Characteristics of the Participants

We obtained complete CGM readings from 355 participants at the beginning and after 14 days of the program start date.

Complete readings of HbA_{1c} levels before and after the program were provided by 112 participants. Complete weight readings were provided by 109 participants. Table 1 shows the baseline characteristics of 109 participants with T2DM who participated in the Fitterfly Diabetes CGM program. The mean age of the participants was 48.90 (SD 12.70) years, with an average duration of diabetes history of 5.37 (SD 8.37) years. Female participants comprised 55.9% (61/109) of this study population. The mean weight and BMI at the baseline were 74.45 (SD 14.96) kg and 27.44 (SD 4.69) kg/m^2, respectively. Apart from being diagnosed with diabetes, 53.2% (58/109) of the participants had other health comorbidities. The analysis of participants' usage of antidiabetic agents while on the program showed that 13.8% (15/109) of the participants were using insulin, 40.4% (44/109) were using oral hypoglycemic agents, 20.2% (22/109) were using both insulin with oral hypoglycemic agents, and 25.7% (28/109) were not using any form of antidiabetic medications. Of all the participants, 47.7% (52/109), 32.1% (35/109), 32.1% (35/109), 13.8% (15/109), 8.3% (9/109), and 1.8% (2/109) were using biguanides, sulfonylureas, dipeptidyl peptidase-4 inhibitors, sodium-glucose co-transporter-2 inhibitors, α-glucosidase inhibitors, and thiazolidinediones, respectively.

Table 1. Baseline characteristics of the study participants (N=109).

Parameters	Values
Gender (female), n (%)	61 (55.9)
Age (years), mean (SD)	48.90 (12.70)
Duration of diabetes (years), mean (SD)	5.37 (8.37)
BMI (kg/m^2), mean (SD)	27.44 (4.69)
Weight (kg), mean (SD)	74.45 (14.96)
Insulin, n (%)	15 (13.8)
Oral hypoglycemic agents, n (%)	44 (40.4)
Insulin and oral hypoglycemic agents, n (%)	22 (20.2)
Biguanides, n (%)	52 (47.7)
Sulfonylurea, n (%)	35 (32.1)
Dipeptidyl peptidase-4 inhibitors, n (%)	35 (32.1)
Sodium glucose co-transporter-2 inhibitors, n (%)	15 (13.8)
α-Glucosidase inhibitors, n (%)	9 (8.3)
Thiazolidinediones, n (%)	2 (1.8)
Other/nonspecified medication, n (%)	2 (1.8)
Comorbid conditions present, n (%)	58 (53.2)

Changes in CGM Metrics After the Initiation of a Modified Lifestyle Plan

Personalized feedback was provided for all the participants based on the analysis of CGM data in the first week of the program. From the second week to the end of the program, the participants followed modified lifestyle prescriptions. CGM sensor data for the second week of the program were compared with those in the first week of the program to understand the immediate change in the glycemic parameters after the introduction of the modified lifestyle plan. The average blood glucose levels of the participants showed a mean reduction by 16.44 (SD 32.05) mg/dL from 152.9 (SD 51.63) mg/dL in week 1 to 136.50 (44.26) mg/dL in week 2. TIR improved by 7.1% (SD 16.7%) from week 1—from a baseline value of 57.5% (SD 25%) to 64.6% (SD 26%) (P<.001). TAR significantly reduced by 8.7% (SD 17.1%) from week 1—from a baseline value of 36.7% (SD 28.4%) to 28.1% (SD 28.1%) (P<.001). No significant increase in time below range (TBR) was observed between week 1 and week 2 (P=.86) (Table 2).

Table 2. Summary of the parameters in the participants before and after the Fitterfly Diabetes continuous glucose monitoring intervention program.

Parameters	Preintervention, mean (SD), median (IQR)	Postintervention, mean (SD), median (IQR)	Change in parameters, mean (SD), median (IQR)	*P* value[a]
Hemoglobin A_{1c} (%)	8.4 (1.7), 8.1 (7.0 to 9.1)	7.2 (1.4), 7.1 (6.4 to 7.8)	–1.2 (1.6), –0.9 (–1.9 to –0.3)	<.001
Weight (kg)	74.45 (14.96), 73.0 (64.50 to 82.50)	72.40 (13.92), 71.0 (64.0 to 80.0)	–2.05 (2.84), –1.40 (–4.0 to 0)	<.001
BMI (kg/m^2)	27.44 (4.69), 26.50 (23.85 to 30.35)	26.70 (4.41), 25.98 (23.43 to 29.53)	–0.74 (1.02), –0.55 (–1.41 to 0)	<.001
ABG[b] (mg/dL)	152.90 (51.63), 139.00 (120.0 to 171.50)	136.50 (44.26), 125.00 (108.0 to 155.50)	–16.44 (32.05), –10.00 (–22.50 to –1.50)	<.001
TIR[c] (%)	57.5 (25.0), 61.0 (45.1 to 75.0)	64.6 (26.0), 72.0 (48.0 to 83.5)	7.1 (16.7), 6.0 (–0.2 to 16.1)	<.001
TAR[d] (%)	36.7 (28.4), 32.7 (13.8 to 51.7)	28.1 (28.1), 16.9 (6.3 to 41.2)	–8.7 (17.1), –5.2 (–16.8 to 0.0)	<.001
TBR[e] (%)	6.0 (11.8), 1.1 (0.0 to 5.6)	7.5 (13.3), 0.9 (0.0 to 8.7)	1.5 (11.2), 0 (–1.3 to 1.0)	.86

[a]Wilcoxon signed-rank test.

[b]ABG: average blood glucose.

[c]TIR: time in range.

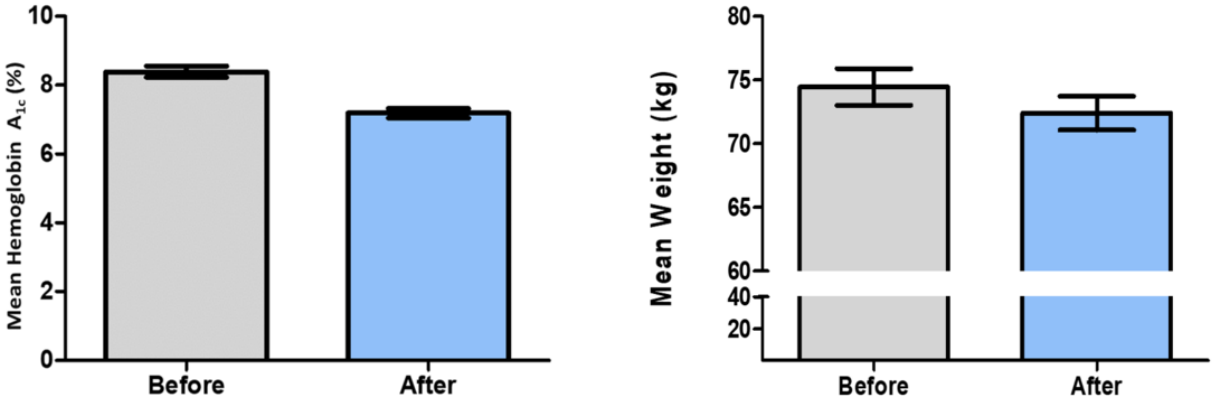
[d]TAR: time above range.

[e]TBR: time below range.

Changes in HbA_{1c} Levels After Program Completion

A significant mean reduction in HbA_{1c} levels by 1.2% (SD 1.6%) (*P*<.001) was observed in all the participants—from a baseline mean of 8.4% (SD 1.7%) to 7.2% (SD 1.4%) after the program (Figure 2A). Of all the participants, 85.3% (93/109) showed a reduction in HbA_{1c} levels after the program, with 43.1% (47/109) reaching the recommended target of HbA_{1c}<7%. Approximately 46.9% (50/109) of the participants showed HbA_{1c} reduction ≥1%, and 86.2% (94/109) of the participants showed reduction in HbA_{1c} levels. Participants with baseline HbA_{1c}<7%, 7%-9%, and >9% showed an average HbA_{1c} reduction by 0.4% (SD 0.7%) (*P*=.008), 0.9% (SD 1.5%) (*P*<.001), and 2.6% (SD 1.7%) (*P*<.001), respectively.

Figure 2. Changes in (A) hemoglobin A1c level and (B) weight before and after the program.



Changes in Weight and BMI After Program Completion

The participants showed a significant mean weight reduction by 2.05 (SD 2.84) kg from a preprogram mean weight of 74.45 (SD 14.96) kg to 72.40 (SD 13.92) kg after the program (*P*<.001, Figure 2B). Weight reduction was observed in 65.1% (71/109) of the participants, with 38.5% (42/109) having weight loss of ≥4%. The mean BMI reduced significantly by 0.74 (SD 1.02) kg/m^2 among all the participants—from a mean baseline BMI of 27.44 (SD 4.69) kg/m^2 to 26.70 (SD 4.41) kg/m^2 (*P*<.001).

Changes in Glycemic Control With Different Antidiabetic Medications

TIR improvement and HbA_{1c} reduction were further analyzed in all the participants based on their uptake of antidiabetic medications for glycemic control, such as insulin, oral hypoglycemic agents, oral hypoglycemic agents with insulin, and no medications. Participants who were not using any antidiabetic medications were dependent solely on the lifestyle modifications for glycemic control. Similar levels of improvement in TIR were observed in the groups receiving oral hypoglycemic agents, insulin, oral hypoglycemic agents with insulin, and no medications, with an average TIR improvement

of 6.6% (SD 17.9%), 5.7% (SD 24.6%), 8.3% (SD 14%), and 7.9% (SD 12%), respectively (*P*=.94). Similarly, no significant difference in the level of HbA_{1c} reduction was observed between these 4 groups, with a mean HbA_{1c} reduction of 1.1% (SD 1.4%), 1.5% (SD 1.3%), 1.4% (SD 2.1%), and 1.1% (SD 1.7%), respectively (*P*=.61).

Program Engagement and Glycemic Control

Participant engagement with the mobile app was studied during the entire 90 days of the program. The average number of times the mobile app was opened by each participant was 108.80 (SD 127.91) times (1.2 logins per day per participant). The average call duration per participant was 1.35 (SD 1.10) hours in 90 days. The average number of meal entries, physical activity entries, and number of body composition entries by each participant during the entire 90 days was 242.18 (SD 244.75), 27.65 (SD 42.01), and 29.35 (SD 29.71), respectively. Reduction in participant weight after the program showed significant correlation with the number of times the mobile app was opened (ρ=0.191; *P*=.04), call duration (ρ=0.221; *P*=.02), meal entry count (ρ=0.246; *P*=.01), activity entry count (ρ=0.315; *P*=.01), and number of body composition entries (ρ=0.227; *P*=.01).

Discussion

Major Findings

Our study discusses the real-world effectiveness of the Fitterfly Diabetes CGM digital therapeutics program for improving glycemic control in people with T2DM after 90 days of program participation. The analysis of deidentified data of 109 participants with T2DM showed the short-term changes in glycemic control after the introduction of a modified lifestyle plan, with improvement in TIR by 7.1% along with a reduction in TAR by 8.7% and no significant increase in TBR (*P*=.86). After the completion of the program, the participants showed an average reduction in HbA_{1c} level by 1.2%, weight by 2.05 kg, and BMI by 0.74 kg/m^2. Approximately 85.3% (93/109) of the participants showed a reduction in the HbA_{1c} levels after program completion. No significant variation was observed in the level of HbA_{1c} reduction among participants who were using only lifestyle modification and those who used antidiabetic medications for glycemic control. A significant correlation was observed between participant engagement in the program and weight reduction after the program (*P*=.01 for counts of meal entries, activity entries, and number of body composition entries). CGM-based monitoring helps in assessing intraday and interday glycemic excursions, which can involve episodes of hypoglycemia and postprandial hyperglycemia [24]. Abnormal glycemic excursions have been shown to be associated with both microvascular and macrovascular complications of diabetes [25]. The postprandial glycemic spike and the extent of glycemic excursion can be more adverse than the sustained glycemic response [26]. Dietary intake is the major determinant of blood glucose levels. Significant variations in postmeal glycemic response have been reported in different people eating identical meals [27]. Thus, it is important for people with diabetes to have a clear understanding of their own glycemic response to different meals and their normal lifestyle. The prediction of personalized glycemic response remains the basis of the Fitterfly Diabetes CGM program, which helps the participants understand their glycemic excursions and receive culturally appropriate techniques by real-time remote expert-based coaching to have their blood glucose levels in the normal range. The CGM data showed significant changes in the glycemic control after 7 days of the introduction of modified lifestyle plans when compared to that during the participants' usual lifestyle in the first 7 days of the program. Significant reductions in average blood glucose levels and TAR indicated reduction in hyperglycemia. TIR improved by 7.12% (SD 16.73%) over a period of 7 days, indicating improved glycemic control in the participants. No significant change in TBR showed that the modified lifestyle plan did not lead to an increase in hypoglycemia episodes. Earlier studies have shown that reduction in TIR by 10% leads to an increase in the hazard rate for retinopathy progression and microalbuminuria by 64% and 40%, respectively, with every 5% improvement in TIR leading to clear clinical benefit in people with T2DM [28,29]. Thus, the modified lifestyle plan resulted in a clinically significant improvement in glycemic control during week 2 of the program.

At the end of the 90 days in the program, the participants showed an average reduction in HbA_{1c} levels by 1.2%. Clinical studies have shown that a 1% reduction in mean HbA_{1c} levels is associated with a reduction in the risk of myocardial infarction by 14%, death related to diabetes by 21%, and microvascular complications by 37% [30]. Another study conducted in the United States among people with T2DM showed that 1% reduction in HbA_{1c} levels led to 2% reduction in all-cause total health care cost and 13% reduction in diabetes-related total health care cost, leading to per individual annual cost saving of US $429 and US $736, respectively [31]. Of all the participants, 85.3% (93/109) showed a reduction in HbA_{1c} levels after the program, with 46.9% (50/109) showing an HbA_{1c} reduction ≥1%. The program was effective in improving glycemic control in participants with different baseline HbA_{1c} levels, with an average HbA_{1c} reduction by 0.4%, 0.9%, and 2.6% among participants with baseline HbA_{1c} levels <7%, 7%-9%, and >9%, respectively. The participants in our study also showed a significant average reduction in weight by 2.05 kg after 90 days of the program. These results were similar to those reported in studies on other programs using a CGM-based virtual diabetes care for people with T2DM, showing a mean reduction in HbA_{1c} levels by 1.6% (SD 1%) after 4 months [32].

Before the start of the program, 87.2% (95/109) of the participants were in the category of overweight or obesity with an initial BMI ≥23 kg/m^2 [33]. A significant mean reduction in BMI by 0.74 kg/m^2 was observed in all the participants (*P*<.001). The reduction in HbA_{1c} levels and improvement in TIR were not significantly different among groups using insulin, oral hypoglycemic agents, insulin with oral hypoglycemic agents, and no medications (*P*=.61 and *P*=.94 for HbA_{1c} and TIR change, respectively). Our findings showed that lifestyle modification can play an important role in improving glycemic control in participants not using any antidiabetic medication and that the Fitterfly Diabetes CGM program played a

significant role in improving glycemic control in participants with different medication histories.

Engagement with the program was analyzed to understand the importance of level of participant engagement in the clinical outcomes of the program. High level of participant engagement was observed in the program, with each participant having an average count of 1.2 logins in the mobile app per day and a mean meal entry count per participant being 242 times during the 90 days. Weight reduction showed significant association with higher level of participant engagement in terms of the number of times the mobile app was opened (P=.04), call duration with coaches (P=.02), meal entry count (P=.01), activity entry count (P=.01), and the number of times the body composition entry (P=.01) was made by the participant. Thus, our study shows that higher engagement with the program led to better outcomes in participants.

The Fitterfly Diabetes CGM program can be highly beneficial to people with T2DM for improving glycemic control. Virtual access to experts from multidisciplinary fields can help in improving diabetes care substantially, especially in low-income countries like India. The application of machine learning and artificial intelligence technology for the prediction of personalized glycemic response with the help of CGM is an emerging technology in India. Further, the program being focused on HbA_{1c} levels as the outcome for lifestyle modification can help in achieving goals in a measured way. The CGM-based analysis in the initial phase of the program helped in providing a personalized approach, while the assessment of HbA_{1c} levels at the beginning and end helped in understanding the program results in a resource-efficient and clinically effective manner.

Strength and Limitations

The strength of this study is the analysis of data in real-world settings by using a commercial program. This preliminary analysis of the results was performed on participants with varied ages, treatment regimens, and baseline HbA_{1c} levels. This study was limited by the nonrandomized design, lack of control group, self-selection bias, and referral bias. This study takes into consideration the change in the glycemic outcome of the participants at the completion of 90 days of the program. Further studies using larger sample size, control groups, and longer durations will be required to understand the effectiveness of this digital diabetes care program. Control groups including healthy people without T2DM and people with T2DM without access to the digital therapeutics program can further help in understanding the efficacy of this program. The impact of such digital therapeutic programs on the psychological well-being and the physical fitness of participants will need to be further evaluated.

Conclusion

Our study shows that participants with T2DM completing 90 days of the Fitterfly Diabetes CGM program showed a clinically significant improvement in glycemic control, as indicated by the significant reduction in HbA_{1c} levels, weight, and BMI. Moreover, the program helped in significantly improving glycemic control in people with different baseline HbA_{1c} values and in people on different treatment regimens of antidiabetic medications or not using any antidiabetic medications. During the 90 days of the program, a high level of participant engagement with the platform was observed. Our study also demonstrates a significant correlation between weight reduction and higher program participation metrics. Thus, the Fitterfly Diabetes CGM program can be an effective tool for improving glycemic control in people with T2DM by providing multidisciplinary care based on personalized glycemic responses.

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Data Availability

The data sets generated during and analyzed during this study are not publicly available due to the contractual obligations of Fitterfly Healthtech Pvt Ltd, but deidentified data sets are available from the corresponding author on reasonable request.

Conflicts of Interest

AKS is the Chief Executive Officer and the cofounder of Fitterfly Healthtech Pvt Ltd. SJ, TL, and CS are consultants at Fitterfly. RV, FM, and MAK are paid employees at Fitterfly.

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Abbreviations

CGM: continuous glucose monitoring
HbA_{1c}: hemoglobin A1c
T2DM: type 2 diabetes mellitus
TAR: time above range
TBR: time below range
TIR: time in range

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Original Paper

Psychological Support Strategies for Adults With Type 2 Diabetes in a Very Low–Carbohydrate Web-Based Program: Randomized Controlled Trial

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Abstract

Background: A very low–carbohydrate (VLC) nutritional strategy may improve glycemic control and weight loss in adults with type 2 diabetes (T2D). However, the supplementary behavioral strategies that might be able to improve outcomes using this nutritional strategy are uncertain.

Objective: This study aims to compare the impact of adding 3 different supplementary behavioral strategies to a web-based VLC diet intervention. To our knowledge, this is the first trial to randomize participants to different frequencies of dietary self-monitoring.

Methods: The study included 112 overweight adults with T2D (hemoglobin A_{1c} ≥6.5%) taking no antiglycemic medications or only metformin. They received a remotely delivered 12-month VLC diet intervention. Participants were randomly assigned through a full factorial 2×2×2 design to supplementary strategies: either daily or monthly dietary self-monitoring, either mindful eating training or not, and either positive affect skills training or not. Our research goal was to determine whether 3 different supplemental strategies had at least a medium effect size (Cohen *d*=0.5).

Results: Overall, the VLC intervention led to statistically significant improvements in glycemic control (−0.70%, 95% CI −1.04% to −0.35%; *P*<.001), weight loss (−6.82%, 95% CI −8.57% to −5.08%; *P*<.001), and depressive symptom severity (Cohen *d* −0.67, 95% CI −0.92 to −0.41; *P*<.001). Furthermore, 30% (25/83) of the participants taking metformin at baseline reduced or discontinued their metformin. Only 1 Cohen *d* point estimate reached 0.5; daily (vs monthly) dietary self-monitoring had a worse impact on depressive symptoms severity (Cohen *d*=0.47, 95% CI −0.02 to 0.95; *P*=.06). None of the strategies had a statistically significant effect on outcomes. For changes in our primary outcome, hemoglobin A_{1c}, the daily (vs monthly) dietary self-monitoring

impact was 0.42% (95% CI −0.28% to 1.12%); for mindful eating, it was −0.47% (95% CI −1.15% to 0.22%); and for positive affect, it was 0.12% (95% CI −0.57% to 0.82%). Other results for daily (vs monthly) dietary self-monitoring were mixed, suggesting an increase in weight (0.98%) and depressive symptoms (Cohen *d*=0.47), less intervention satisfaction (Cohen *d*=−0.20), more sessions viewed (3.02), and greater dietary adherence (Cohen *d*=0.24). For mindful eating, the results suggested a benefit for dietary adherence (Cohen *d*=0.24) and intervention satisfaction (Cohen *d*=0.30). For positive affect, the results suggested a benefit for depressive symptoms (Cohen *d*=−0.32), the number of sessions viewed (3.68), dietary adherence (Cohen *d*=0.16), and intervention satisfaction (Cohen *d*=0.25).

Conclusions: Overall, our results support the use of a VLC diet intervention in adults with T2D. The addition of monthly (not daily) dietary self-monitoring, mindful eating, and positive affect skills training did not show a definitive benefit, but it is worth further testing.

Trial Registration: ClinicalTrials.gov NCT03037528; https://clinicaltrials.gov/ct2/show/NCT03037528

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KEYWORDS

eHealth; type 2 diabetes; T2D; very low–carbohydrate diet; weight loss; glycemic control; text messages; self-monitoring

Introduction

Type 2 diabetes (T2D) is one of the most prevalent contemporary public health problems in the United States. If the current trajectory of prevalence continues, 1 in 3 US adults will have T2D by 2050 [1]. Nutritional management is one of the cornerstones of T2D treatment, and several dietary approaches are recommended for T2D, including a very low–carbohydrate (VLC) diet [2]. For example, a report by the American Diabetes Association's Nutrition Review Committee noted the benefits of a VLC diet and updated the policy guidelines to recommend that for people with T2D "...not meeting glycemic targets or where reducing antiglycemic medications is a priority, reducing overall carbohydrate intake with a low- or VLC eating plan is a viable approach" [3]. Physiologically, carbohydrate intake increases blood glucose levels, which, in turn, increase insulin secretion from the pancreas. Insulin then inhibits lipolysis and the subsequent release of fatty acids from cells [4]. Numerous studies indicate that VLC diets can be effective at improving glycemic control, reducing the need for glucose-lowering medications, and increasing weight loss in adults with T2D [5-8].

However, long-term adherence to any behavioral intervention can be challenging, and the behavioral strategies that may help improve the outcomes of VLC interventions are unclear. In this trial, we screened 3 potentially effective supplemental behavioral strategies using a full factorial design. This was informed by the Multiphase Optimization Strategy framework [9]. This approach suggests that before conducting large clinical trials of multicomponent interventions, particular aspects of the intervention should be tested, especially those that might be costly, burdensome, or simply have not been previously tested enough to be clearly appropriate for a particular intervention. Such an approach is becoming more common in behavioral intervention development, for example, in the areas of weight loss [10], physical activity promotion [11], and our previous pilot study of the VLC diet for adults with T2D [12].

In this trial, we examined 3 supplemental strategies that were low-cost and varied in their degree of burden and level of previous testing. The first strategy we tested was dietary self-monitoring, wherein we varied whether we encouraged participants to practice dietary self-monitoring daily versus monthly (with monthly being defined as monitoring one's diet in bursts of 3 days every 4 weeks). Weight loss trials involving dietary changes typically encourage daily dietary self-monitoring, as this can help people become more aware of their dietary adherence, and it tends to be associated with weight loss [13]. However, people commonly dislike daily monitoring, and their adherence to it tends to fade over time [14,15]. Thus, we compared daily versus monthly dietary self-monitoring, as a monthly amount may still be able to help participants self-regulate their dietary intake but in a less burdensome manner. To our knowledge, this is the first trial to randomize participants to different frequencies of the same type of dietary self-monitoring.

The second strategy we assessed was mindful eating. We included exercises to increase awareness of the physical, cognitive, and emotional triggers of overeating; the awareness of internal cues that signal hunger, fullness, and taste satisfaction; "surfing" the urges to reduce emotional eating; and the cultivation of healthier alternatives [16,17]. The materials included, for example, a guided mindful eating exercise, a guided mini meditation to try before meals, and a hunger awareness exercise. We also included more general mindfulness topics, including how to respond versus react to situations. These approaches aim to help participants become more aware of their hunger-related bodily sensations, food cravings, and eating triggers, so that they can choose to respond more deliberately. Previous research has shown that mindful eating training helps reduce emotional eating, which is an important barrier for dietary adherence [18,19], and evidence suggests that increased mindful eating is associated with decreased fasting glucose levels in participants of a mindful eating weight loss intervention [20]. However, these strategies require extra time and attention from participants, which could be burdensome.

The third strategy we tested was positive affect skills training, whose goal was to increase the frequency that participants experienced positive emotions. We taught participants skills such as noticing and savoring positive events, gratitude, acts of kindness, positive reappraisal, applying one's personal strengths, and setting attainable goals [21]. To adhere to any dietary

intervention, participants need to effectively cope with life stressors, and according to the revised Stress and Coping Theory [22,23], positive affect can serve as a psychological *time-out* from stress and increase adaptive coping [24-26]. Moreover, interventions that increase the experience of positive affect can reduce depressive symptoms, anxiety, and stress [27], which themselves may decrease treatment adherence [28]. Positive affect training may improve dietary adherence to the prescribed diet, which can be challenging. Dietary adherence, in this setting, requires participants to cope both emotionally and cognitively without using food-based coping strategies that they may have used in the past. For example, participants must (1) follow external instructions about what to eat and when to do so multiple times a day; (2) maintain supplies of appropriate foods in their homes, workplaces, and social gatherings, which requires planning, negotiating with others, and food refusal skills; (3) follow a way of eating that significant others may not follow or support, which can be isolating and frustrating; (4) plan financially for meals and snacks that other household members might reject or could lead to increased financial stress; (5) override any personal preferences for food or food-based rituals that they might have (such as eating chips at a restaurant or eating popcorn at movie theaters), which are not consistent with their new way of eating; and (6) overcome typical urges to eat when stressed or bored. In addition, hedonic theories of behavior propose that people do more of what they enjoy [29], possibly because positive emotional responses to behaviors increase the motivation and nonconscious desire to engage in those behaviors [30,31], so participants may be more likely to engage in an intervention that they enjoy. Similarly, previous research has demonstrated an association between higher eating plan satisfaction rates and adherence [32,33]. However, as with the mindful eating skills, the positive affect skills require extra time and attention from participants, which could be burdensome.

The primary aim of this study was to assess whether 3 supplementary strategies (daily vs monthly dietary self-monitoring, mindful eating, and positive affect skills training) could improve outcomes in this VLC intervention with adults with T2D.

Methods

Ethics Approval

The institutional review board at the University of Michigan approved this research (HUM00115537).

Participants

This study was registered at ClinicalTrials.gov (NCT03037528). We recruited participants between February 4, 2017, and February 28, 2020, and completed data collection by June 4, 2021. We placed advertisements or notices of the research on the web (including Craigslist, University of Michigan's web-based portal for clinical trials, and ResearchMatch) and sent invitation letters to potentially eligible participants identified from the health plan records at Michigan Medicine. Interested prospective participants were directed to the study website, which contained the University of Michigan logo, pertinent study information, and a link to a web-based self-reporting screening survey (Qualtrics). Those who were eligible for further screening based on their survey responses were asked to provide web-based electronic consent for the trial and subsequently to complete a second web-based survey (Qualtrics) that included the 8-item Patient Health Questionnaire (PHQ-8) to measure depressive symptoms [34]; a fingerstick self-collected mail-in blood test kit for hemoglobin A_{1c} (HbA_{1c}) test from DTI Laboratories, Inc, a Clinical Laboratory Improvement Amendments Certified Reference Laboratory [35]; and 3 days of dietary self-monitoring [36]. We also mailed participants a body weight scale that was connected to their own cellular network (BodyTrace).

Eligibility Criteria

Prospective participants were invited to enroll if they were aged 21 to 70 years, had a baseline HbA_{1c} of ≥6.5%, had a BMI of 25-45 kg/m^2 (based on self-reported height and measured weight from the study-provided scale), had regular access to the internet, were willing to check their email at least once a week, were comfortable reading and writing in English, had no potentially serious comorbidities such as liver or kidney failure, were planning on living in the United States for the duration of the trial, were not vegetarian or vegan, were not on weight loss medications, and were not taking warfarin or lithium. We also excluded people who were pregnant or breastfeeding, had an untreated thyroid condition, had an untreated mental health condition, had undergone weight loss surgery in the previous year, or were undergoing cancer treatments. Given that this study was conducted remotely, to mitigate the risk of hypoglycemia, we excluded participants who reported taking any antiglycemic medications other than metformin. Participants who met all the eligibility criteria following the screening process were invited to participate in the trial. They consented using an approved web-based consent form that described the study procedures and goals.

Trial Design

This 2×2×2 full factorial experimental design examined the impact of 3 experimental, 2-level supplementary strategies. The factorial trial design allows the entire trial population to be used to assess the effects of each factor on the outcome, allowing the efficient assessment of multiple behavioral factors in a single trial [37]. In this design, analysis is conducted to estimate the main effect of each factor by comparing outcomes between combinations of experimental conditions that match, except for the factor whose main effect is being estimated, and combining results across each set of matching combinations, for example, the main effect of including positive affect skills is essentially the difference between conditions (1 – 2) + (3 – 4) + (5 – 6) + (7 – 8; Table 1). Once all baseline measurements had been completed, the study staff randomized the participants to 1 of the 8 combinations of experimental conditions (Table 1) using a computer program to reveal the next assignment. The order was created using block randomization procedures, with blocks randomly allocated to size 8 or 16 and with the seed numbers used for randomization of 64655102233242, 64655183677600 from the Sealed Envelope website [38]. We stratified the randomization by gender.

Some participants were amid their participation in the trial when the COVID-19 outbreak occurred in the United States (30/112, 26.8%). As the intervention was already completely remote, we were able to continue with the trial; however, this may have affected the outcomes.

Table 1. Experimental conditions and levels of experimental supplemental strategies.

Experimental condition	Core intervention	Daily dietary self-monitoring frequency	Mindful eating	Positive affect skills
1	Yes	Yes or daily	Yes	Yes
2	Yes	Yes or daily	Yes	No
3	Yes	Yes or daily	No	Yes
4	Yes	Yes or daily	No	No
5	Yes	No or monthly	Yes	Yes
6	Yes	No or monthly	Yes	No
7	Yes	No or monthly	No	Yes
8	Yes	No or monthly	No	No

Core Intervention

Once participants were assigned to the different intervention strategies, we emailed all participants links to the core intervention on the web, primarily educational VLC intervention materials throughout the 12-month intervention, weekly for the first 4 months, and then every 2 weeks for the remaining 8 months, for a total of 32 emails. Each of the 32 sets of materials focused on a different topic related to following a VLC diet. The emailed links connected participants to (1) a short survey to assess intervention-related dietary adherence and any health concerns; (2) a short, embedded video teaching session topic (eg, managing their diet during holidays or shifting particular meals to be VLC); (3) downloadable handouts to accompany the video; and (4) links to external web-based resources supporting session topics. Transcripts of the embedded videos were also provided.

All participants received the same core, web-based nutritional intervention. This taught participants to eat a VLC diet based on our previous protocol [12], which aimed to limit carbohydrate intake to between 20 and 35 nonfiber grams of carbohydrates per day with the goal of achieving nutritional ketosis. A positive urine dipstick (Bayer Ketostix, which measures ketone acetoacetate) was used as an indicator of nutritional ketosis. Participants were advised to follow a diet that included meat, fish, cheese, eggs, fats, nuts, seeds, and low-carbohydrate vegetables and eliminated starchy and sugary foods. Participants also had email access to a dietary coach (either author KR or MP), as coaches have generally been found to be effective additions to behavioral interventions [39]. Both coaches had extensive experience with the VLC diet, and all messages were checked for fidelity by the first author, LRS, before being sent. Whenever the participants emailed questions to the coaches, they would receive prompt responses with support and resources. Overall, the coaches emailed participants a minimum of every 2 weeks. The participants also received a body weight scale at the start of their participation, and we asked the participants to monitor their body weight regularly, aiming for weighing themselves at least weekly. Coaches used this information to monitor participant success and tailor support. Starting from week 6 of the intervention, we provided goals for physical activity and sleep. Using the Diabetes Prevention Program [40] as a guide, we encouraged participants to be physically active for at least 150 minutes per week. We also encouraged participants to target 7-9 hours of total sleep per day. To encourage the adoption and maintenance of the new intervention-related behaviors, we sent participants text messages up to 5 times a week about the targeted behaviors and skills, depending on which supplemental strategies they were randomized to, as reminders about targeted behaviors are tied to greater behavioral adherence [41]. To help participants change their dietary patterns, we mailed the following cookbooks to participants: *Keto Living 3 Cookbook: Lose Weight with 101 All New Delicious and Low Carb Ketogenic Recipes* [42] at baseline; *Bacon & Butter, the Ultimate Ketogenic Diet Cookbook* [43] at month 3; *The Wicked Good Ketogenic Diet Cookbook: Easy, Whole Food Keto Recipes for Any Budget* [44] at month 6; and *The Everyday Ketogenic Kitchen With More Than 150 Inspirational Low-Carb, High-Fat Recipes to Maximize Your Health* [45] at month 10. As an incentive for continued participation, we paid participants US $25 for completing their outcome measurements at 4 months, US $25 at 8 months, and US $50 at 12 months.

Experimental Supplemental Strategies

Overview

We randomized the participants to receive a VLC diet and 1 of the 8 possible combinations of the 3 supplemental strategies: dietary self-monitoring, mindful eating, or positive affect skills. The program materials were modified for each supplemental strategy, including different content added to the videos, handouts, and text messages. Participants were aware of the study design, but we did not explicitly state that participants were in the on or off group of each behavioral strategy.

Dietary Self-monitoring

All participants were asked to self-monitor their diet using the free web-based or mobile app MyFitnessPal [46], which has a wide variety of foods in its database that are common to the diet assigned in this trial (reducing participant burden and increasing accuracy). Participants were randomized to track

their diet either daily or monthly (defined as 3 days every 4 weeks).

Mindful Eating Skills

Roughly half of the participants were randomized to training in mindful eating, how to practice the skills in everyday life, research supporting the use of the skills, how and why the skills were expected to help, and targeted suggestions for practicing these skills. We asked participants to focus on consciously savoring their food; eating more slowly; and noticing the textures, flavors, and aromas of their food more carefully. For example, during 1 session, we asked them to practice slowly savoring their food with a snack and encouraged them to practice this skill for at least 1 meal per day over the following week. Multimedia Appendix 1 provides an example handout [47-49].

Positive Affect Skills

Roughly half of the participants were randomized to receive training in positive affect skills. They were taught how to practice these skills in everyday life, informed about research supporting the use of the skills, how and why the skills were expected to help, and provided with targeted suggestions for practicing the skills. The skills we taught included noticing and savoring positive events, gratitude, positive reappraisal, and setting attainable goals, similar to our previous research [21]. Multimedia Appendix 1 provides an example handout.

Assessments

We conducted the following assessments for 1 primary outcome (HbA_{1c}), 2 secondary outcomes (weight and depressive symptoms), and several exploratory outcomes (sessions viewed, dietary adherence, intervention satisfaction, metformin use, and qualitative feedback).

Glycemic Control

We measured our primary outcome, change in glycemic control at 12 months from baseline, with an at-home HbA_{1c} kit (DTI Laboratories, Inc). The company was masked to the intervention design.

Weight

We assessed 1 of our secondary outcomes, change in percent body weight at 12 months from baseline, using the scale we had mailed to participants (BodyTrace). The company was blinded to the intervention design. We asked the participants to stand on the scale twice in 5 minutes at each period, and we used the average of these 2 measurements as their recorded weight.

Depressive Symptoms

We assessed 1 of our secondary outcomes, change in depressive symptoms at 12 months from baseline, using the PHQ-8 [34]. This was part of a web-based survey (Qualtrics), which was masked to the intervention design.

Sessions Viewed

We tracked the total number of sessions that were viewed by participants.

Dietary Adherence

With each session, we asked whether, based on self-assessment, participants were following a VLC diet rated from 1="not at all" to 7="very much so," and we used the average of these ratings as an indicator of self-reported dietary adherence.

Intervention Satisfaction

At month 12, we asked participants, "How would you rate your overall satisfaction with the program?" (response options ranged from 1="not at all satisfied" to 7="very satisfied"), similar to previous research [50]. This was part of a web-based survey (Qualtrics).

Metformin Use

We considered a participant to have changed their metformin dose at 12 months if they reported such a change in their surveys, using the most recent description of the changes as their outcome in the trial.

Qualitative Feedback

We asked participants, using open-ended survey questions, about their thoughts about the intervention itself, their health changes, and the responses they had previously received from their physicians. The questions included, "Do have any overall suggestions for improving anything about the program or study?," "Do have any suggestions about how we can improve how and how much people track what they are eating?", "Please describe any changes in your medical issues since starting the study. Have they gotten better or worse since starting the study?" and "Have you gotten any feedback from family, friends, or physicians/health care providers about this program or your experience with it? If so, what did they say?"

Statistical Analysis

To assess the 12-month intervention changes, we conducted complete case analyses, excluding participants who did not complete the relevant 12-month assessment. Collapsing across all participants, we examined pre-post changes in HbA_{1c} (our primary outcome), percent weight, PHQ-8, number of sessions participants viewed, self-reported dietary adherence, and intervention satisfaction, using between subjects 2-tailed *t* tests with SPSS (version 28.0; IBM Corp). We explored the outcomes using intent-to-treat analyses (n=112) with linear mixed regression models using SPSS. This approach makes use of all available data at the baseline and 12-month time points, with the outcomes as dependent variables, time (pre and post), and all 3 strategies in a full factorial design. We explored the overall changes across strategies using within-subjects *t* tests with SPSS. For the qualitative results, we examined open-ended comments and summarized common themes and exemplar quotes.

Sample size calculations were performed using an SAS macro written by Dziak et al [51], designed for factorial trials. Our goal was to screen for supplemental strategies that had at least a medium effect size (Cohen *d*=0.5; Cohen suggested that a small effect size was 0.2, a medium effect size was 0.5, and a large effect size was 0.8). In addition, we planned to explore whether HbA_{1c} and weight changed by a clinically meaningful amount: a reduction by a unit of 0.5% for HbA_{1c} [52] and 3%

to 5% reduction in weight [53]. The sample size was also estimated using a desired power of 0.8, a 2-tailed *P* value of .05, and a pretest-posttest correlation of HbA_{1c} (the primary outcome of interest) of between 0.30 and 0.40 (based on pilot data). This led to a sample size goal of 108 to 117 of analyzable cases, which, with a planned attrition rate of 20%, would be 130 to 140 randomized participants. Therefore, our final sample size of 112 was slightly underpowered, after attrition, to detect changes between strategies based on our sample size estimates.

Results

We screened 793 potential participants, 112 (14.1%) of whom were randomized (Figure 1). Common reasons for exclusion included being nonresponsive or not completing enrollment steps (n=259), taking an excluded medication such as a nonmetformin antiglycemic medication (n=236), not having T2D or not having an HbA_{1c} measurement in range (n=214), a diet-related issue such as already following a VLC diet (n=37), having an excluded health condition such as an untreated mental illness (n=52), or some other issues such as participating in another study already (n=35). At baseline, participants were on average aged 54.1 (SD 9.6) years, with a BMI of 35.0 (SD 5.1) kg/m^2 and an HbA_{1c} level of 7.5% (SD 1.1%), and 22.7% (25/110) of the participants had elevated depressive symptoms at baseline according to the PHQ-8. Most patients were White (81/112, 72.3%) and non-Hispanic (108/112, 96.4%; Table 2). We also compared the participants who dropped out and those who did not for these baseline variables (Table 2). No serious adverse events were reported during the trial.

Figure 1. A CONSORT (Consolidated Standards of Reporting Trials) diagram depicting participant flow through the study. HbA_{1c}: hemoglobin A_{1c}.

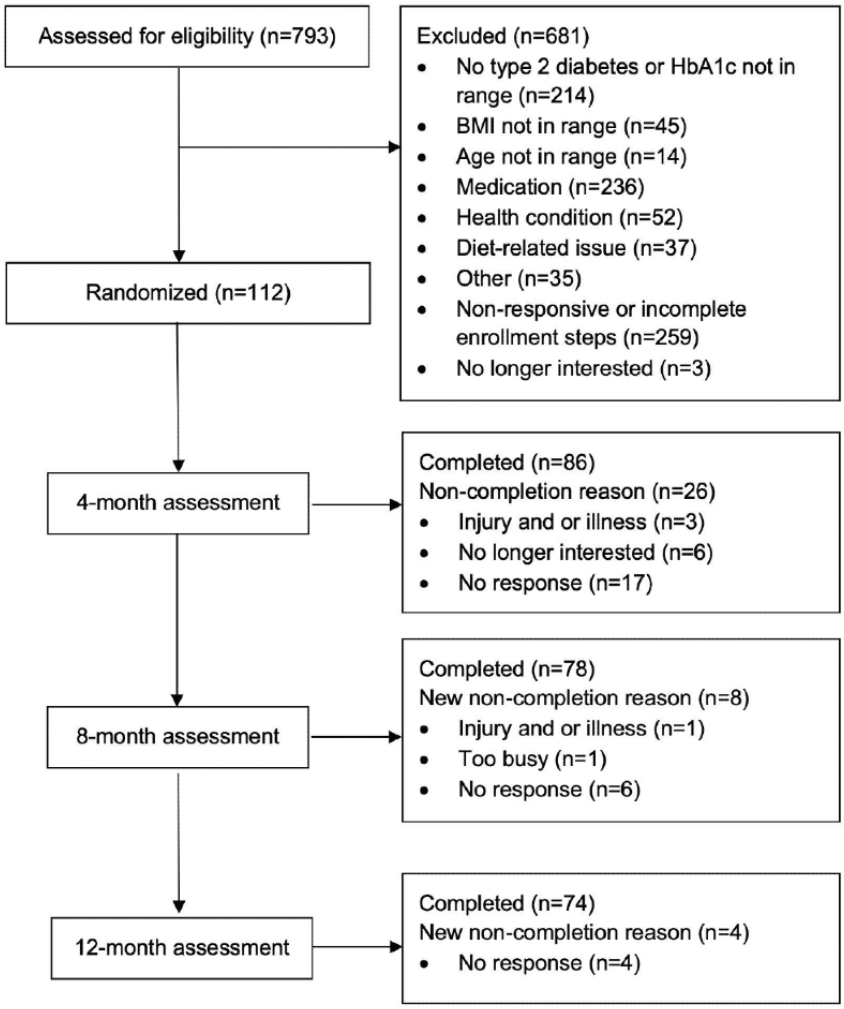

Table 2. Baseline participant characteristics by strategy level (N=112).

Experimental supplemental strategy	Age (years), mean (SD)	Gender (female), n (%)	Hemoglobin A_{1c} (%), mean (SD)	BMI (kg/m^2), mean (SD)	Depressed, n (%)	Race, n (%)			Ethnicity, n (%)	
						White	AA[a]	Other	Hispanic	Not Hispanic
Overall (n=112)	54.1 (9.6)	80 (71.4)	7.5 (1.1)	35.0 (5.1)	61 (54.5)	81 (72.3)	25 (22.3)	7 (6.3)	3 (2.7)	108 (96.4)
Daily dietary self-monitoring										
Yes (n=57)	52.3 (10.3)	41 (71.9)	7.3 (0.9)	35.5 (5.2)	29 (50.9)	42 (73.7)	13 (22.8)	3 (5.3)	1 (1.8)	56 (98.2)
No (n=55)	55.9 (8.7)	39 (70.9)	7.7 (1.2)	34.7 (5.1)	32 (58.2)	39 (70.9)	12 (21.8)	4 (7.3)	2 (3.6)	52 (94.5)
Mindful eating										
Yes (n=57)	53.1 (9.2)	40 (70.2)	7.5 (1.2)	35.0 (5.5)	32 (56.1)	44 (77.2)	10 (17.5)	4 (7.0)	1 (1.8)	56 (98.2)
No (n=55)	55.0 (10.1)	40 (72.7)	7.5 (1.0)	35.1 (4.8)	29 (52.7)	37 (67.3)	15 (27.2)	3 (5.5)	2 (3.6)	52 (94.5)
Positive affect										
Yes (n=56)	54.7 (9.2)	41 (73.2)	7.4 (1.1)	35.7 (5.3)	30 (53.6)	37 (66.1)	14 (25.0)	5 (8.9)	0 (0.0)	55 (98.2)
No (n=56)	53.4 (10.1)	41 (73.2)	7.6 (1.1)	34.4 (4.9)	31 (55.4)	44 (78.6)	11 (19.6)	2 (3.6)	3 (5.4)	53 (94.6)
Dropout										
Yes (n=38)	53.5 (10.7)	28 (73.7)	7.7 (1.3)	34.9 (5.6)	11 (28.9)	26 (68.4)	10 (26.3)	2 (5.3)	2 (5.3)	36 (94.7)
No (n=73)	54.4 (9.1)	54 (73.9)	7.4 (1.0)	35.0 (4.9)	14 (19.2)	55 (75.3)	17 (23.3)	1 (1.4)	1 (1.4)	71 (97.3)

[a]AA: African American.

The gender of 1 participant was unknown. Participants could specify more than 1 race, and 1 person's ethnicity was unknown.

Table 3 summarizes the outcomes at 12 months for the complete case analyses, for which no results reached statistical significance and only 1 Cohen *d* point estimate reached 0.5: daily versus monthly dietary self-monitoring had a worse impact on change in depressive symptoms. For our primary outcome, change in HbA_{1c}, the 95% CI overlapped with negligible benefit to significant harm for daily (vs monthly) dietary self-monitoring (−0.28% to 1.12%), with significant benefit to negligible harm for mindful eating (−1.15% to 0.22%), and with moderate benefit or harm for positive affect (−0.57% to 0.82%). Other results for daily (vs monthly) dietary self-monitoring were mixed, suggesting an increase in weight (0.98%) and depressive symptoms (Cohen *d*=0.47), less intervention satisfaction (Cohen *d*=−0.20), more sessions viewed (3.02), and greater dietary adherence (Cohen *d*=0.24). For mindful eating, the results suggested a benefit for dietary adherence (Cohen *d*=0.24) and intervention satisfaction (Cohen *d*=0.30). For positive affect, the results suggested a benefit for depressive symptoms (Cohen *d*=−0.32), the number of sessions viewed (3.68), dietary adherence (Cohen *d*=0.16), and intervention satisfaction (Cohen *d*=0.25).

In the linear mixed models, the results of regressions predicting HbA_{1c}, weight, and depressive symptoms were similar, and none of the factor × time interactions statistically significantly predicted outcomes (Multimedia Appendix 2).

We also explored overall changes across the groups. In the complete case analyses, across all participants, HbA_{1c} (−0.70%, 95% CI −1.04% to −0.35%; *P*<.001) and percent weight (−6.82, 95% CI −8.57 to −5.08; *P*<.001) improved by a clinically meaningful amount, and PHQ-8 dropped by a Cohen *d* with a medium effect size (−0.67, 95% CI −.92 to −.41; *P*<.001). Overall, 74.1% (83/112) of the participants were taking metformin at baseline. Although we made no medication management recommendations in the trial, by month 12, 30% (25/83) of the participants reduced or discontinued their metformin. None of the participants increased their antiglycemic medications.

Table 3. Changes in outcomes from baseline to 12 months using complete case analyses[a].

Outcome and strategy	Yes, mean change (95% CI)	No, mean change (95% CI)	Yes versus no, mean difference (95% CI)	Yes versus no, Cohen *d* (95% CI)	*P* value
Change in hemoglobin A_{1c} (%)					
Daily dietary self-monitoring (yes or daily, n=45; no or monthly, n=29)	−0.53 (−0.96 to −0.11)	−0.95 (−1.55 to −0.35)	0.42 (−0.28 to 1.12)	0.28 (−0.19 to 0.75)	.24
Mindful eating (yes, n=39; no, n=35)	−0.92 (−1.43 to −0.40)	−0.45 (−0.90 to 0.00)	−0.47 (−1.15 to 0.22)	−0.32 (−0.78 to 0.14)	.18
Positive affect (yes, n=40; no, n=34)	−0.64 (−1.20 to −0.08)	−0.76 (−1.14 to −0.39)	0.12 (−0.57 to 0.82)	0.08 (−0.37 to 0.54)	.72
Change in percent body weight					
Daily dietary self-monitoring (yes/daily, n=47; no/monthly, n=30)	−6.45 (−8.78 to −4.11)	−7.42 (−10.15 to −4.69)	0.98 (−2.61 to 4.57)	0.13 (−0.33 to 0.59)	.59
Mindful eating (yes, n=40; no, n=37)	−7.22 (−9.42 to −5.02)	−6.40 (−9.26 to −3.55)	−0.81 (−4.32 to 2.70)	−0.11 (−0.56 to 0.34)	.65
Positive affect (yes, n=41; no, n=36)	−7.06 (−9.84 to −4.28)	−6.56 (−8.68 to −4.44)	−0.50 (−4.02 to 3.01)	−0.07 (−0.51 to 0.38)	.78
Change in depressive symptoms (PHQ-8[b])					
Daily dietary self-monitoring (yes or daily, n=43; no or monthly, n=27)	−2.26 (−3.61 to −0.91)	−4.33 (−6.13 to −2.53)	2.08 (−0.13 to 4.29)	0.47 (−0.02 to 0.95)	.06
Mindful eating (yes, n=37; no, n=33)	−2.97 (−4.07 to −1.88)	−3.15 (−5.16 to −1.14)	0.18 (−2.00 to 2.36)	0.04 (−0.43 to 0.51)	.87
Positive affect (yes, n=37; no, n=33)	−3.73 (−5.51 to −1.95)	−2.30 (−3.48 to −1.12)	−1.43 (−3.58 to 0.73)	−0.32 (−0.79 to 0.16)	.19
Number of sessions viewed					
Daily dietary self-monitoring (yes or daily, n=57; no or monthly, n=55)	21.93 (19.30 to 24.56)	18.91 (15.75 to 22.07)	3.02 (−1.03 to 7.08)	0.28 (−0.09 to 0.65)	.14
Mindful eating (yes, n=57; no, n=55)	20.46 (17.49 to 23.38)	20.44 (17.55 to 23.37)	0.02 (−4.07 to 4.11)	0.02 (−0.36 to 0.37)	.99
Positive affect (yes, n=56; no, n=56)	22.29 (19.53 to 25.04)	18.61 (15.60 to 21.62)	3.68 (−0.36 to 7.71)	.34 (−0.03 to 0.71)	.07
Self-reported dietary adherence					
Daily dietary self-monitoring (yes or daily, n=56; no or monthly, n=53)	4.87 (4.50 to 5.24)	4.51 (4.05 to 4.97)	0.36 (−0.22 to 0.94)	0.24 (−0.14 to 0.61)	.22
Mindful eating (yes, n=55; no, n=54)	4.87 (4.48 to 5.27)	4.51 (4.07 to 4.94)	0.37 (−0.21 to 0.95)	0.24 (−0.13 to 0.62)	.21
Positive affect (yes, n=55; no, n=54)	4.82 (4.40 to 5.23)	4.56 (4.14 to 4.98)	0.25 (−0.33 to 0.84)	0.16 (−0.21 to 0.54)	.39
12-month intervention satisfaction					
Daily dietary self-monitoring (yes or daily, n=44; no or monthly, n=28)	6.07 (5.66 to 6.48)	6.32 (5.91 to 6.73)	−0.25 (−0.86 to 0.35)	−0.20 (−0.68 to 0.27)	.40
Mindful eating (yes, n=38; no, n=34)	6.34 (5.99 to 6.69)	5.97 (5.48 to 6.46)	0.37 (−0.21 to 0.96)	0.30 (−0.16 to 0.76)	.21
Positive affect (yes, n=38; no, n=34)	6.32 (5.99 to 6.64)	6.00 (5.48 to 6.52)	0.32 (−0.29 to 0.92)	0.25 (−0.21 to 0.72)	.29

[a]Results from 2-sided *t* tests and *P* values are for the mean differences between receiving and not receiving the behavioral factor.

[b]PHQ-8: 8-item Patient Health Questionnaire.

We explored the participants' perceptions of the 3 supplemental strategies using open-ended questions on the self-report survey at months 4, 8, and 12. Some participants had a positive experience with dietary self-monitoring, finding it to be helpful ("Tracking forced me to measure and that was an eye-opener at times."). Others noted that it was difficult to motivate themselves to self-monitor ("It is so easy to eat too much when you don't keep track, but for some reason I drag my heels on doing it."), they avoided dietary self-monitoring when they ate food off of the assigned dietary approach ("I actually found myself tracking less especially when I know that I had gone over the carb limit—even a little."), and reported that it could be difficult to use the app ("I still find MyFitnessPal hard to use. I ended up making my own list of foods I ate and still eat and refer to it often."). Some participants felt daily tracking was tedious to do ("I hate, hate, hate the tediousness of inputting every freaking tablespoon of butter or every 1/4 cup of half and half or every miniscule morsel that goes into my mouth every day. So, I only actually input that info once a week or so."), or found it was easy to forget to do ("...I forget about doing it [tracking] and then I forget what I have eaten."). Participants also felt it was unnecessary to do once they understood what to eat ("I was really good at it in the beginning but once I felt I knew what to do, it just felt too time consuming."), and it was challenging to keep up long term ("I tracked very well for the first 4 months and then burned out."). Participants recommended that dietary self-monitoring a couple of times a week would have been ideal. For example, for those in the daily dietary self-monitoring condition, daily self-monitoring may have been too often. One person in the daily self-monitoring condition suggested the following:

> *I would suggest tracking no more than 3 times a week. Then it wouldn't be so time consuming.*

For those in the monthly self-monitoring condition, self-monitoring only monthly may not have been sufficient. Someone else in the monthly self-monitoring condition suggested the following:

> *If you tell me I have to track I will, if it's my choice I won't. So, [ask participants] to track 1-2 days a week, every week.*

The participants also commented on the mindful eating and positive affect skills. Participants who were assigned to both mindful eating and positive affect skills noted the following:

> *I liked the other parts of this program. Breathing, self-meditation, doing good for others.*
>
> *The psychological challenges were good, but I was already familiar with most of them.*

One participant who received mindful eating and positive affect skills noted that the text messages about those skills were "...quite annoying. Personally, I don't need that type of encouragement." Thoughts were specifically mixed regarding mindful eating. One participant described the following:

> *My least favorite subject was the whole mindful eating thing—a bit squishy for me. I'm sure some people love it, but just not my cup of tea. I just can't see getting so connected with the process. However, I have started eating like a European—slows you down a bit.*

One person noted, "Mindfulness was valuable to me." Another person assigned to receive mindful eating text messages noted the following:

> *Sometimes if I feel like cheating, I'd get a text. It was great to get a reminder and encouragement not to give in to the sweets and to stick with what I am doing. It's like you are all out there rooting me on every day, having a personal cheerleader through text messages.*

Another participant noted the following:

> *The support and psychological skills have made me want to try to stick with it, just to get those benefits.*

We examined the qualitative comments regarding other changes and their impacts. Other notable health and medication changes were described by participants:

> *I no longer take Metformin XR, tums/Rolaids, or the anti-inflammatory medications I was taking for my Ankylosing Spondylitis.*
>
> *I was going to need a CPAP [continuous positive airway pressure] machine for sleep apnea, but the sleep apnea is gone!!*

Another participant commented the following:

> *When I was diagnosed with diabetes, I felt kind of hopeless. I imagined a life of more and more medication and complications from diabetes. Now I have hope that there is another way, and I'm very thankful.*

Participants noted that the physicians were generally supportive:

> *My internist was floored by my bloodwork results and weight loss...*
>
> *My doctor calls me her poster child of diabetes. She can't believe I've made the decision from the moment I was diagnosed to not take the metformin, and instead take the harder path of changing my diet to keep my body under control. She applauds my willpower, but to me, if they told me I had cancer, I'd do whatever it took to live. This disease is no different.*

Discussion

Principal Findings

This study addressed different ways to improve outcomes in a web-based VLC intervention for adults with T2D by using the Multiphase Optimization Strategy framework to examine which of the 3 potentially helpful supplemental behavioral strategies significantly contributed to reduced HbA_{1c} and other outcomes. Overall, the VLC intervention led to statistically significant improvements in glycemic control, weight loss, and depressive symptoms. However, none of the 3 strategies had a statistically significantly different effect on outcomes, and only 1 Cohen *d* point estimate reached our targeted level of 0.5: daily (vs monthly) dietary self-monitoring, such that greater dietary self-monitoring frequency was associated with increased depressive symptoms.

More specifically, we found mixed results for daily dietary self-monitoring. The 95% CIs suggested that daily dietary self-monitoring may be less effective at reducing HbA_{1c} levels than monthly dietary self-monitoring, which may also be less effective at reducing body weight and improving depressive symptoms but more effective at increasing the number of sessions viewed and increasing self-reported dietary adherence. The results also suggest that daily (vs monthly) dietary self-monitoring had lower intervention satisfaction. Our mixed results regarding dietary self-monitoring were echoed in the qualitative feedback, which suggested that participants found frequent (daily vs monthly) self-monitoring to be useful but burdensome. Similarly, previous qualitative research on participants' experiences with dietary self-monitoring found comparable complaints, such as the experience of tedium [54]. In a study of dietary self-monitoring with MyFitnessPal, approximately half of the participants experienced increased negative emotions [55], and focus groups have found that people dislike dietary self-monitoring apps [56].

Our results suggest that monthly versus daily dietary self-monitoring may improve participant outcomes. Notably, our results contrast with a recent review, which found that 80% (16/20) of the trials found that the more participants self-monitored their diet, the greater was their weight loss. However, the results of the review were correlational, describing how participants' behavior was associated with the outcomes [57]. As the review described, "no known published, digital weight loss trials randomized participants to varying frequencies of self-monitoring" [57]. Therefore, to our knowledge, this is the first trial to randomize participants to different frequencies of the same type of dietary self-monitoring.

For mindful eating, for our primary outcome of change in HbA_{1c}, the 95% CI overlapped with a significant benefit to negligible harm, and other results suggested a possible moderate benefit for dietary adherence and intervention satisfaction. This aligns with previous research, such as a systematic review finding that in randomized trials, mindfulness-based interventions reduced HbA_{1c} levels [58] and another review finding that mindfulness-based interventions may improve medication adherence [59].

The positive affect skills had no detectable impact on changes in HbA_{1c} levels or percent body weight. However, the 95% CIs for positive affect suggest a moderate benefit for changes in depressive symptoms, number of sessions viewed, dietary adherence, and intervention satisfaction. These results align with previous research, such as the finding that positive affect interventions can reduce depressive symptoms, anxiety, and stress [27], including in adults with T2D [21], and that positive affect has been positively correlated with medication adherence [60]. In observational studies, positive affect was associated with better health outcomes including viral load suppression in people living with HIV [61] and better physical function during recovery from stroke, heart attack, or hip fracture [62]. Positive affect is associated with better health behaviors such as physical activity [63-65] and better medication adherence among people living with chronic illnesses [60]. The Positive Pathways to Health theoretical model [66] posits that interventions that increase positive affect have a host of proximal effects including providing a time-out from stress, encouraging more adaptive coping strategies, broadening attention and cognition, reducing reactivity to daily stress, and enhancing social relationships. These proximal effects, in turn, lead to improved health behaviors and better psychological and physical well-being.

Overall, across all conditions, the core VLC diet intervention for adults with T2D led to improved glycemic control, weight loss, and reductions in antiglycemic medication, replicating previous results in adults with T2D [12,67-70]. Participants' depressive levels were also reduced, replicating some previous research on a VLC diet in adults with T2D [71], although in 1 of our previous trials, we did not find a statistically significant reduction in depressive symptoms [68].

Limitations and Strengths

Our study has several limitations and strengths. A limitation of the trial was that 80% of the sample were women, 81% were White, and 96% were non-Hispanic, which limits our ability to understand the impact of these supplementary approaches in a more representative sample. Another limitation of the trial was that 27% of the participants were in the trial when COVID-19 began in the United States in 2020; therefore, our conclusions about which supplementary strategies might be most helpful may have been influenced by this. The supplementary strategies all involve self-control, time, and planning to practice regularly. During the pandemic, some people experienced disruptions in their daily routines, such as increased stress, anxiety, and depressive symptoms; financial stress; and social isolation, all of which may have made practicing the supplemental strategies more challenging. Given budgetary limitations, we did not use a gold standard method of tracking dietary adherence, such as 24-hour dietary recalls, but future research should do so when possible. Moreover, the qualitative section was merely an exploration of open-ended comments and not a rigorously conducted qualitative analysis; therefore, caution should be used when interpreting these results, and future research should use a more rigorous approach. In addition, partly because of COVID-19, we did not recruit our intended number of participants, so the trial was underpowered. Moreover, we could only test a finite set of supplementary strategies; therefore, we cannot generalize our conclusions beyond the strategies tested.

A strength of the trial is its innovation, as it is one of the few trials thus far to conduct such a screening experiment, testing a variety of behavioral components, in a behavioral intervention for adults with T2D with HbA_{1c} as an outcome. Another strength was that we were able to recruit participants nationally, enabling for a more nationally representative sample, as we required no in-person measurements. The web-based nature of the trial allowed participants to continue in the trial, regardless of the COVID-19 social distancing protocols. Moreover, because participants did not have to travel to attend the sessions and the sessions, coaching, and assessments occurred when the participants chose, this made participation more convenient and less costly. Finally, to the best of our knowledge, this is the first trial to randomize participants to different frequencies of the same type of dietary self-monitoring.

Conclusions

Our study was designed to test whether several supplemental behavioral strategies (daily vs monthly dietary self-monitoring, mindful eating skills, and positive affect skills) could improve glycemic control and other outcomes in adults with T2D who were recommended to follow a VLC diet. Overall, we found that none of the 3 selected supplemental strategies under consideration resulted in statistically significant changes. However, for changes in our primary outcome of 12-month HbA_{1c}, the 95% CI overlapped with clinically meaningful improvements in glycemic control for monthly (vs daily) dietary self-monitoring and for mindful eating skills (vs no such skills). The addition of monthly (not daily) dietary self-monitoring, mindful eating, and positive affect skills training did not show a definitive benefit, but it is worth further testing. For example, other future tests could use more intensive versions of the behavioral strategies, such as weekly video-based meetings with a coach who actively guides participants through the strategies, or the strategies could be tested with participants with other health conditions, risk factors, or sociocultural needs. Overall, our results support the use of a VLC diet intervention in adults with T2D.

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Conflicts of Interest

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Multimedia Appendix 1
Example educational materials.
[PDF File (Adobe PDF File), 3355 KB - diabetes_v8i1e44295_app1.pdf]

Multimedia Appendix 2
Change in outcomes from baseline to 12 months using intent-to-treat analyses from linear mixed models.
[PDF File (Adobe PDF File), 32 KB - diabetes_v8i1e44295_app2.pdf]

Multimedia Appendix 3
CONSORT-eHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 1280 KB - diabetes_v8i1e44295_app3.pdf]

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Abbreviations

HbA_{1c}: hemoglobin A_{1c}
PHQ-8: 8-item Patient Health Questionnaire
T2D: type 2 diabetes
VLC: very low–carbohydrate

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Original Paper

Hypoglycemia Detection Using Hand Tremors: Home Study of Patients With Type 1 Diabetes

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Abstract

Background: Diabetes affects millions of people worldwide and is steadily increasing. A serious condition associated with diabetes is low glucose levels (hypoglycemia). Monitoring blood glucose is usually performed by invasive methods or intrusive devices, and these devices are currently not available to all patients with diabetes. Hand tremor is a significant symptom of hypoglycemia, as nerves and muscles are powered by blood sugar. However, to our knowledge, no validated tools or algorithms exist to monitor and detect hypoglycemic events via hand tremors.

Objective: In this paper, we propose a noninvasive method to detect hypoglycemic events based on hand tremors using accelerometer data.

Methods: We analyzed triaxial accelerometer data from a smart watch recorded from 33 patients with type 1 diabetes for 1 month. Time and frequency domain features were extracted from acceleration signals to explore different machine learning models to classify and differentiate between hypoglycemic and nonhypoglycemic states.

Results: The mean duration of the hypoglycemic state was 27.31 (SD 5.15) minutes per day for each patient. On average, patients had 1.06 (SD 0.77) hypoglycemic events per day. The ensemble learning model based on random forest, support vector machines, and k-nearest neighbors had the best performance, with a precision of 81.5% and a recall of 78.6%. The results were validated using continuous glucose monitor readings as ground truth.

Conclusions: Our results indicate that the proposed approach can be a potential tool to detect hypoglycemia and can serve as a proactive, nonintrusive alert mechanism for hypoglycemic events.

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KEYWORDS

acceleration; hand tremors; tremor; hypoglycemia; blood sugar; glucose; diabetes; diabetic; noninvasive; measurement tool; digital measurement; monitoring; wearable; accelerometer; machine learning; wearable device; smart watch; detect; time domain; frequency domain; model; algorithm

Introduction

Diabetes is a chronic condition that is estimated to affect over 9.3% of the global population as of 2019 [1], resulting in the death of 12% of the US population [2] and an estimated US $327 billion in economic costs each year [3]. About 10% of the population with diabetes have type 1 diabetes mellitus (T1DM), and the remaining 90% have type 2 diabetes mellitus [4]. Regular blood sugar monitoring and special attention to food intake are critical to managing diabetes [5,6].

Low blood glucose (BG), also known as hypoglycemia, is a serious condition that affects patients with diabetes when their BG level falls below 70 mg/dL [7]. This is more common for patients with T1DM [8]. Values below 54 mg/dL may cause severe hypoglycemia, leading to cognitive impairment, seizure, and even loss of consciousness [9].

The most prevalent method of monitoring BG has been via BG meters, which require manually pricking the finger to get a reading. However, the main limitation of these meters is that the measurement is periodic and manual. Continuous glucose monitors (CGMs) were commercialized at the beginning of the 21st century [10] and have gained popularity, especially among patients with T1DM [11], as they are capable of monitoring BG levels continuously and autonomously. CGMs can provide information about BG trends and warn against the onset of both hyper- and hypoglycemia. However, despite their benefits, many generations of CGMs have several drawbacks. Although CGMs automatically read BG at short intervals, multiple daily finger sticks are necessary to calibrate the CGM for accuracy [12]. CGMs are usually intrusive, and many patients face barriers to the adoption and continuous use of CGM systems, such as pain, complexity, the need for frequent sensor changes, and frequent calibrations [13]. Newer generations of CGMs (such as Dexcom G6) are less irritating and do not require finger stick BG calibrations, as they are factory calibrated. However, they are still expensive, with or without insurance, because they require a transmitter as well as sensors. Moreover, these sensors could fall off the body or may fail early before the end of the sensor session, and they are difficult to restart after they fail [14-16].

"Tremor" or "trembling" has been reported to be a common sign of hypoglycemic events among patients with diabetes [17,18]. In one study surveying 132 older adults with diabetes, 71% (n=92) reported trembling [19]. Other studies have also shown tremors to be a significant symptom of hypoglycemia whether reported subjectively [20-23] or measured objectively in the lab [24]. No methods are currently available to capture and assess hypoglycemic hand tremors at home. Home monitoring can be a viable tool to provide insight into the tremors and thus help detect hypoglycemia.

Monitoring tremors may provide a cost-effective and nonintrusive method to detect the onset of hypoglycemic events. Accelerometer sensors are validated devices to measure motion and have been used in various applications such as assessing physical activity [25-31], aiding in the management of Parkinson disease [32-34], and gait analysis [35,36]. However, outside of conceptual framework development efforts [37], the only study that attempted to detect hypoglycemia using accelerometer data was our recent work on adolescents with T1DM [38].

Machine learning has shown promise for prognosis in medicine [39]. Supervised machine learning models find patterns across input features to predict the target. With the recent advent of inexpensive wearable physiological sensors, hypoglycemia prediction can be improved. Previous researchers used physiological signals, including photoplethysmography, electrocardiogram (ECG), heart rate (HR), HR variability, galvanic skin response, and skin temperature, to predict hypoglycemic events [6,40-45]. However, the application of machine learning to monitor hypoglycemic events through hand tremors remains a research gap despite the initial promise of extracting physiologic tremor features in adults with T1DM [17,46]. Key barriers to addressing this gap are (1) access to longitudinal tremor data sets in diabetic populations and (2) clinical thresholding of hypoglycemic events based on BG levels.

With these challenges in mind, the objective of this research is to develop machine learning algorithms to detect hypoglycemia through hand tremors using acceleration data from a 1-month home study on adults with T1DM. We expect this research to enable real-time monitoring of hypoglycemia through noninvasive and nonintrusive wearable technologies with a built-in accelerometer sensor. The remainder of this paper describes our methods used to collect data, discusses the data processing steps, presents the results of developed algorithms, and concludes with a discussion of our findings and recommendations for future work.

Methods

Data Collection

A home study was designed to collect continuous accelerometer data from participants with T1DM. Accelerometer data were collected using Apple Watch Series 5 (Apple Inc) with a sampling frequency of 64 Hz. We used a mobile app called TremorApp to record, archive, and transfer the accelerometer data. TremorApp is an app our team customized in the lab to run continuously in the background of the watch. It allows participants to make a single tap on the Apple watch whenever they feel they have low blood sugar, and it is logged automatically. In addition, the app is connected to participants' iPhones, where they can track the number of hypoglycemic events they have reported, as well as their HR and acceleration. The participants then transferred their data from the phone to our cloud folder upon completion of the study.

Participants who had an Apple Watch Series 5 were allowed to use their own watch. We monitored the data for 1 week, and if there were any issues with running the app or data collection, then we mailed them our own Apple Watch Series 5 for the purpose of this study under the agreement that they would return it upon completion.

The inclusion criterion was patients with T1DM who regularly used CGMs. To be consistent, only patients who were using a Dexcom CGM (G5 and G6; Dexcom Inc) were enrolled in the study. Dexcom uses a sensor wire inserted underneath a person's skin to measure glucose readings in interstitial fluid throughout the day and night, with a sampling frequency of 5 minutes [47].

Procedures

The participants were instructed to wear the smart watch continuously for 1 month and report the instances of tremors. Every week, participants would upload their accelerometer data file, subjective low blood sugar logs, HR data file, and CGM logs over their phones to a secure server after being trained on how to do so over the internet with the help of a researcher from the team (author KZ). In this study, we only used acceleration

data and CGM logs for the classification problem. Self-reported hypoglycemia and heart data were not used in this study.

Participants

Adults (>18 years old) diagnosed with T1DM who use a CGM device were invited to participate in this study through the university's campus bulk mail. A total of 45 participants started the study, among whom 7 dropped out due to nonconformance or technical issues with the phone, Apple Watch, or CGM. In addition, 5 patients' devices did not correctly record accelerometer data. The data collected from 33 patients, including 21 (64%) females and 12 (36.4%) males, aged between 18 and 56 (mean 25.35) years were included in this study. Out of the 33 participants, 3 (9 %) identified as having 2 or more races, and the remaining (n=30, 91%) all identified as White. Additionally, 6 (18%) participants identified as being of Hispanic/Latino heritage. On average, patients wore CGM devices 95.44% (SD 3.27%) of the time per day. Each patient was expected to wear their watch the whole day. However, it was worn 39.93% (SD 29.57%) each day. Therefore, on average, 31.26% (SD 16.52%) of overlapped accelerometer and CGM data equal to 450.14 (SD 237.89) minutes were available per day for each patient. These overlapped data were used in this study. Note that data recorded during sleep were also included and treated the same way as nonsleep data. Additionally, there was no particular period in the day where data were unavailable for all patients. In other words, in every hour of a 24-hour day, there was at least 1 patient with available data.

Ethics Approval

The study was approved by the institutional review board of Texas A&M University (IRB2019-0261F) and complied with the American Psychological Association Code of Ethics. All participants provided informed consent.

Data Preprocessing

All data preprocessing was completed using Python version 3.6.9 software (Python Software Foundation). Acceleration components were filtered using a second-order Butterworth low-pass filter (cutoff frequency was set to 30 Hz). The magnitude of the 3D acceleration was calculated as the square root of acceleration components in the x, y, and z directions. To provide sufficient patterns of data for hand tremor detection, accelerometer data were divided into 3-second sliding windows with 50% overlap [48]. Acceleration windows between 150 seconds before and 150 seconds after the CGM sampling were labeled as hypoglycemic or nonhypoglycemic based on their corresponding BG levels. Windows with BG levels less than 70 mg/dL were labeled hypoglycemic, and windows with BG levels between 90 and 140 mg/dL were labeled nonhypoglycemic [49,50]. We also explored sequential classification based on 9 consecutive windows. To facilitate this analysis, only data with 9 consecutive windows were included in the final analysis. After cleaning, labeling, windowing, and consecutive windows consideration, the data set had 89,634.45 minutes of data consisting of 3,585,378 windows with 113,975 hypoglycemic events. One of the challenges of training the algorithms to detect hypoglycemia was the imbalanced data set, with an average of 3.3% hypoglycemic windows per patient. To address this issue, we performed random oversampling (also called "upsampling of the minority class") by duplicating examples from the hypoglycemic class in the training set [51]. Upsampling was used because it reduces information loss in the quantification process by using the entire data set. In addition, upsampling has proven to be more robust to noise, and it performs better for predictions compared to downsampling [27,52]. Different resampling ratios (1-1, 2-1, 3-1, 3-2, 4-1, 4-2, and 4-3) were evaluated, and the ratio 3 (nonhypoglycemic events) to 1 (hypoglycemic events) was selected based on performance results. Note that oversampling was performed only on the training data, and data were not upsampled in the validation set.

Feature Extraction

Once signals were preprocessed, a total of 86 features (42 for the time domain and 44 for the frequency domain) were extracted from the windowed acceleration data (x, y, z, and the magnitude) [17,46]. Table 1 provides descriptions and abbreviations of the features employed. Different statistical features were extracted from the time domain, including mean, SD, variance, maximum, minimum, range, number of peaks (NOP), skewness, and kurtosis. The time domain features showed discriminative power for tremor detection [53]. To calculate NOP, we used the mean value of each window as a required threshold of peaks. Additionally, the Pearson correlation coefficients (CORRs) [54] between all combinations of acceleration components (x, y, z) and their magnitudes were computed and used as features. CORR components have been shown to be relevant for tremor detection [55]. In total, 42 features were extracted in the time domain.

The fast Fourier transform was used for the frequency domain analysis. Hypoglycemia is characterized by hand tremors with a frequency range between 4 and 14 Hz [46]. The power spectral density (PSD) of the acceleration windows was calculated using the Welch periodogram [56]. The Welch method computes an estimate of the PSD by dividing the time signal into successive blocks, computing a modified periodogram for each segment, and then averaging the periodograms [56]. Several frequency domain features were extracted from the PSD of all acceleration components x, y, z, and magnitude, including mean, maximum, SD, NOP, average band power (ABP), normalized ABP (NABP), and frequency of maximum PSD (Fmax). The mean of each PSD window was used as a required threshold to calculate NOP. We also calculated mean, maximum, SD, and ABP for the PSD of frequencies between 4 and 14 Hz. We call these features hand tremor frequency range (HTFR) features. In total, 44 features were extracted from the frequency domain of the acceleration data.

Table 1. Summary of features included in the machine learning models.

Category and features	Abbreviation
Time domain	
Mean	M
Standard deviation	SD
Variance	V
Maximum	Max
Minimum	Min
Range	R
Number of peaks	NOP
Skewness	SK
Kurtosis	KS
Correlation coefficient	CORR
Frequency domain	
Mean	M
Maximum	Max
Standard deviation	SD
Number of peaks	NOP
Average band power	ABP
Normalized average band power	NABP
Frequency of maximum power spectral density	Fmax
Frequency domain in 4-14 Hz range (HTFR[a])	
Mean	M
Maximum	Max
Standard deviation	SD
Average band power	ABP

[a]HTFR: hand tremor frequency range.

Classification Models

Many classification approaches have been used to classify tremors versus normal states, mainly for Parkinson disease or essential tremor disorder [57-64]. However, these approaches have not been applied to tremors caused by hypoglycemia. Tremor studies have used random forest [57-60], support vector machines (SVMs) [60,61,65,66], k-nearest neighbors (KNNs) [58,62,63], and naïve Bayes [58,64]. Among the current approaches, random forest, SVM, and KNN are the most widely used. Comparative analyses in the tremor literature have shown that random forest and KNN models outperform naïve Bayes [58] and perform comparably to SVM [60]. However, because of the diversity in feature extraction methods, ground truths used, and different domains, it is difficult to generalize these findings.

Based on the promise of models used in the tremor literature, we used 3 machine learning models—random forest, SVM, and KNN—to classify hand tremors (hypoglycemic state) from nonhypoglycemic states in patients with hypoglycemia. Randomized searches were performed to tune the models. Random forest is a flexible supervised machine learning algorithm comprising uncorrelated decision trees, which are combined to create more accurate predictions and reduce variance [67]. For random forest, the following hyperparameters were tuned: the number of decision trees in the forest, maximum depth, and the criteria with which to split on each node (Gini or Entropy). Based on the model performance, 100 decision trees with a maximum depth of 5 and the Gini function were used. KNN is a nonparametric algorithm that assumes that similar data points can be found near each other. It seeks to compute the distance (usually through Euclidean distance) between data points and then allocates a category based on the most frequent neighboring data points [68]. A wide range of K neighbors, from 3 to 159, was tested, and finally, K=27 was chosen as it resulted in the best model performance. In addition, Euclidean distance was used to measure the distance between the data points. SVM is typically used for classification problems. In the SVM algorithm, a hyperplane, also called a decision boundary, will be built where the distance between 2 classes of data points is at its maximum. This hyperplane separates the classes of data points on either side of the plane [69]. Different kernel types such as linear, poly, radial basis function (RBF), and sigmoid were tested to map the data set

into higher dimensional spaces. The regularization parameter C was also changed from 0.1 to 10, and no significant changes were observed. Finally, an RBF kernel with C=1 was used, as a better performance was observed. Moreover, for all 3 algorithms (ie, random forest, KNN, and SVM), a classification threshold of 0.5 was used.

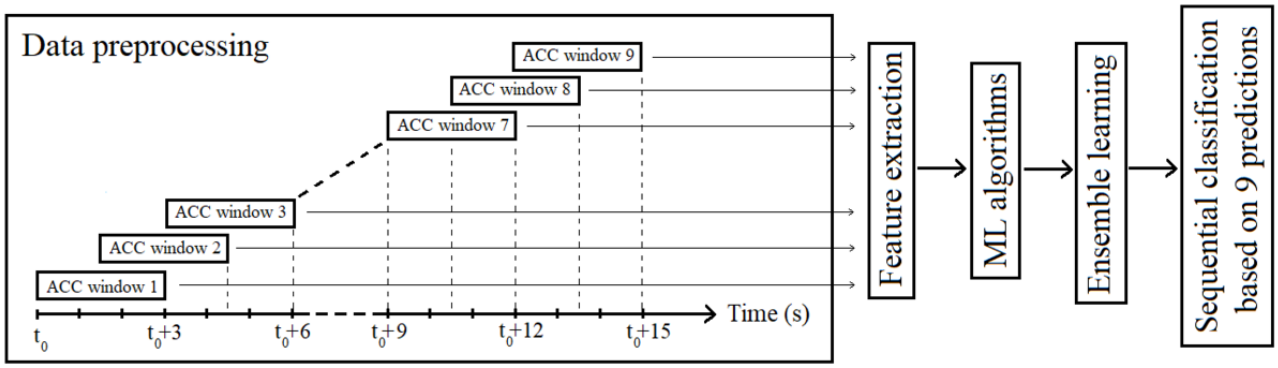
The 3 machine learning models were trained on the acceleration features. We also used ensemble learning for the hypoglycemia classification. Ensemble methods are techniques that create multiple models and then merge them to improve classification performance [70]. Ensemble methods usually result in more accurate solutions than a single algorithm. We combined random forest, KNN, and SVM for the ensemble learning model. Different approaches exist for the ensemble learning technique, such as majority voting, bagging, boosting, and stacking [71]. We used the majority voting method for the classification task. In this approach, each model makes a prediction (vote) per test instance, and the final output prediction will be the one with more than half of the votes [72].

Sequential Classification

We performed sequential classification, which is a predictive modeling approach where a consecutive sequence of inputs over time is considered, and the task is to predict the hypoglycemia category for the aggregated sequence as a whole [73]. The inputs were the 3-second windows of acceleration data with 50% overlap. We classified a sequence as hypoglycemia if at least 50% of the 3-second inputs were predicted as such. Otherwise, the sequence was classified as nonhypoglycemia. We tested different sequence times, including 15 seconds, 30 seconds, and 60 seconds containing 9, 19, and 39 windows, respectively. The best performance was obtained for 15-second sequences, and the results reported are based on those sequences.

All analyses were implemented in Python software (Python Software Foundation). As shown in Figure 1, recordings from 33 patients with hypoglycemia were imported to Python and preprocessed. Time and frequency domain features were extracted from the 3 axes of the acceleration signal and their magnitude. The feature vector was fed to the machine learning models for classification and subsequently for ensemble and sequential models.

Figure 1. Overview of the analysis approach. ACC: acceleration. ML: machine learning.



Evaluation

To evaluate the classification models, we used 2 cross-validation (CV) strategies, 10-fold CV and leave-one-subject-out (LOSO) CV [74,75]. The 10-fold CV performed the fitting procedure a total of 10 times, with each fit being performed on a training set consisting of 90% of the data selected at random. The remaining 10% of the data were used as a hold-out set for validation. Note that data from the same participant were not present simultaneously in the training/validation sets. LOSO CV is a special case of CV where the number of folds equals the number of participants in the data set. In this scheme, the learning algorithms are evaluated once for each participant, using all other participants as a training set and the selected participant as a test set. LOSO CV is a robust estimate of model performance, as each participant is given an opportunity to represent the entirety of the test data set [76]. Precision, recall, F_1-score, and accuracy were computed on the validation sets. Precision quantifies the number of positive class predictions that belong to the positive class. Recall quantifies the number of positive class predictions made of all the positive samples in the data set. The F_1-score measures a combination of precision and recall (ie, the harmonic mean of them. Accuracy is the sum of true negatives and true positives over all samples. The following equations define the evaluation criteria used in this study:

Where *t*, *f*, *p*, and *n* respectively denote true, false, positive, and negative. The hypoglycemia class is considered positive, and the nonhypoglycemia class is negative.

Results

The mean duration of the hypoglycemic state was 27.31 (SD 25.15) minutes per day for each patient. On average, patients had 1.06 (SD 0.77) hypoglycemic events per day. We used acceleration features in time and frequency domains to classify hypoglycemic versus nonhypoglycemic states through hand tremors. The mean PSD for the frequencies between 4 and 14 Hz 4 for the hypoglycemic windows was .

However, for the nonhypoglycemic windows, it was .

Figures 2 and 3 show exemplar acceleration magnitude and the corresponding PSD in 3-second windows for hypoglycemic and

nonhypoglycemic instances during resting and active positions, respectively. Resting position is when there is no activity; therefore, the acceleration magnitude is close to 1 g. Active position is when the user is moving his/her hand; therefore, the acceleration magnitude is larger than 1 g.

Figure 2. Exemplar acceleration magnitude and the corresponding power spectral density (PSD) for hypoglycemic and nonhypoglycemic states during resting position. ACC: acceleration; HG: hypoglycemic; non-HG: nonhypoglycemic.

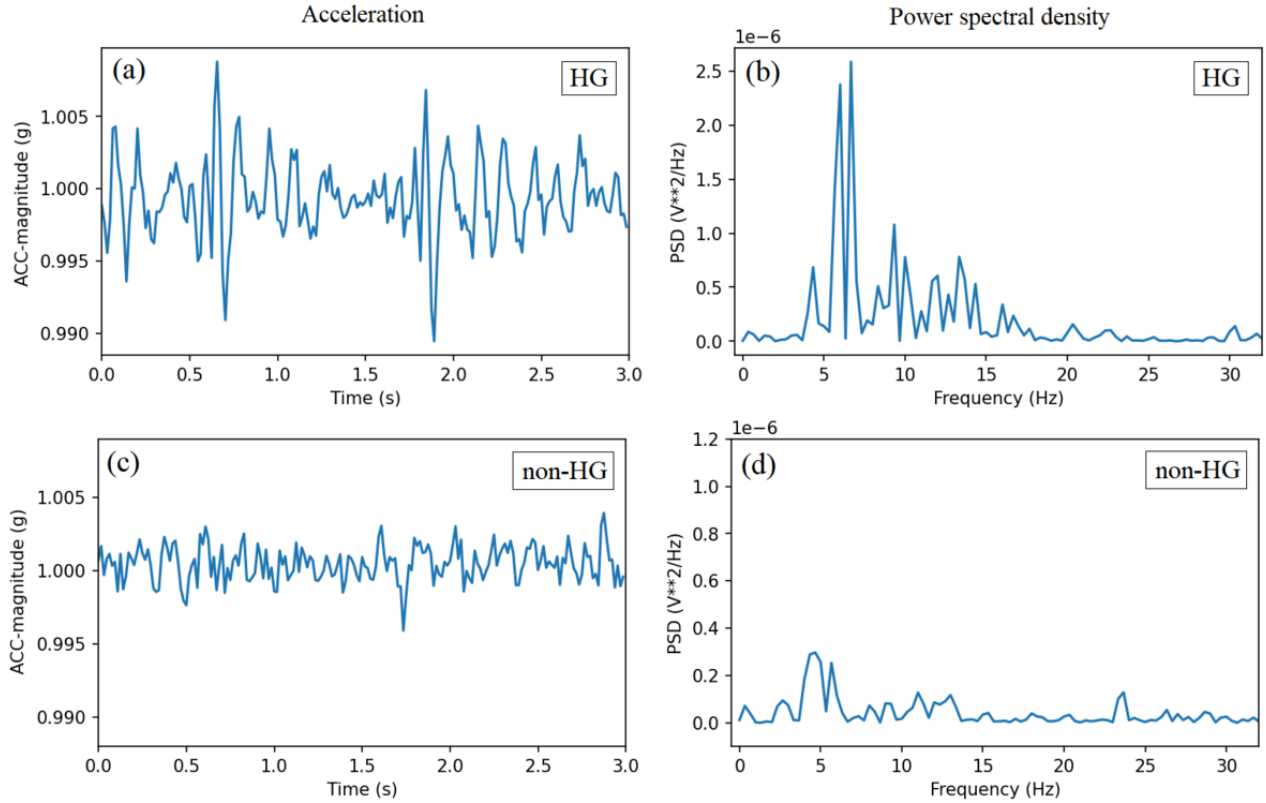
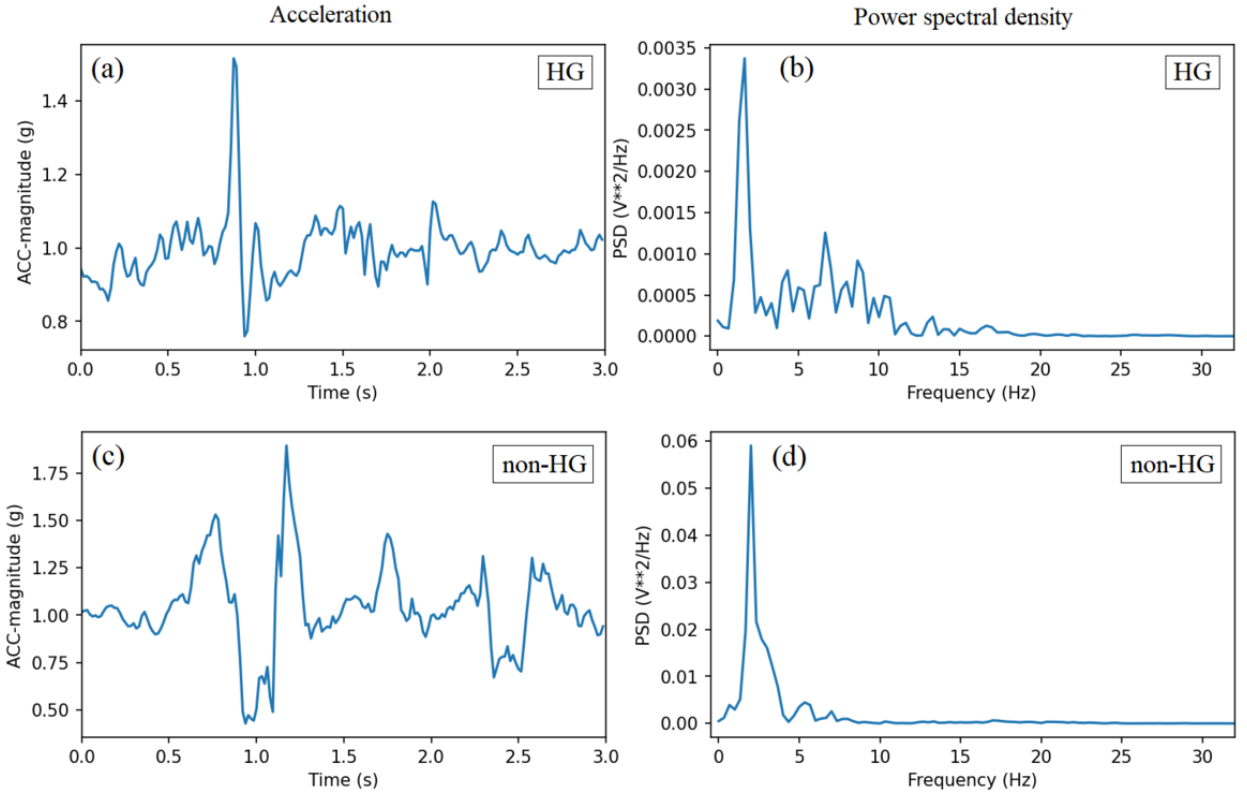


Figure 3. Exemplar acceleration magnitude and the corresponding power spectral density (PSD) for hypoglycemic and nonhypoglycemic states during active position. ACC: acceleration; HG: hypoglycemic; non-HG: nonhypoglycemic.



It was observed that in the resting position, the amplitude of the acceleration in the time domain and the amplitude of the frequencies in the tremor range (4-14 Hz) were higher for the hypoglycemic state compared to the nonhypoglycemic state. Additionally, in both resting and active positions, higher variations were observed in the PSD of frequencies between 4 and 14 Hz for the hypoglycemic states than nonhypoglycemic states. The average SD of PSD in frequencies between 4 and 14 Hz for the hypoglycemic windows was .

However, for the nonhypoglycemic windows, it was .

Most of the higher amplitude frequencies in hypoglycemic states were in the 4 to 14 Hz range, with some patient-specific variations.

To better understand which features are more relevant, we computed the mean decrease in impurity (MDI) based on Gini impurity from the random forest algorithm [77]. As shown in Figure 4, the HTFR features and, in particular, the ABP in frequencies between 4 and 14 Hz had the highest importance factors in distinguishing hypoglycemic states. Feature selection was attempted by removing the least relevant features (starting from skewness) based on MDI values shown in Figure 4. Finally, the best model performances were observed when the following time-domain features were excluded from all acceleration dimensions x, y, z, and magnitude: skewness (4 features), minimum (4 features), range (4 features), maximum (4 features), kurtosis (4 features), and CORR (6 features). These features were the least relevant ones based on the MDI values in Figure 4. The results are reported for the feature-optimized classification models based on the remaining 60 features.

Figure 5 shows the receiver operating characteristic (ROC) curve and the area under the ROC curve (AUROC) for the 3 algorithms using 10-fold CV. The area under the curve (AUC) is a robust measure of binary classification performance since it is not sensitive to class disparities [78]. All algorithms predicted significantly better than random. The random forest model had the highest AUC of 0.9, although the KNN was within 0.02 AUC, and the SVM was within 0.03 AUC. Pairwise comparisons indicated no significant differences between the algorithms.

Figure 4. Feature importance using mean decrease in impurity (MDI) from the random forest structure, along with their intertree variability represented by the error bars. ABP: average band power; CORR: correlation between axis; Fmax: frequency of maximum power spectral density; HTFR: hand tremor frequency range; KS: kurtosis; M: mean; Max: maximum; Min: minimum; NABP: normalized average band power; NOP: number of peaks; SK: skewness; R: range; V: velocity.

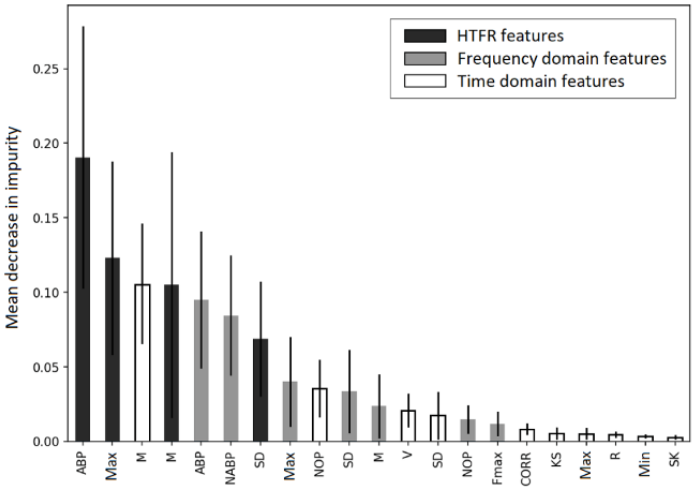


Figure 5. Receiver operating characteristic (ROC) curve and corresponding area under the curve (AUC) values for the 3 algorithms evaluated in this study. KNN: k-nearest neighbor; SVM: support vector machine.

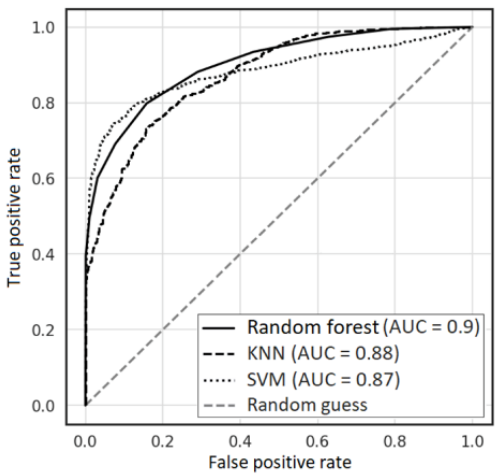


Table 2 shows the classification performance with all the models based on 10-fold CV and LOSO CV. The random forest model performed better (accuracy of 81.09%, and precision of 82.67%) when evaluated using 10-fold CV, while KNN performed better (accuracy of 79.93% and precision of 82.03%) when evaluated using LOSO CV. The ensemble learning model improved the prediction performance to an accuracy of 81.46% using 10-fold CV and 80.14% for LOSO. The key mechanism for improved performance with ensembles is often the reduction in the variance component of prediction errors made by the models [79]. The ensemble learning model achieved a recall of 78.59%.

Table 2. Performance of classification models using 10-fold cross-validation (CV) and leave-one-subject-out (LOSO) CV.

Model	AUROC[a]		Specificity (%)		Precision (%)		Recall (%)		F_1-score (%)		Accuracy (%)	
	LOSO[b]	10-fold	LOSO	10-fold	LOSO	10-fold	LOSO	10-fold	LOSO	10-fold	LOSO	10-fold
KNN[c]	0.88	0.88	83.15	80.78	82.03	79.92	76.95	76.97	79.41	78.40	79.93	78.83
SVM[d]	0.87	0.87	81.15	82.93	81.48	79.98	75.94	77.72	78.28	78.83	78.46	80.24
Random forest	0.88	0.90	80.51	84.48	80.37	82.67	77.45	77.96	78.88	80.24	78.95	81.09
Ensemble learning	N/A[e]	N/A	81.51	84.55	80.74	81.53	78.82	78.59	79.76	80.03	80.14	81.46

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

[b]LOSO: leave one subject out.

[c]KNN: k-nearest neighbor.

[d]SVM: support vector machine.

[e]N/A: not available.

Discussion

Principal Results

The primary purpose of this study was to use a wrist-worn accelerometer sensor to detect hand tremors associated with hypoglycemia in patients with T1DM. We used the acceleration and CGM data collected from 33 patients with T1DM. Several machine learning algorithms were employed to develop the detection system. The ensemble learning model achieved the highest accuracy of 81.46%, with 81.5% precision and 78.6% recall for the hypoglycemic class.

Collectively, the results provide support for the use and further development of ensemble techniques (such as random forest), KNN, SVM, or a combination of these models for hypoglycemia hand tremor detection. These results align with previous explorations of tremor detection [50,57,59-61,64,80,81]; however, our findings are focused on hypoglycemia.

Comparison With Prior Work

The acceleration-based detection system in this study is comparable to the recent research on hypoglycemic detection using other noninvasive sensor-based data such as HR, HR variability, ECG, and temperature. Maritsch et al [82] collected physiological data from patients with T1DM over 1 week using an Empatica E4 smart watch and derived HR and HR variability features to detect hypoglycemic episodes. They achieved a maximum accuracy of 82.7%, with 76.7% sensitivity for hypoglycemic detection using the gradient-boosted decision trees algorithm and 10-fold CV. Elvebakk et al [83] used multiple sensors to collect sudomotor activity data at 3 skin sites, ECG-derived HR, HR-corrected QT interval, near-infrared, and bioimpedance spectroscopy data from 20 patients. They found that hypoglycemia could be identified with a maximum F_1-score accuracy of 88%. Marling et al [40] used HR, galvanic skin response, and skin and air temperatures collected over 2 months to detect hypoglycemia in patients with T1DM who were middle-aged. They showed that an SVM model with a linear kernel could differentiate hypoglycemic from nonhypoglycemic states. Porumb et al [84] used a personalized medicine approach and deep learning models, convolutional neural network, and recurrent neural network, to automatically detect nocturnal hypoglycemia using a few heartbeats of raw ECG signals recorded with wearable sensors. They achieved a maximum accuracy of 85.7% and sensitivity of 84.7% for hypoglycemia detection using their proposed convolutional + recurrent system. The presented model in our study achieved a maximum accuracy of 81.46%, with 78.82% recall for hypoglycemic detection solely relying on a wrist-worn accelerometer sensor.

Strengths, Limitations, and Future Work

The method documented in this paper represents our initial computational work for detecting hand tremors associated with hypoglycemia using acceleration data in a naturalistic setting. To our knowledge, this is the first paper documenting the application of machine learning for the detection of the onsets of hypoglycemia using hand tremors. We used a longitudinal data set collected within 1 month, comprising 21 females (64%) and 12 males (36%), with an average of 24.04 and 26.26 minutes hypoglycemic per day, respectively. The obtained results suggest that wrist-worn accelerometers may provide the necessary sensory information to detect the presence of hand tremors associated with hypoglycemia. Given the increased availability, affordability, discreetness, accuracy, and nonintrusiveness of smart watch–based accelerometer sensors, these results show promise as an alternative to CGM for the early detection of hypoglycemic events, and they may have life-saving implications.

However, this study is not without limitations. First, the analysis presented here is based on a limited sample. In addition to the

5 patients (13%) whose devices did not adequately record their accelerometer data, 3 (9%) patients did not have any low blood sugar readings recorded on their CGM. This might be due to some CGM users setting higher thresholds for hypoglycemic alerts (eg, 75-80 mg/dL), perceiving hypoglycemic events early, or better managing hypoglycemic events. In addition, participant age could also be an important limitation since most of the participants in this study were college students with an average age of 24.56 (SD 9.67) years.

HTFR features were extracted from the PSD between 4 and 14 Hz frequencies to distinguish hypoglycemic states from nonhypoglycemic states. Although HTFR features helped improve the classification performance, there were several windows labeled hypoglycemic without showing noticeable power density in the 4 to 14 Hz frequencies and several windows labeled nonhypoglycemic with high power density in the 4 to 14 Hz frequencies. Different reasons can cause these to happen during accelerometer or CGM readings, such as motion artifacts or nonhypoglycemic tremors. This study collected data during activities of daily living. Motion artifacts are unavoidable when an acceleration sensor is used in dynamic conditions. Sensor measurements are usually contaminated by motion artifacts due to hand movement, wearable tightness level [85], physiological tremors [86], and so on. Noise will become more critical with the smart watch's tightness level. When worn too loosely, the device will frequently slide along the wrist, thus negatively impacting sensor accuracy. The effect of the tightness in terms of signal quality will be exacerbated during high-intensity activities.

People who experience hypoglycemic events are likely to experience repeated episodes of hypoglycemia. Over time, repeated episodes of hypoglycemia can cause hypoglycemia unawareness. The brain and body no longer produce symptoms that warn of low blood sugar, such as tremors or irregular heartbeat [87,88]. The approach proposed in this paper is not capable of capturing such events. Another limitation was that the hypoglycemia threshold is personal, and it can change based on the physical activity level [89]. In this study, the patient definition (personalized threshold) of hypoglycemia was not available. Therefore, for all patients, we used an average value of 70 mg/dL, which is commonly cited as a threshold of hypoglycemia for many people [7,90-92] and is the clinically prescribed threshold for hypoglycemia [93]. Future work should set a personalized threshold of hypoglycemia for different patients to capture this event accurately.

In this study, we do not distinguish between the different causes of low glucose values and hand tremors. For example, high-intensity physical activities may cause blood sugar to drop below this threshold in some instances [94]. Future work should explore activity-aware methods to remove such instances from the hypoglycemia class to improve the performance of learning algorithms. In addition, hand tremors may be induced by either toxins (such as excess of certain heavy metals in the body) or medications (such as antidepressants) [95], or they may be related to essential tremors [96]. Therefore, future studies should account for these potential confounding factors in recruitment and analysis efforts. Future work may also analyze additional measures, such as HR variability [97,98], to differentiate hypoglycemic events from nonhypoglycemic events and improve the performance of learning algorithms.

Finally, the objective of this research was not to evaluate an intervention. As a result, participants were not instructed to undertake any particular action to manage hypoglycemia (such as eating or drinking certain foods) beyond their normal habits. However, the findings documented in this paper can inform the design of nonintrusive accelerometer-based hypoglycemia detection and monitoring tools and systems.

Conclusion

Hypoglycemia is a prevalent disease that affects millions of people worldwide. While tools and technologies exist to help patients with hypoglycemia monitor their BG, they are either invasive, requiring finger pricking, or intrusive and expensive. The proposed work utilized a combination of nonintrusive and noninvasive sensing and machine learning methods to develop detection algorithms for hypoglycemic events via hand tremors. This paper documents the potential of linear accelerator data to provide significant utility for classification models that detect hypoglycemic hand tremors and distinguish between hypoglycemic and nonhypoglycemic states. Our results, while preliminary, suggest that wearable monitoring technology for the continuous detection and remote monitoring of hypoglycemic events through hand tremors is an achievable goal in the near future.

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Conflicts of Interest

None declared.

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Abbreviations

ABP: average band power
AUC: area under the curve
AUROC: area under the receiver operating characteristic curve
BG: blood glucose
CGM: continuous glucose monitor
CORR: correlation coefficient
CV: cross-validation
ECG: electrocardiogram
Fmax: frequency of maximum power spectral density
HR: heart rate
HTFR: hand tremor frequency range
KNN: k-nearest neighbor
LOSO: leave one subject out
MDI: mean decrease in impurity
NABP: normalized average band power
NOP: number of peaks
PSD: power spectral density
RBF: radial basis function
ROC: receiver operating characteristic
SVM: support vector machine
T1DM: type 1 diabetes mellitus

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Original Paper

Long-Term Benefits of an Integrated Continuous Glucose Monitoring and Insulin Pump System for Emergency Admissions, Hospitalization, and Metabolic Control in a Cohort of People With Diabetes: Retrospective Cohort Study

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Abstract

Background: There is evidence in the literature that the use of sensor-augmented insulin pumps in patients with high-complexity diabetes improves metabolic control. However, there is no long-term information on clinical outcomes such as hospitalization or admission to the emergency room. This study describes outcomes for metabolic control, incidence of hospitalizations, and emergency room visits in a specific population using this technology.

Objective: We aimed to assess long-term glycemic and clinical outcomes after the use of continuous subcutaneous insulin infusion and continuous glucose monitoring in people with diabetes.

Methods: A retrospective cohort study was carried out in patients with diabetes previously treated with an intensive insulin regimen at a specialized diabetes treatment center who required a sensor-augmented insulin pump due to nonoptimal glycemic control. Glycated hemoglobin, severe hypoglycemic episodes, nonsevere hypoglycemic episodes, perception of hypoglycemia, and the incidence of emergency room visits and hospitalizations before and after treatment were evaluated.

Results: Between January 2013 and August 2020, 74 patients with a median age of 36 (IQR 27-46) years were included in the study with a median 4 (IQR 2-7) years of follow-up. We found a statistically significant reduction in glycated hemoglobin (8.35% vs 7%; *P*<.001), nonsevere hypoglycemic episodes (71/74, 96% vs 62/74, 84%; *P*=.01), emergency room visits (42/73, 58% vs 4/62, 6%; *P*<.001), and hospitalizations (36/72, 50% vs 10/72, 14%; *P*<.001) after use of continuous subcutaneous insulin infusion.

Conclusions: The use of a sensor-augmented insulin pump associated with a strict follow-up program for patients with high-complexity diabetes led to a significant and sustained reduction in glycated hemoglobin and hypoglycemic episodes, as well as in the rate of emergency room visits and hospitalizations. These results encourage the adoption of this technology in patients who do not achieve metabolic control with optimal management of diabetes.

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KEYWORDS

automated insulin delivery; continuous glucose monitoring; CGM; glycemic control; hypoglycemia; sensor-augmented insulin pump; type 1 diabetes

Introduction

Background

An estimated 537 million people worldwide have diabetes, and it is projected that by 2045, more than 783 million people will have the disease (a prevalence of 12.2%) [1]. The complexity of this condition and its complications has led to a growing burden in health care systems. For example, the management of people with type 1 diabetes (T1D) or beta-cell failure has been challenging due to the complete lack of insulin reserve, leading to hypo- and hyperglycemia and high glucose fluctuations. To ensure adequate care for this condition, patients require education on diabetes, dietary advice, knowledge on counting carbohydrates, and the application of multiple daily injection (MDI) of insulin, including dosage adjustment. In some situations, the use of sensor-augmented insulin pump (SAP) therapy, which combines continuous subcutaneous insulin infusion (CSII) and continuous glucose monitoring (CGM), is fundamental to achieving glucose targets.

The current American Diabetes Association (ADA) and International Society for Pediatric and Adolescent Diabetes (ISPAD) guidelines recommend the therapeutic goal of glycated hemoglobin (HbA_{1c}) <7% in most patients (or <7.5% or <8% depending on the risk of hypoglycemia), access to technology, and the ability to manage their condition [2,3]. In addition, there is widespread evidence of the limitations of using HbA_{1c} as the only guide for managing diabetes. The lack of information regarding intra- and interdaily glycemic excursions and the acute complications derived from hyper- and hypoglycemia are some of the reasons for considering other tools for managing diabetes [4-6].

With recent advances over the last few years, such as better safety profiles in insulin pharmacokinetics and new diabetes devices, the risk of hypoglycemia has been reduced, and patients have been able to achieve better HbA_{1c} goals [7-12]. The benefits of adjusting treatment based on continuous glucose monitoring metrics (time in range, time below range, time above range, and coefficient of variation) have led to their widespread use and resulted in better metabolic control in patients and the reduction of hypoglycemic episodes [13-17]. However, the quality of diabetes programs is vitally important for both the care and management of these patients, to achieve adequate metabolic control, and to prevent micro- and macrovascular complications, as well as hypoglycemic episodes, emergency room visits, and hospitalizations.

Although there is evidence of the benefit of CSII therapy for glycemic control [18-20] and the reduction of hypoglycemia [14,21], other studies have not demonstrated the usefulness of this type of therapy [22,23], and there is scant evidence of its long-term benefit in reducing emergency room visits and hospitalizations [24].

The objective of our study was to evaluate the long-term effects of SAP therapy in patients at a specialized diabetes care center who were using this type of technology. We present a retrospective longitudinal study with a median 4-year follow-up.

Methods

Design and Participants

This was an analytical, retrospective observational study designed to evaluate the long-term effect of the use of SAP on clinical outcomes and metabolic control after the admission of people with diabetes to a specialized care program using this type of technology. The included patients were affiliated to a health care insurance company in Bogotá, Colombia (Compensar Entidad Promota de salud).

The inclusion criteria were being aged 18 years or older; having a diagnosis of type 1, 2, or another type of diabetes; and being on a basal-bolus insulin regimen. All patients were referred to our center due to nonoptimal metabolic control (HbA_{1c} >7%) or frequent hypoglycemic episodes (<70 mg/dl), defined as >4 hypoglycemic events per week or one episode of severe hypoglycemia (needing a third party for correction assistance) during the last year [2,10,25,26] despite optimal treatment and diabetes self-management education and support (DSMES), which was defined as the adequate use of insulin self-titration, frequent self-monitoring of blood glucose (SMBG; at least 4 times a day), management of hypoglycemic episodes, and education in carbohydrate counting based on international and local guidelines for T1D management [27-29].

Prior to SAP therapy, all patients in our center were using insulin analogues (long-acting insulin glargine 100 units/mL and fast-acting insulin, ie, lispro, aspart, or glulisine); after 2017, they used second-generation basal insulin (ie, insulin glargine 300 units/mL or insulin degludec 100 units/mL). The patients used SAP therapy from the time of their admission to the program, following the consensus statement of the insulin pump management task force [30,31]. The data were collected from that point and patients were recruited from January 2013 until November 2020. No patients were excluded, given the specific focus of the program in which they were participating.

The primary outcomes of the study were to evaluate clinical and glycemic control, including changes in glycemic control, the proportion of patients who achieved an HbA_{1c} less than 7%, the number of severe hypoglycemia (SH) episodes and nonsevere hypoglycemia (NSH) episodes, and the number of hospitalizations or emergency room visits prior to beginning the program and during follow-up in the insulin pump program.

All study participants used an insulin pump (Paradigm VEO, MiniMed 640G or 670G, Medtronic Inc) and real-time CGM (Enlite or Guardian Link 3, Medtronic Inc). On initiation of SAP, all participants were trained by the Medtronic team. During the first 3 days of SAP, they received advice on diabetes and nutrition and intensive classes on how to manage the SAP technology. They were subsequently contacted over the next 3 days to verify the correct use of SAP, its drawbacks, and how to solve them. They were encouraged to perform SMBG at least 6 times per day, sensor calibration 3 to 4 times per day, and infusion set changes (the reservoir, catheter and cannula) every 3 days. Based on medical criteria, the patients were re-educated in carbohydrate counting and management of hypo- and hyperglycemic episodes and encouraged to follow the correct

use of SAP throughout follow-up. Initially, the follow-up visits were done face-to-face monthly or every 2 months. Owing to the COVID-19 pandemic, consultations were conducted by means of telephone. The data were obtained from a chart review, the insurance company's database for their affiliated hospitals, and direct patient surveys. Adherence to treatment and the measurement of variables related to insulin pump use were reviewed using the CareLink Medtronic system software. We used the Gold scale as an assessment tool for hypoglycemia awareness, with lower values indicating a greater perception of hypoglycemia and higher values reflecting a lack of perception [32].

To minimize bias, the data were independently reviewed by one of the authors to assess biologically implausible or missing data.

Statistical Analysis

The categorical variables were expressed as absolute and relative frequencies. The Kolmogorov-Smirnov test was used to evaluate the normality of numerical variables. Parametric data are expressed as the mean (SD), while nonparametric data are reported as the median (IQR).

Changes in variables over time were evaluated with a 2-tailed Student *t* test for paired data or the McNemar test for categorical variables. The Wilcoxon test was used for paired data and the Friedman test was used for nonparametric data.

Ethics Approval

The study was approved by the local ethics committee in Bogotá, Columbia (Clinical Committee, Cardioinfantil Foundation, Cardiology Institute), on February 11, 2021 (04-2021).

Results

Patient Characteristics

We analyzed data from 74 patients who used SAP between January 2013 and August 2020. During the follow-up period, 1 patient was lost in the first year due to changes in their residential address and health care provider, making it unfeasible to continue their evaluation. Another person left the program after 4 years for the same reason, but their data were included in the analysis.

The median age was 36 (IQR 27-46) years. The median BMI was 24.3 (IQR 22.7-27.2) kg/m^2. Of the total population, 41 (55%) were female and most had a diagnosis of T1D (n=71; 95%), with a median of 20 (IQR 14-33) years since diagnosis. The median number of years of follow-up after starting to use SAP was 4 (IQR 2-7) years. Altogether, 85% (63/74) of the patients had glycemia above the optimal target, with a median HbA_{1c} of 8.35% (IQR 7.3%-9.8%). The baseline demographic and clinical characteristics are shown in Table 1. In our country, SAPs are currently the only device provided by health care insurance. CSII alone has never been a treatment option in Colombia. The CGM Freestyle Libre flash glucose monitoring system became available in 2019.

The hospitalization and emergency room visit rates prior to SAP therapy were 0.5 (IQR 0.5-1.0) events per patient-year and 1.0 (IQR 0.5-2.0) events per patient-year, respectively. All patients had a history of hypoglycemic episodes with an NSH rate of 20 (IQR 11-35) events per patient-year and an SH rate of 1.5 (IQ 1-6) events per patient-year, with a Gold score of 4 (IQR 2-4); the mean total daily insulin dose was 52.5 (SD 21.9) international units (IU) prior to treatment.

Table 1. Baseline patient characteristics (N=74).

Characteristics	Values
Male, n (%)	32 (45)
Female, n (%)	42 (55)
Age (years), median (IQR)	36 (27-46)
BMI (kg/m^2), median (IQR)	24.3 (22.7-27.2)
Type 1 diabetes, n (%)	71 (96)
Type 2 diabetes, n (%)	2 (3)
Diabetes, other, n (%)	1 (1)
Duration of diabetes (years), median (IQR)	20 (14-33)
Basal bolus, n (%)	74 (100)
Total daily insulin doses (international units), mean (SD)	52.5 (21.9)
Type of pump[a], n (%)	
Paradigm VEO	6 (8)
MiniMed 640	40 (54)
MiniMed 670	28 (38)
Glycated hemoglobin (%), mean (SD)	8.8 (2.7)
Glycated hemoglobin (%), median (IQR)	8.35 (7.3-9.8)
Gold score, median (IQR)	4 (2-4)
Gold score ≥4, n (%)	44 (56)
Nonsevere hypoglycemia episodes, EPY[b] (IQR)	20 (11-35)
Severe hypoglycemia episodes, EPY (IQR)	1.5 (1-6)
Hospitalization rate, EPY (IQR)	0.5 (0.5-1.0)
Emergency room visit rate, EPY (IQR)	1.0 (0.5-2.0)

[a]Type of pump initiated at the start of follow-up.

[b]EPY: events per patient-year.

In the first year, the median percentage sensor use, the mean number of SMBG measurements per day and the mean number of calibration readings per day were 90% (IQR 95%-90%), 5.83 (SD 1.48), and 5.22 (SD 2.96), respectively. At the end of the follow-up period, these values were 89.5% (IQR 80%-92%), 4.14 (SD 0.89), and 4.43 (SD 1.07), respectively. More detail is given in Table 2.

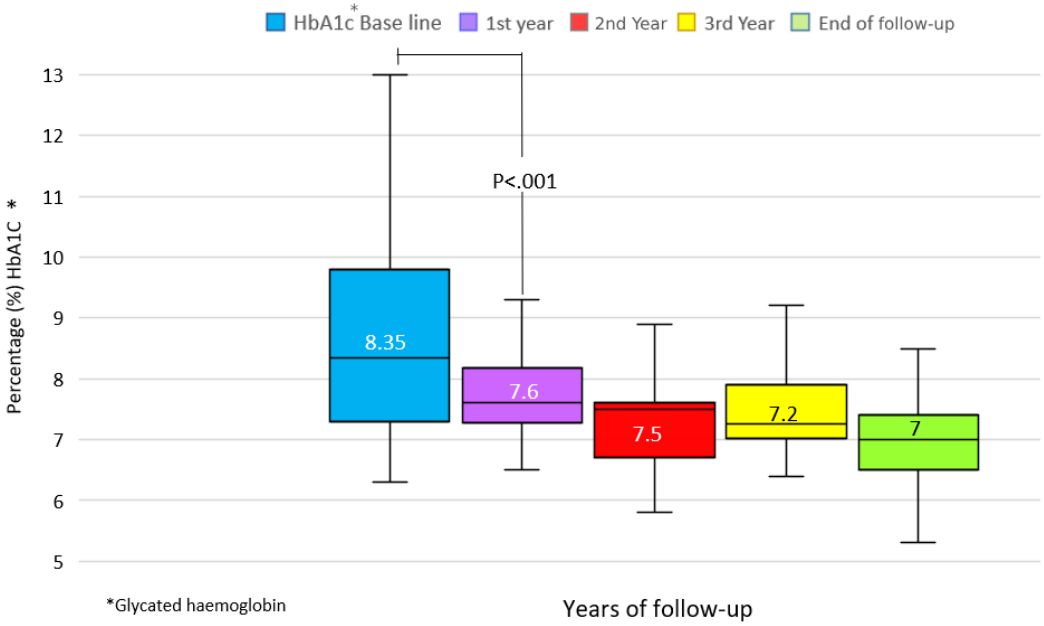
Table 2. Variables associated with sensor-augmented insulin pump technology during different stages of the follow-up period.

	First year	Second year	Third year	Final follow-up
Sensor use, % (IQR)	90 (95-90)	80.5 (65.5-90)	89.5 (80-94)	89.5 (80-92)
Number of self monitoring of blood glucose measurements per day, mean (SD)	5.83 (1.48)	5.53 (1.45)	5.03 (1.39)	4.14 (0.89)
Number of calibration readings per day, mean (SD)	5.22 (2.96)	5.03 (1.59)	4.80 (1.51)	4.43 (1.07)

Metabolic Control During Follow-Up

A significant improvement in glucose control was observed at the final follow-up, with the median HbA_{1c} decreasing to 7% compared with the baseline of 8.35% (P<.001). The percentage of patients with an HbA_{1c} less than 7% prior to treatment was 15% (11/74), and this increased significantly to 41% (30/74) of patients at the end of follow-up (P<.001; Figure 1).

Figure 1. HbA_{1c} during follow-up. HbA_{1c}: glycated hemoglobin.



During the follow-up period, a noteworthy reduction in HbA_{1c} levels was observed within the first year, decreasing from 8.35% (IQR 7.3%-9.8%) to 7.6% (IQR 7.3%-8.1%; *P*<.001). In the second year, HbA_{1c} levels remained consistent at 7.5% (IQR 6.7%-7.7%), and in the third year and the final follow-up, stabilized at 7.25% (IQR 7%-7.9%) and 7% (IQR 6.5%-7.4%), respectively. These findings indicate an initial improvement followed by a sustained stabilization in HbA_{1c} levels among the patients under study.

At the end of follow-up, the median time in range (TIR) for a blood glucose level 70 to 180 mg/dL was 75.5% (IQR 70%-80.5%), with 21% (IQR 15%-29%) time above 180 mg/dL and 3% (IQR 1%-4%) time below 70 mg/dL.

Hypoglycemic Episodes

There was a statistically significant decrease in both the rate of NSH episodes and the percentage of patients with at least one episode in the last year, falling from 20 (IQR 11-35) episodes per patient-year to 4 (IQR 2-7) episodes per patient-year (*P*<.001) and from 96% (71/74) to 84% (62/74; *P*=.01), respectively (odds ratio [OR] 0.91, 95% CI 0.083-0.99).

Severe hypoglycemia, expressed in rates and percentage of episodes in the last year, decreased from 1.5 (IQR 1-6) episodes per patient-year to 0.5 (IQR 0.31-0.5) episodes per patient-year (*P*=.14), and from 28.3% to 14.3% (*P*=.14), respectively, but without statistical significance.

An assessment using the Gold scale was made at the beginning of SAP therapy and at the end of follow-up. The scale showed a reduction from a score of 4 (IQR 2-4) at baseline to 2 (IQR 1-3) at the end of follow-up (*P*<.001). Likewise, the percentage of patients with a score of 4 or higher prior to using this technology decreased from 60% (44/74) to 41% (30/74; *P*<.001).

Emergency Room Visits and Hospitalizations

Significant differences were found before and after the use of SAP therapy in terms of a reduced number of hospitalizations, with an initial rate of 0.5 (IQR 0.5-1) events per person year decreasing to 0.26 (IQR 0.16-0.667) events per patient-year (*P*=.004). The percentage of patients requiring hospitalization (during the last 2 years) was 50% (36/72) prior to and 14% (10/72) after beginning SAP therapy (OR 0.23, 95% CI 0.001-0.58; *P*<.001).

Moreover, prior to beginning SAP therapy, 58% (42/73) of the patients had to be admitted to the emergency room, but at the end of the study, only 6% (4/62) of them had to be admitted (OR 0.11, 95% CI 0.01-0.83; *P*<.001). Emergency room visits fell from 1 (IQR 0.5-2.0) event per person year to 0.25 (IQR 0.16-0.6) events per person year (*P*<.001; Table 3; Multimedia Appendix 1).

Table 3. Follow-up data on the clinical outcomes.

Outcomes	Patients at baseline, n/N (%)	Patients at final follow-up, n/N (%)	*P* value
At least one severe hypoglycemia episode	21/74 (28)	10/70 (14)	.14
At least one nonsevere hypoglycemia episode	71/74 (96)	62/74 (84)	.01
Gold score ≥4	44/74 (60)	30/74 (40)	<.001
Required emergency room visit	42/73 (58)	4/62 (6)	<.001
Required hospitalization	36/72 (50)	10/72 (14)	<.001

Discussion

Principal Findings

The most relevant result of this study is the long-term (4-year) benefit we observed; there was a reduction in the number of hospitalizations and emergency room visits, in addition to better metabolic control, with the use of SAP therapy, which combines CSII and real-time CGM (rt-CGM). Many publications [19,20,24,33-35] have shown that SAP therapy has clinical and glycemic benefits in patients not controlled with a basal-bolus regimen. Previous studies, such as Gómez et al [21], have shown HbA_{1c} reductions with SAP therapy from 8.8% (SD 1.9%) to 7.5% (SD 1%) at 5 months (mean difference –1.3%, 95% CI –1.09 to –1.5; *P*<.001) and 7.1% (SD 0.8%; mean difference –1.7%, 95% CI –1.59 to –1.9; *P*<.001) after 47 months of follow-up. Likewise, the incidence of SH decreased significantly, from 66.6% to 2.7% (*P*<.001). In addition to HbA_{1c} reduction (from 8.7%, SD 1.7% to 7.4%, SD 0.8%; *P*<.05), Ramirez-Rincon et al [24] found a decline in hospitalizations, from 16.5% to 6% (*P*<.05), as well as a reduction in the incidence of SH, from 32% to 7.1%, at 1 year of follow-up. Our results are similar to those of the abovementioned studies. This confirms the utility of SAP technology in these high-complexity treatment groups. In Colombia, some health care programs perform follow-up monthly or every 3 months with an interdisciplinary team (medical and administrative support) that resolves clinical or administrative issues that might hamper adherence and glycemic control.

However, some studies have shown no benefit for metabolic control with the use of this type of technology. Blair et al [23] found no HbA_{1c} reduction or cost-effectiveness in using CSII compared with MDI (CSII: 7.72%, 95% CI 7.5%-7.94%; MDI: 7.5%, 95% CI 7.28%-7.72%). However, they evaluated results from patients aged from 7 months to 15 years. The outcomes were examined in patients with a de novo T1D diagnosis and analyzed within the first year of the disease. This protocol made it difficult to determine any benefit or difference between therapies due to complex glycemic control and known limitations in the pediatric population [36]. The glycemic and pathophysiological behavior of T1D in this age group, especially in the first year after diagnosis [37,38], may have masked the differences that might otherwise be seen in patients with a medium- to long-term duration of the disease. Bolli et al [22] found no differences between the use of MDI or CSII. The mean HbA_{1c} reduction was similar in both groups: CSII was –0.7% (SD 0.7%) and MDI was –0.6% (SD 0.8%), with an adjusted difference of 0.1% (95% CI 0.5%-0.3%). However, the patients had previously used neutral protamine Hagedorn (NPH) insulin and were randomized to a glargine insulin regimen or CSII. The design of this study limited the ability to find differences between groups, as long-acting insulin should be the standard treatment today, not a comparative alternative to CSII. The indication to initiate CSII should be in patients with untargeted glycemic control or persistent hypoglycemic events after using a basal-bolus regime with second-generation and rapid-acting insulin [30,31,39].

It should be noted that only a small (but ever-growing) group of subjects with T1D, T2D, and other types of diabetes will be able to access SAP technology due to the increasing use of CGM (with intermittent scanning or real-time monitoring) as a standard of care, with encouraging outcomes in glycemic goals and avoiding hypoglycemic episodes [7,8,40-44]. Furthermore, the economic burden of these technologies is a barrier in low-income countries; however, we think the costs will probably decrease as the technology becomes more available. Even our study demonstrates the utility and probable cost-effectiveness of the use of these technologies [45-47].

In our study, the patients had been diagnosed with T1D for an average of 20 years and had nongoal glycemic control with MDI despite having complete diabetes training, including the techniques for applying and self-titrating insulin, carbohydrate counting, managing hypoglycemia, and using second-generation insulin analogues, as recommended by T1D International and local management guidelines [27-29]. This is vitally important because in our population, SAPs are used as a step-up treatment only when the metabolic control goals are not met despite interdisciplinary and specialized management and not as an alternative treatment in patients who will potentially be controlled through optimized management with education and training in disease management.

One of the advantages of our study is that the majority of the patients used recent insulin pump models, which in other publications have been shown to be beneficial in reducing hypoglycemic episodes and HbA_{1c} [48,49]. The study by Bolli et al [22] was performed using the MiniMed 508 model, which did not have technologies such as the Bolus Wizard. The latter is useful for estimating the bolus dose using a calculation of the insulin-to-carbohydrate ratio, the insulin sensitivity factor, the target blood glucose, and active insulin. The most recent devices allow more stringent targets to be pursued, reducing the risk of hypoglycemia and the coefficient of variation [50].

Throughout the follow-up period, remarkable adherence to the therapy was recorded, with an average sensor use time exceeding

80%. This high adherence was attained through regular medical consultations and follow-ups, which were conducted at least 6 times per year for all patients, while promoting proper sensor use for as long as possible along with calibration and blood glucose measurement.

There was a small difference in the number of blood glucose measurements and calibrations when comparing the first year of follow-up to the subsequent years of follow-up, likely due to the use of new devices such as the MiniMed 670 pump, which requires fewer calibrations and has improved precision. Additionally, some level of fatigue or sense of security may have arisen from the prolonged use of these devices.

The most significant improvement in HbA_{1c} levels occurred during the first year of therapy, with a reduction from 8.35 (IQR 7.3-9.8) to 7.6 (IQR 7.3-8.1; P<.001). This improvement progressed gradually, reaching a median of 7.0 (IQR 6.5-7.4), which can also be attributed to technological advancements during the follow-up period.

Strict and frequent follow-up among this young population, along with consistent and adequate adherence to the therapy, allowed for high percentages of sensor use, SMBG measurements, and calibrations. These factors are reflected in our results.

Limitations

The main limitation of this study is its retrospective character. It is a common situation in the analysis of retrospective cohorts that there is a loss of some data in the clinical history records. Some data were taken from the chart review and the insurance company's database and others from patient surveys, which may have led to various types of bias. We performed a comprehensive review of the data and chose the worst-case scenarios.

Another limitation of our study is the lack of a control group (without SAP therapy). However, given the type of population to which we had access in this program, it was not possible to include patients without this technology and carry out long-term follow-up.

Moreover, the results may have been influenced by the trial design. The switching of the previous diabetes management regime with MDI plus SMBG to SAP is a significant step that entails a probable benefit in all outcomes, as was found in this trial. Nowadays, use of CGM is growing as a diabetes standard of care. Recently, much evidence has been published showing that CGM reduces hypoglycemic events and leads to lower HbA_{1c} with increases in TIR. In Colombia, intermittently scanned CGM (is-CGM; the FreeStyle Libre system) was the first device, approved in 2019, and its use is increasing rapidly. In our opinion, this technology promises to have clinical benefits like those demonstrated in this trial, but nevertheless this needs to be confirmed.

Finally, one interesting question is the future of CGM versus SAP as a tool for diabetes management. Choudhary et al [51] compared is-CGM and an advanced hybrid closed loop (AHCL) system. The latter showed an additional benefit in HbA_{1c} reduction (AHCL: –1.54%; is-CGM: –0.20%), resulting in a treatment effect of −1.42% (95% CI −1.74% to −1.10%; P<.001). Thus, new technologies such as AHCL can provide effective therapy and have advantages for the treatment of this complex disease.

Conclusion

This study is the first to evaluate the safety, as well as the clinical and glucose benefits, of using SAP therapy in a population with T1D, with real-life data and long-term follow-up. The use of this technology for an average of 4 years led to a significant HbA_{1c} reduction, achievement of HbA_{1c} goals, and a lower number of NSH episodes, emergency room visits, and hospitalizations. These results should encourage the adoption of this technology in patients who do not achieve metabolic control with optimal care for T1D. It should be noted that its efficacy requires a multidisciplinary team with experience in the use of this technology and close patient support. Finally, we recommend carrying out experimental studies to compare this technology with other therapies.

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Authors' Contributions

MO and JCMA contributed to the concept and design of the study and drafting the manuscript. All authors contributed to acquisition, analysis, and interpretation of data and critical revision of the manuscript for important intellectual content. MO performed the statistical analysis. AU supervised the study. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Follow-up of the clinical outcomes.
[XLSX File (Microsoft Excel File), 24 KB - diabetes_v8i1e46880_app1.xlsx]

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Abbreviations

ADA: American Diabetes Association
AHCL: advanced hybrid closed loop system
CGM: continuous glucose monitoring
CSII: continuous subcutaneous insulin infusion
DSMES: diabetes self-management education and support
HbA_{1c}: glycated hemoglobin
is-CGM: intermittently scanned continuous glucose monitoring
ISPAD: International Society for Pediatric and Adolescent Diabetes
IU: international units
MDI: multiple daily injection
NPH: neutral protamine Hagedorn
NSH: nonsevere hypoglycemia
OR: odds ratio
rt-CGM: real-time continuous glucose monitoring
SAP: sensor-augmented insulin pump
SH: severe hypoglycemia

SMBG: self-monitoring of blood glucose
T1D: type 1 diabetes
T2D: type 2 diabetes
TIR: time in range

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Original Paper

Glycemic Outcomes and Feature Set Engagement Among Real-Time Continuous Glucose Monitoring Users With Type 1 or Non–Insulin-Treated Type 2 Diabetes: Retrospective Analysis of Real-World Data

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Abstract

Background: The benefits of real-time continuous glucose monitoring (RT-CGM) are well established for patients with type 1 diabetes (T1D) and patients with insulin-treated type 2 diabetes (T2D). However, the usage and effectiveness of RT-CGM in the context of non–insulin-treated T2D has not been well studied.

Objective: We aimed to assess glycemic metrics and rates of RT-CGM feature utilization in users with T1D and non–insulin-treated T2D.

Methods: We retrospectively analyzed data from 33,685 US-based users of an RT-CGM system (Dexcom G6; Dexcom, Inc) who self-identified as having either T1D (n=26,706) or T2D and not using insulin (n=6979). Data included glucose concentrations, alarm settings, feature usage, and event logs.

Results: The T1D cohort had lower proportions of glucose values in the 70 mg/dl to 180 mg/dl range than the T2D cohort (52.1% vs 70.8%, respectively), with more values indicating hypoglycemia or hyperglycemia and higher glycemic variability. Discretionary alarms were enabled by a large majority in both cohorts. The data sharing feature was used by 38.7% (10,327/26,706) of those with T1D and 10.4% (727/6979) of those with T2D, and the mean number of followers was higher in the T1D cohort. Large proportions of patients with T1D or T2D enabled and customized their glucose alerts. Retrospective analysis features were used by the majority in both cohorts (T1D: 15,783/26,706, 59.1%; T2D: 3751/6979, 53.8%).

Conclusions: Similar to patients with T1D, patients with non–insulin-treated T2D used RT-CGM system features, suggesting beneficial, routine engagement with data by patients and others involved in their care. Motivated patients with diabetes could benefit from RT-CGM coverage.

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KEYWORDS

type 1 diabetes; T1D; type 2 diabetes; T2D; time in range; engagement; continuous glucose monitoring; continuous glucose monitor; CGM; diabetes management; hyperglycemia; health data

Introduction

Real-time continuous glucose monitoring (RT-CGM) systems, which measure glucose levels in the interstitial fluid at regular intervals, benefit from ongoing improvements to sensor accuracy, improved integration with smartphones, and the inclusion of innovative functionalities such as alerts and alarms. These include high and low glucose level alerts, an urgent low soon alert, and rate of change alerts. The accuracy, functionality, and expanded insurance coverage of CGM has led to the rapidly growing adoption of this technology.

Numerous studies have demonstrated the safety and clinical efficacy of RT-CGM in individuals with type 1 diabetes (T1D) [1-4] and intensive insulin-treated type 2 diabetes (T2D) [5]. Based on this evidence, current medical practice guidelines now strongly recommend RT-CGM for all persons with diabetes treated with intensive insulin therapy, defined as 3 or more doses of insulin per day or the use of an insulin pump [6,7]. However, the guidelines also state that RT-CGM can also be considered for patients treated with basal insulin [6,7].

Studies analyzing glycemic outcomes [3-5] and effects on health care resource utilization [8] demonstrate the value of RT-CGM, but further research into the usefulness of various RT-CGM functionalities is needed. Only recently have there been studies on whether, and to what extent, patients incorporate use of the various RT-CGM functionalities and features into their daily diabetes self-management [9-11].

While current guidelines do not address RT-CGM use in patients with T2D not using insulin, some patients with non–insulin-treated (NIT) T2D do initiate use of RT-CGM with their physician's prescription. We sought to further understand this population by analyzing their glycemic metrics, as well as their use of RT-CGM features such as alerts and retrospective data analysis. We report findings from a large, retrospective database study that quantified and compared glycemic outcomes and engagement with RT-CGM features in individuals with either T1D or NIT T2D.

Methods

Ethical Considerations

Historical data were from US-based Dexcom G6 users who had agreed to the privacy policy and provided consent to the use of their anonymized data for research purposes; therefore, no ethics board approval was sought.

Study Design and Population

This retrospective, observational database analysis used anonymized data from US-based Dexcom G6 (Dexcom, Inc) users who self-identified on the G6 app as having either T1D or NIT T2D. During account initialization, those in the T1D cohort answered "Type 1" to the diabetes type question and "Yes" to the insulin use question. Those in the T2D cohort answered "Type 2" to the diabetes type question, answered "No" to the insulin use question, and did not enter any insulin doses during the observation window. Included patients had recorded use between September 1, 2021, and January 31, 2022.

Study Device

The G6 system measures interstitial glucose concentrations and provides real-time numerical and graphical information about the current level and its rate of change. Glucose data can be viewed on a dedicated, hand-held receiver, displayed on a compatible smart device via the G6 app, or viewed on a compatible insulin pump. When the app is installed, users can access several discretionary features, including the "High Glucose" threshold alert (programmable between 120 mg/dl and 400 mg/dl), the "Low Glucose" threshold alert (programmable between 60 mg/dl and 100 mg/dl), and the "Urgent Low Soon" (ULS) alert that is triggered when a glucose value <55 mg/dl is predicted within the next 20 minutes. The app also allows users to log insulin doses, carbohydrate intake, exercise, and other health events such as stress or symptoms of hypo- or hyperglycemia.

The built-in Share feature allows users to share their glucose data and real-time alarms or alerts with up to 10 people. When "followers" download the Dexcom Follow app, they can view users' glucose data directly from their smart device. Users and health care providers also have access to Dexcom Clarity, a suite of analytic tools and reports with up to 90 days of glucose information. The Clarity reports are available to providers through an internet portal, whereas users can access the reports on their smart device using the Clarity mobile app. The Clarity app can be programmed to allow receipt of "push" notifications, which prompt a weekly review of retrospective data and associated reports.

Outcomes Measures

Glycemic metrics were based on recent international consensus recommendations [12]. These included the percentage of time in the 70 mg/dl to 180 mg/dl range, the percentage of time below range (either <70 mg/dl or <55 mg/dl), the percentage of time above range (either >180 mg/dl or >250 mg/dl), and the coefficient of variation. Engagement measures included screen views within the G6 app, use of Clarity, use of the data sharing feature (Share), events logged in the G6 app, and enabling or customization of alert settings.

Analysis

Glycemic metrics and engagement with the specified system features were calculated over the 3-month observation period. Engagement with the Share feature was calculated by detecting the presence of at least 1 follower. Daily engagement with Clarity was considered if the software was used to process a patient's data on any given day.

Outcome metrics calculated in this study considered data from the full 6-month retrospective window and aggregated over all patients within each diabetes-type segment. Glycemic metrics were obtained from the CGM-derived glucose values that update during patient use of CGM. Glycemic metrics were calculated as the mean daily percent of time spent in, above, and below range. Alert-use outcomes were reported as the percent of patients in each segment that had the given alert enabled at any point during the study window. Similarly, we reported the percentage of patients who chose to customize alert settings during the study window by either disabling G6 mobile alerts

that are enabled by default ("Urgent Low Soon," "Low," "High," "No Readings," and "Out of Range"), enabling alerts that are disabled by default ("Rise" and "Fall"), as well as the percent of those who changed the default glucose threshold setting for the "High" and "Low" glucose alerts (250 mg/dl and 70 mg/dl, respectively). Screen views were calculated as the mean daily number of (G6 app) screen views in each glucose sync day for which there were any screen views. Numerical comparisons are presented here with no hypothesis testing. Statistical significance tests were not performed given that the large sample sizes of the T1D and NIT T2D groups would result in very small between-group differences considered statistically significant at conventional Type 1 error rate alpha levels.

Results

Glycemic Metrics

A total of 33,685 US-based users of an RT-CGM system were included in the analysis and self-identified as having either T1D (n=26,706) or T2D and not using insulin (n=6979). Overall, users with NIT T2D had a higher time in range, lower time above range, and lower time below range than users with T1D (Table 1). Their coefficient of variation, a measure of glucose variability, was also lower (Table 1).

Table 1. Mean glycemic metrics for users with type 1 diabetes or non–insulin-treated type 2 diabetes.

Diabetes type	TIR[a] (%)	TAR[b] (%)		TBR[c] (%)		CV[d]
	70-180 mg/dl	>180 mg/dl	>250 mg/dl	<70 mg/dl	<55 mg/dl	
Type 1 diabetes	52.1	45.5	21.2	2.4	0.7	0.35
Non–insulin-treated type 2 diabetes	70.8	28.5	7.6	0.8	0.4	0.23

[a]TIR: time in range.

[b]TAR: time above range.

[c]TBR: time below range.

[d]CV: coefficient of variation.

Engagement Metrics

The vast majority of users in both cohorts enabled the ULS alert, high and low glucose alerts, and the Always Sound feature (Table 2). More users customized the high glucose alert threshold than the low glucose alert threshold, and more users with T1D customized these settings than users with NIT T2D (Table 2).

Some patients chose to use the event logging features of the G6 app. Among the users with T1D, 27.2% (7272/26,706)—compared to 15.2% (1058/6979) of users with NIT T2D—logged an event of any kind (Table 3). The retrospective analysis feature (Clarity) was used by a majority in both groups (T1D: 15,783/26,706, 59.1%; NIT T2D: 3751/6979, 53.8%) (Table 3) and typically accessed within 10 days of their first data sync. In addition, use of the Share feature, which allows a trusted contact to view a user's glycemic status on their mobile device, was higher among users with T1D (10,327/26,706, 38.7%) but still occurred in users with NIT T2D (727/6979, 10.4%) (Table 3). Finally, screen views of the G6 app were similar between the two groups (T1D: 6.6 views/day; NIT T2D: 5.8 views/day).

Table 2. Level of real-time continuous glucose monitoring feature use and customization.

Diabetes type	Enabled the alert or feature, n (%)				Customized alert threshold, n (%)	
	Urgent Low Soon	Low threshold	High threshold	Always Sound	Low threshold	High threshold
Type 1 diabetes (n=26,706)	25,765 (96.5)	26,326 (98.6)	25,622 (95.9)	24,222 (90.7)	16,109 (60.3)	19,669 (73.7)
Non–insulin-treated type 2 diabetes (n=6979)	6228 (89.2)	6879 (98.6)	6804 (97.5)	5967 (85.5)	3091 (44.3)	4318 (61.9)

Table 3. Use rates of specific real-time continuous glucose monitoring features.

Diabetes type	Event logging					Engagement or sharing		
	Any event, n (%)	Carbs, n (%)	Insulin, n (%)	Health, n (%)	Exercise, n (%)	Clarity, n (%)	Share use, n (%)	Followers[a], mean
Type 1 diabetes (n=26,706)	7272 (27.2)	4599 (17.2)	6383 (23.9)	1616 (6.1)	1797 (6.7)	15,783 (59.1)	10,327 (38.7)	1.95
Non–insulin-treated type 2 diabetes (n=6979)	1058 (15.2)	756 (10.8)	0 (0)	314 (4.5)	437 (6.3)	3751 (53.8)	727 (10.4)	1.25

[a]The mean number of followers for those using the feature.

Discussion

Principal Results

In this analysis of 33,685 Dexcom G6 app users with T1D or NIT T2D, we sought to understand the level of feature engagement in these groups. We found a high degree of engagement in both cohorts in terms of enabling alerts such as the ULS alert and low and high glucose threshold alerts, as well as high levels of screen views. The higher use of data sharing in users with T1D was expected given their intensive insulin use and higher potential to contain pediatric patients. While a higher percentage of users with T1D logged events, these primarily consisted of insulin logs that users with NIT T2D did not log by definition. The number of screen views per day and Clarity usage were similar between the two groups, which suggests both groups regularly engaged with their glucose data for intraday monitoring and therapy decision-making.

Comparison With Prior Work

CGM is associated with improved glycemic outcomes in people with T1D [1-4] and intensive insulin-treated T2D [5]. Currently, consensus recommendations include a time in range of >70% and a time below 70 mg/dl of <4% for most patients [6,12]. Higher time in range was associated with clinically significant improvements in the risk of microvascular complications [13-15] and adverse cardiovascular events [16,17]. There is a growing body of evidence demonstrating that use of CGM in individuals with T2D treated with basal insulin only or NIT is associated with improved glycemic benefits and outcomes similar to those treated with intensive insulin regimens [18-21]. Previous studies have also demonstrated an association between improved glycemic outcomes and a high level of feature usage [9,22] or persistent CGM use [9,11].

Despite the differences in diabetes therapies between individuals with T1D and NIT T2D, their similar rate of RT-CGM feature utilization is notable. However, people with T2D treated with basal insulin only or NIT are often not considered for RT-CGM, and most insurance plans do not cover RT-CGM for this population [23,24]. However, the magnitude of the glycemic benefits can be particularly high, especially for those with poorly controlled T2D. In a study of 38 patients with poorly controlled T2D (glycated hemoglobin [HbA1c]: mean 10.1%, SD 1.8%), a significant HbA1c reduction of 2.8 percentage points was observed after 3 months in the group using routine RT-CGM [21]. Similarly, a subanalysis of the MOBILE study found that participants with the highest HbA1c derived the greatest benefit from CGM (up to a 32 percentage point increase in time in range) [25] and CGM initiation in patients with poorly controlled T2D may help prevent glycemic deterioration [26]. In addition to improved glycemic control, RT-CGM is associated with reduced rates of emergency department visits and hospitalizations in patients who use insulin [27] as well as reduced diabetes-related distress and hypoglycemic concerns [28]. Additionally, large retrospective database studies of intermittently scanned CGM use in individuals treated with less intensive therapies have shown similar HbA1c improvements [20] as well as improvements in quality of life [29] and reductions in acute diabetes-related events and all-cause hospitalizations [19]. Even intermittent use of RT-CGM in individuals with T2D treated with fewer therapies has shown significant improvements in HbA1c [30,31], reductions in diabetes-related distress [32], and increased understanding of diabetes self-management concepts [31]. Moreover, evidence suggests that RT-CGM system use contributes to patients' disease-specific knowledge [33] and may be an effective motivational tool that encourages the adoption of healthier behaviors [34-38]. This suggests that users with NIT T2D may be using the RT-CGM system and its features to monitor their glucose level in response to meals or exercise and reduce their highs and lows.

Limitations

Limitations of this study include the use of data from only one CGM system and the all-US population, which could reduce the generalizability of our results to other systems or other countries. We also do not know why these users began using RT-CGM or their motivation level, especially those with NIT T2D who are not typically eligible for insurance coverage. In order to have a broad cohort of users, there were no restrictions with regard to CGM use rate in either cohort and, as a result, the extent of feature use could vary between avid and more sporadic users. We also do not know many patient characteristics such as the use of antidiabetic medications or whether users with T1D are using continuous subcutaneous insulin infusion (ie, an insulin pump). Metrics such as screen views could be underestimated in insulin pump users who are able to view their glucose data on the insulin pump's interface. Additionally, the glycemic outcomes reported cannot be interpreted as causal effects of users' engagement with the system features. Finally, the clinical relevance of the between-group differences we observed remains unknown, and we do not know the long-term effects on diabetes self-management associated with feature engagement.

Conclusions

The high level of engagement as measured by screen views and use of features such as alerts, retrospective analysis (Clarity), and data sharing support the argument for increased CGM availability to people with NIT T2D. The RT-CGM users in our analysis were highly engaged with the various features studied.

Regardless of diabetes type and therapy regimen, users of the Dexcom G6 RT-CGM system had high levels of engagement with the system's features. Feature use among people with NIT T2D was high and often similar to engagement levels seen in people with T1D. Improved access to RT-CGM technology should be considered as a viable option for people with diabetes who are willing to incorporate it into their treatment regimens.

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Authors' Contributions

RD, GJN, RT, and KL conceived the study. RD, LHJ, and GJN analyzed the data. CRG wrote the manuscript in consultation with all authors.

Conflicts of Interest

All authors are shareholders and current or former employees of Dexcom, Inc.

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Abbreviations

CGM: continuous glucose monitoring
HbA1c: glycated hemoglobin
NIT: non–insulin-treated
RT-CGM: real-time continuous glucose monitoring
T1D: type 1 diabetes
T2D: type 2 diabetes
ULS: Urgent Low Soon

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Original Paper

Mobile Health Apps for the Control and Self-management of Type 2 Diabetes Mellitus: Qualitative Study on Users' Acceptability and Acceptance

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Abstract

Background: Mobile health apps are promising tools to help patients with type 2 diabetes mellitus (T2DM) improve their health status and thereby achieve diabetes control and self-management. Although there is a wide array of mobile health apps for T2DM available at present, apps are not yet integrated into routine diabetes care. Acceptability and acceptance among patients with T2DM is a major challenge and prerequisite for the successful implementation of apps in diabetes care.

Objective: This study provides an in-depth understanding of the perceptions of patients with T2DM before use (acceptability) and after use (acceptance) regarding 4 different mobile health apps for diabetes control and self-management.

Methods: A descriptive qualitative research design was used in this study. Participants could choose 1 of the 4 selected apps for diabetes control and self-management (ie, Clear.bio in combination with FreeStyle Libre, mySugr, MiGuide, and Selfcare). The selection was based on a systematic analysis of the criteria for (functional) requirements regarding monitoring, data collection, provision of information, coaching, privacy, and security. To explore acceptability, 25 semistructured in-depth interviews were conducted with patients with T2DM before use. This was followed by 4 focus groups to discuss the acceptance after use. The study had a citizen science approach, that is, patients with T2DM collaborated with researchers as coresearchers. All coresearchers actively participated in the preparation of the study, data collection, and data analysis. Data were collected between April and September 2021. Thematic analysis was conducted using a deductive approach using AtlasTi9.

Results: In total, 25 coresearchers with T2DM participated in this study. Of them, 12 coresearchers tested Clear, 5 MiGuide, 4 mySugr, and 4 Selfcare. All coresearchers participated in semistructured interviews, and 18 of them attended focus groups. Personal health was the main driver of app use. Most coresearchers were convinced that a healthy lifestyle would improve blood glucose levels. Although most coresearchers did not expect that they need to put much effort into using the apps, the additional effort to familiarize themselves with the app use was experienced as quite high. None of the coresearchers had a health care professional who provided suggestions on using the apps. Reimbursement from insurance companies and the acceptance of apps for diabetes control and self-management by the health care system were mentioned as important facilitating conditions.

Conclusions: The research showed that mobile health apps provide support for diabetes control and self-management in patients with T2DM. Integrating app use in care as usual and guidelines for health care professionals are recommended. Future research is needed on how to increase the implementation of mobile health apps in current care pathways. In addition, health care professionals need to improve their digital skills, and lifelong learning is recommended.

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KEYWORDS

type 2 diabetes; self-management; mobile health; mHealth; mobile apps; mobile phone; acceptability; acceptance; diabetes

Introduction

Background

The number of patients with type 2 diabetes mellitus (T2DM) is increasing worldwide, creating substantial economic difficulties in many countries, especially in Western Europe [1,2]. In the Netherlands, it is one of the most common chronic diseases, with an expected prevalence of 1.14 million people with T2DM in 2025 and up to 1.33 million people in 2040 [3]. A healthy lifestyle, that is, adherence to regular physical activity and a healthy diet, contribute to the treatment and prevention of T2DM [4-9]. Bassuk and Manson [6] demonstrated that physical activity may contribute to a 30% to 50% reduction in the development of T2DM.

Apps for Diabetes Control and Self-management

Patients with T2DM require diabetes control and self-management skills to change their lifestyle and adhere to a healthy lifestyle. Self-management has been defined as "day-to-day activities or actions an individual must undertake to control or reduce the impact of disease on their health and well-being to prevent further illness" [10,11]. Self-monitoring blood glucose levels, food intake, physical activity, and stress can increase the self-management of patients with T2DM. Hence, mobile health apps are promising tools to help patients with T2DM in diabetes education, self-management, and lifestyle modifications to improve their health status and thereby reach diabetes prevention [12-14]. Greenwood et al [13] concluded that the most effective technology-enabled diabetes self-management solutions incorporated 2-way communication, personal data analysis, tailored education, and individualized feedback. The availability of mobile health apps for T2DM has increased significantly in recent years. Although there is a wide array of apps currently available, they are not yet integrated in routine diabetes care. Previous studies have described that end users, staffing, technology, systems, clinical and cultural issues, and costs hinder the acceptance and implementation of mobile health apps for diabetes control and self-management in routine care [15-18].

Technology Acceptability and Acceptance

The acceptance of apps for diabetes control and self-management among patients with T2DM is a complex process that can vary between different diabetes apps and individuals. Different definitions of acceptability, acceptance, and adoption have been proposed. In this study acceptability is defined as "a persons' perception of a system before use" and acceptance as "a persons' perception of the system after use" [19]. The Technology Acceptance Model and the Unified Theory of Acceptance and Use of Technology (UTAUT) are widely used technology acceptance models to understand why users accept or reject a specific technology [20,21]. Acceptability and acceptance are key elements of these technology acceptance models. To explain acceptance, UTAUT includes 4 key constructs: performance expectancy (the belief that an app will help improve health performance), effort expectancy (level of ease associated with using an app), social influence (social support), and facilitating conditions (infrastructural support).

Aim

This study aimed to gain an in-depth understanding of the perceptions of patients with T2DM both before use (ie, acceptability and expectations) and after use (ie, acceptance and actual experiences) regarding 4 different mobile health apps for diabetes control and self-management.

Methods

Research Design

This study is based on a qualitative descriptive research design [22]. The methodological orientation underpinning this approach was a naturalistic inquiry [23] to explore the multiple and subjective expectations, perceptions, and actions of patients with T2DM before and after the use of apps for diabetes control and self-management. To explore the acceptability and acceptance of the 4 different apps, 25 semistructured in-depth interviews were conducted, followed by 4 focus group discussions.

This study used the citizen science approach [24]. Patients with T2DM, who were lay people (nonscientists) from the community, collaborated with the researchers as coresearchers in all phases of the study. All coresearchers actively participated in the preparation of the study, data collection, and data analysis. Hence, the coresearchers participated in the development of the interview guide and topic list of the focus group discussion and tested 1 of the 4 apps for diabetes control and self-management. Furthermore, the researchers discussed their perceptions before and after use with other coresearchers. Coresearchers also played an active role as chairs of the focus group discussions, giving feedback on the report, and contributing to interviews for publication as news items in journals and webinars.

Setting

This study was part of the TOPFIT Citizenlab project. TOPFIT Citizenlab is a 3-year research and innovation program in the eastern part of the Netherlands. Citizens, health care professionals (HCPs), and companies have joined forces with researchers to develop and implement technology for health and well-being.

In this study, 4 apps (ie, Clear.bio in combination with FreeStyle Libre, mySugr, MiGuide, and Selfcare) for diabetes control and self-management were selected. The 4 apps were selected as they were specifically developed for T2DM control and self-management. Furthermore, these 4 apps met mobile health app requirements [25], and providers were willing to participate in citizen science projects. The (functional) requirements were categorized as follows: (1) monitoring (eg, the possibility of

monitoring blood glucose levels and different lifestyle factors), (2) data collection and interpretation (eg, visualization of data), (3) provision of information (eg, education regarding healthy lifestyle and diabetes control), (4) coaching (eg, coaching based on behavior change models), and (5) privacy and security (eg, privacy statement, data storage and sharing, and certificates). These (functional) requirements were defined based on different conversations with experts (eg, HCPs involved in diabetes care, IT experts, technology providers, and privacy and security officers).

The Clear.bio app provides insights into a person's response to nutrition by measuring their blood glucose levels continuously using the FreeStyle Libre flash glucose monitoring system. In addition, Clear is used to monitor food intake, mood, exercise, and sleep. mySugr is an app used to monitor blood glucose levels, food and medication registration, and daily activities. MiGuide is an app focused on healthy lifestyle and behavior changes by coaching patients with T2DM regarding food intake, daily activity, and blood glucose monitoring following a blended care approach. Selfcare is a personal health environment that connects sensors and wearable devices for health and well-being on an independent platform and includes, for example, challenge-based gamification.

Recruitment Strategy and Sample Size

Coresearchers were recruited via the Dutch Diabetes Association, flyers, and announcements on social and regional media. All those interested in the study were invited to join an introductory webinar. During this webinar, participants digitally met the researchers and representatives of the companies using the 4 apps for diabetes control and self-management. An introduction to the project and the 4 apps was presented, and the participants could ask questions about the project. After the webinar, the participants were asked whether they wanted to participate and, if so, which app they were particularly interested in. Those interested in participation received a letter containing written information about the project and an informed consent form. The informed consent was obtained before the first interview.

Only people who were diagnosed with T2DM and had the intention to work together with the researchers, as coresearchers, were included in this citizen science project. Furthermore, a minimal level of digital skills and having a mobile phone was required to participate in this study. The coresearchers had no previous experience with any of the apps. The time since the diagnosis was not included in the inclusion or exclusion criteria. According to the guidelines for qualitative research, we attempted to include a minimum of 20 coresearchers [26].

Data Collection

Data were collected between April and September 2021 through semistructured interviews and focus groups. All coresearchers performed a short exercise in preparation for the interviews. They received 2 pictures of flowers with empty leaves [27]. They were asked to share their motivations to participate in the study, especially regarding the app and their role as coresearchers, and write them down on the leaves of the flower (Multimedia Appendix 1). Semistructured in-depth interviews were conducted via telephone calls. The calls lasted between 30 and 60 minutes. The interviews were audio recorded and the researchers took notes during the interviews. Three researchers conducted interviews (MB, CMvL, and TJJO). The interviews focused on the perceptions and expectations of the coresearchers, considering their choice to test and use one of the apps for diabetes control and self-management (Multimedia Appendix 2). In addition, one question derived from the Personal Innovativeness Scale was included in the topic list [28].

The interviews were followed up by 4 focus group discussions with the same coresearchers 4 months after testing the app of their choice. The focus groups took place at a central location in one of the affiliated research centers to minimize the burden and travel distance to participate in the focus groups. Three researchers (MB, CMvL, and TJJO) and 2 coresearchers arranged and chaired the focus group discussions. The focus group discussions lasted for approximately 90 minutes. Audio recordings were made of the focus groups, and a researcher (CMvL) observed and made notes on the discussions and interactions between the participants. Two focus groups were organized to discuss user acceptance of Clear, one about MiGuide, and in one focus group, coresearchers who tested mySugr and Selfcare were combined (owing to the smaller number of participants). The topic list for the focus group was prepared in collaboration with several other coresearchers. The topics included perceptions, experiences, reflections on the expectations, role of HCPs, and the information provided by the apps for diabetes control and self-management (Multimedia Appendix 3).

Data Analysis

Data from flower associations were analyzed and described in infographics. The data from the semistructured in-depth interviews and focus groups were combined and analyzed following the same steps. First, the interviews were transcribed verbatim, and extensive observation notes from focus group discussions were used. On the basis of the coding process, the notes of the focus groups were complemented with verbatim transcriptions where needed. Measures were taken to avoid cross-contamination of data: that is, by a clear overview of which coresearcher used which app, checks in the follow-up questions to ensure which app they were talking about, adding researchers' notes to the transcripts (link with app), and a summary was sent to all participants linking the quotes and results to the different apps (member check). All data were analyzed using a deductive approach [29]. This deductive approach followed the elements of the UTAUT model (Multimedia Appendix 4). The transcripts and observation notes were read, and codes were assigned to specific passages. Three researchers (MB, CMvL, and TJJO) coded the data and compared them. The findings were discussed iteratively with the project team during weekly meetings. The researchers used the software package AtlasTi9 to analyze the data. Data saturation was achieved when no new themes emerged in the transcripts.

Trustworthiness

Credibility was established through several procedures [23]. Method triangulation (ie, interviews and focus groups) was

conducted to increase the credibility of the data and study. In addition, audio recordings, notes, and observations were combined to gain in-depth insight into the perceptions of patients with T2DM before and after the use of mobile health apps. Investigator triangulation was achieved as several researchers designed the study, read the transcripts and notes, analyzed the data, and compared the findings. Furthermore, the research team consisted of professional researchers from different research institutes and patients with T2DM as coresearchers. Peer debriefing took place at weekly meetings with the project team, where both scientific and organizational aspects were discussed. The summarizing document of the project was shared with all the coresearchers and app developers as part of the member check.

A thick description was developed for transferability, which included recruitment, coresearchers' selection, data collection, and data analysis. This citizen science approach to testing apps for diabetes control and self-management is a transferable method to be used in other settings and development contexts.

Ethics Approval

Ethical review and approval were obtained from the Ethics Review Committee of the University of Twente (210043). The coresearchers provided written informed consent and were informed about their right to withdraw at any time. Data were anonymized, and data confidentiality was maintained.

Results

Demographic Characteristics of the Coresearchers

In total, 25 coresearchers with T2DM participated in this study. Overall, 48% (12/25) of the coresearchers tested Clear, 20% (5/25) MiGuide, 16% (4/25) mySugr, and 16% (4/25) Selfcare. All coresearchers participated in semistructured in-depth interviews, and 18 of them attended focus groups. Of the coresearchers, 52% (13/25) were female, and 48% (12/25) were male (Table 1). The mean age of the coresearchers was 63 (SD 7.6, range 47-77) years. More than half (14/25, 56%) of the coresearchers had been diagnosed with T2DM ≥10 years ago, and 44% (11/25) had been diagnosed with T2DM ≤10 years ago. Most coresearchers used oral medication (14/25, 56%) or insulin (9/25, 36%).

Table 1. Demographic characteristics of the coresearchers (N=25).

Characteristics	Value, n (%)
Sex	
Male	12 (48)
Female	13 (52)
Intersex	0 (0)
Age range (years)	
40-49	1 (4)
50-59	8 (32)
60-69	10 (40)
70-79	6 (24)
Disease duration (years)	
<5	4 (16)
5-9	7 (28)
10-14	8 (32)
15-20	5 (20)
>20	1 (4)
Type of medication	
None	2 (8)
Oral	14 (56)
Insulin	9 (36)

UTAUT Constructs

The results are based on the constructs of the UTAUT model, describing performance expectancy, effort expectancy, social influence, facilitating conditions, anxiety, and trust in data security and knowledge. General findings and quotes from the coresearchers were acquired during the interviews and focus groups. Within each construct of the UTAUT model, perceptions regarding expectations before use (ie, acceptability) are followed by actual experiences after use of the app (ie, acceptance) for diabetes control and self-management.

Performance Expectancy

Personal health was the main driver of app use. This was already visible in the flower associations. There were quite some written comments, such as "losing weight," "less medication," "understand the effect of nutrition," and "less stress." All coresearchers had their personal goals and believed that the apps would help reach these health-related goals. The goals ranged from reaching a stable blood glucose level to losing weight, more healthy diets, or exercising more often. A small number of coresearchers had the expectation of lowering the need for medication. Overall, all the coresearchers expected that they would learn more about the influence of nutrition:

> *I can imagine that one kind of carbohydrate will have a different effect on my body compared to another kind of carbohydrate, for example pasta or bread. This does not mean I will eat all these different carbohydrates to test the effect on my body, but I would like to know on which kind of nutrition I react best or worst. Also, the severity of the reaction and the moment I will feel some effect on my body is interesting to get more knowledge on.* [Clear coresearcher]

Most coresearchers were convinced that a healthy lifestyle would improve blood glucose levels. This was the main finding after the testing period. They mentioned nutrition, exercise, and stress as having an impact on their lifestyle. "It would be nice to have this overview in the app, to see when you did a lot and when you need to work a bit more on your lifestyle" [MiGuide coresearcher]. Coresearchers wanted insight into their lifestyles to find a balance in their lives. These apps provided helpful insights. However, some coresearchers asked the companies for help, and MiGuide coresearchers all used the app in consultation with a lifestyle coach. The lifestyle coach was a valuable addition to understanding and adhering to advice based on the data from the app.

Continuous monitoring is especially a performance expectation of coresearchers who tested the Clear app. "It will probably help if the sensor just measures, that is more accurate than the measurements I will do myself and it might show how my glucose level is actually evolving during the day" [Clear coresearcher]. However, coresearchers also expected that the use of apps might give them knowledge about their disease and how the disease influences them:

> *I hope the app will give me a vision on diabetes and how I personally can control the disease. For example, if I eat this, I will know what happens with my blood glucose level, a kind of self-consciousness.* [MiGuide coresearcher]

They expected the app will "save my choices. There will be a log of everything I eat and how much exercises I performed, which makes me possibly more conscious of making choices" [mySugr coresearcher]. After the test period, most coresearchers confirmed that the apps influenced their lifestyle, but the extent was debatable. Some agreed that "the app was a real 'eyeopener' for me" [Clear coresearcher], but others thought that the app just showed them the obvious or was not accurate enough. The impact of the test period ranged from lowering medication and changing the entire diet to taking some advice into account.

Effort Expectancy

In general, most coresearchers did not expect that they need to put much effort into using the apps. For example, coresearchers who measured their blood glucose levels expressed that the option for more continuous measurements was desirable and that the transition would be small: "I do not like the fingerstick, and with the sensor that will not be necessary" [Clear coresearcher]. Comparing this expectation with the actual experience, coresearchers stated that it was amazing how much data were available and how easily this could be visualized in graphs. The Selfcare app also provided clear visualizations: "the logged data was always visible and visualized in very pretty graphs" [Selfcare coresearcher]. A disadvantage experienced by a Clear coresearcher was that she sometimes forgot to upload data from her sensor to her phone in time. The sensor could only save the last 8 hours of the measurements; therefore, the graphs had some gaps.

Before using the apps, coresearchers wrote in the flower associations that the apps might minimize efforts to maintain a healthy lifestyle. They expected that apps would provide suggestions or directions for action, mainly focusing on nutrition and exercise. This supports coresearchers to keep a grip on their own lives and understand the impact of external factors:

> *Currently I must figure everything out by myself. When I can test and note everything the app will give me the required feedback to stay on the right track.* [Clear coresearcher]

The positive experiences of using the app outweigh the additional effort required to use the app. "When you reach a certain success, think about a different lifestyle and gain more knowledge, that is worth testing it" [mySugr coresearcher]. However, based on the experiences during the test period, the additional effort to familiarize themselves with app use was quite high. For all 4 apps, the coresearchers had to keep track and log many details, such as exercise and food intake. As one of the Selfcare coresearchers described:

> *It was a lot of work to log everything every day, this was a disadvantage of the app. You had to log everything yourself and it is easy to make mistakes.*

Social Influence

None of the coresearchers had a HCP who provided suggestions on using apps. They visited their HCP regularly, but "I visit my general practitioner twice a year, we discuss the blood test results, but it is always a snapshot when they measure the blood glucose levels" [Clear coresearchers]. Although they obtained some knowledge from regular visits, most coresearchers expressed their desire to gain more knowledge about their own bodies and diabetes:

> *We [diabetes care specialist and patient] discuss the blood test and then it is always the same: "it looks very good, please continue," but this is not enough.* [mySugr coresearcher]

The coresearchers who tested the MiGuide app were also supported by a lifestyle coach. The combination of an app and a coach is a positive experience. The coach has a positive influence on coresearchers. She did not forbid the coresearchers anything, but "she holds a mirror and then you can understand yourself what is wrong." In addition, regular appointments with lifestyle coaches have a positive social influence on adherence to lifestyle changes. All other coresearchers expressed a desire to have such a relationship with HCPs:

> *The health care professional need to play an important role in our care with the Clear app as daily support. Starting with such an app without the assistance of a health care professional could cause a lot of confusion. Especially someone who is 'new' to diabetes can benefit a lot and find its way toward a healthy life pattern.* [Clear coresearcher]

According to coresearchers, it is simple to monitor, show, and share data with HCPs.

Next to HCPs, social networks (ie, family and friends) play an important role in managing T2DM. Before the start of the test period, almost all the coresearchers felt supported or strengthened by their close relatives. With the challenges provided in the Selfcare app, the coresearchers received support from their relatives. For example, the entire family participated in the "wholegrain-challenge." In contrast, they sometimes felt misunderstood regarding specific lifestyle choices, for example, not wanting to have a piece of pie during a party. There was one coresearcher, who was going to test Clear, who told us, "My wife will not be interested. She does not want to know about all the things I can do and sees it as a waste of time." At the start of the study, this complaint was only mentioned one partner. During the test period, more partners complained about the effort needed and "he complained about the amount of time I was using the app" [Clear coresearcher].

Facilitating Conditions

An issue often mentioned during the interviews, focus groups, and flower associations are the reimbursement options of technologies for self-management and control of people with T2DM.

> *I mean, normally I will not receive any reimbursement. If I want to perform a fingerstick blood glucose test, I must pay for it.* [Clear coresearcher]

After the test period, all coresearchers expressed the need for this type of technology to assist people with T2DM and the need for reimbursement. They could test the products now for free, and some agreed that they would pay for it, but they acknowledged that many others would not have the possibility to pay for the technologies themselves.

Another necessary facilitating condition according to the coresearchers was the acceptance of the apps for diabetes control and self-management by the health care system. This could include all the different HCPs involved in diabetes care, as well as improving or changing the standards and protocols on which HCPs base their treatment:

> *Nowadays they search for a treatment by adding or lowering the number of pills. I am not in favor of such an approach, if it is needed and there is no other option it is ok, but it should be the last resort.* [Selfcare coresearcher]

If the health care system could facilitate professionals to support diabetes treatment by technology, it would be beneficial for people with T2DM.

Anxiety

Most of the coresearchers participated in this study because of their interest in technology. None of them expressed any feelings of anxiety regarding technology. However, they were anxious that this technology would not be available to them or would be too expensive for most people with T2DM. Another link with anxiety is their distrust in developers because they have no idea how to live with diabetes. They feel that the technology should be developed more specifically to their needs to assist them in reaching their personal goals of living with diabetes. This might also increase new users' trust in technology:

> *I want to experience the technology. Tell the developers about my experience and help them to define which elements works and where they need to improve the app. This is needed to make it future-proof for everyone living with diabetes.* [Selfcare coresearcher]

One element of the Clear app that raised anxiety was the sensor:

> *I had to apply the sensor on my arm without help... I left it on my table for two weeks, I was too anxious.*

More assistance is required in the first phase of technological use. Finally, all coresearchers applied the sensors themselves or with the help of a family member. Asking for help was an important barrier.

Trust in Data Security

There were no concerns regarding the data security. All coresearchers expected that the data would be stored safely by companies. In addition, if they would share data (in the future) with their HCPs, the coresearchers expected that the information in the app would be treated with strict confidentiality. Furthermore, all coresearchers had a lot of trust in technology, in general:

> *I try to know everything about new technologies or other assistive tools for diabetics. I dive into the material and believe that it might improve my life or make it easier.* [MiGuide coresearcher]

All coresearchers were interested in technology, and most of them performed their own searches on newly available technologies for diabetes:

> *When a new app crosses my path, I will try to see how useful it is. I would describe myself as that kind of person.* [Clear coresearcher]

Although most of them were frontrunners in trying out the technology, some coresearchers were more hesitant and curious about experiencing apps. Although most of these more hesitant coresearchers had a difficult start and needed more help from

the companies to use the app, they were enthusiastic about the results after using the app, and 2 bought an actual subscription to be able to continue using it after the research period.

Knowledge

Half of our coresearchers' group knew apps to support them in their lives with diabetes. Some of them had already tried several apps or were still using them at the start of the study. They used the apps to improve their knowledge about their own body, in addition to acquiring knowledge by reading magazines or searching the internet. However, most coresearchers mentioned that they still struggled to cope with the disease:

> *I know a lot and learned a lot myself, but I do not understand why it is not working for me. I have tried a lot, but need more help from external factors.* [Clear coresearchers]

As every person with T2DM is different, they expressed a desire for more personalized care and the integration of apps. Some also mentioned "unique knowledge" in flower associations.

Another aspect of the knowledge discussed after the test period was the need for more information on how to use the app. Coresearchers needed more assistance, especially at the beginning. Where some tried and figured out themselves, "during the course of the test period I scrolled more and more through the app and could use more and more elements of the app" [Selfcare coresearcher], others got lost and confused, "I was completely lost when the scores of my previous meal showed" [Clear coresearcher], and others asked for help, "I contacted the MiGuide developers and they really quickly helped me with everything" [MiGuide coresearcher]. Overall, all coresearchers agreed that more knowledge of apps for diabetes control and self-management was required before the test period and maybe already at an earlier phase in their diabetes trajectory. Their idea was to disseminate the knowledge gained about these apps among HCPs and associations, such as the Dutch Diabetes Association, and to try to reach all people who have recently been diagnosed with T2DM through these channels.

Discussion

Summary of Findings

This study provided an in-depth understanding of both the perceptions of patients with T2DM before use (acceptability) and the perceptions of patients with T2DM after use (acceptance) regarding 4 different mobile health apps for diabetes control and self-management. Personal health was the main driver of app use. Most coresearchers were convinced that a healthy lifestyle would improve blood glucose levels. The performance expectation among the coresearchers when using the apps was high. This mainly concerned the expectation that the app would have a positive influence on their health, diabetes control, and self-management by acquiring knowledge and gaining insight into blood glucose levels in relation to diet and exercise. Although most coresearchers did not expect to put much effort into using the apps, the additional effort to familiarize themselves with the app use was quite high. None of the coresearchers had a HCP who provided suggestions on using the apps. One of the reasons might be that mobile health apps are not yet part of the practical guidelines and protocols. When coresearchers are guided by a lifestyle coach when using the apps for diabetes control and self-management, the discipline of participants in pursuing a healthy lifestyle seems to increase. Coresearchers prefer more information about mobile health apps for diabetes control and self-management and how to use these apps. Reimbursement from insurance companies and acceptance of apps for diabetes control and self-management by the health care system were mentioned as important facilitating conditions.

Reflection With the Literature

The degree of acceptability and acceptance of mobile health apps for the control and self-management of T2DM can vary per app and per patient, as shown in this study. This variety was related to the coresearchers' personal characteristics, preferences, needs, and experiences. In this study, 96% (24/25) of the participants were aged ≥50 years. Previous research has shown that age is associated with both the intention to use (mobile health) apps and performance expectancy is moderated by age [30]. Hence, future studies should investigate whether similar results are observed in younger patients with T2DM. In addition, apps with functionalities that can adapt to personal preferences and changes in consumer demands are more likely to be used continuously, thereby maintaining positive behavior [31]. This is in line with the recommendations of coresearchers to include personal preferences (settings) in mobile health apps and to receive personalized feedback.

Effort expectancy is one of the main drivers of technology use (eg, apps) [21]. Beforehand, coresearchers did not expect that the use of apps would take a lot of time. In practice, however, coresearchers had to understand the app and thereafter track and log data such as food intake and exercise. Relatives and family members also noticed investment in time. Relatives were usually closely involved in the lives of the coresearchers and the impact of diabetes on their lives, but they were also regularly critical of the time it took to process all data in the app. Hence, realistic information should be provided to patients with T2DM and their relatives to facilitate the long-term use of apps. Especially for patients with minimal digital skills, instruction and coaching of in-app use is of utmost importance [32].

Another barrier was trust in the app developers. Coresearchers have stated that the needs and wishes of patients are not always taken into account when developing apps. The positive effects of mobile health apps for diabetes self-management are maximized through the integration of more comprehensive functionalities, input from patients and professionals, and evidence-based design [33,34].

Smartphones can facilitate communications between patients and caregivers and customize health monitoring for individual patients. Hence, smartphones are uniquely positioned to enable patients to support their daily diabetes self-management [35]. However, HCPs rarely use the data collected by patients to adjust for the treatment of T2DM. Alaslawi et al [36] conducted a review and concluded that HCPs remained hesitant to use diabetes self-management apps. HCPs play an important role in both treatment adherence and long-term health outcomes. Ashrafzadeh and Hamdy [17] showed that patient-professional

interactions are essential for improving health outcomes and preventing long-term complications in patients with T2DM. In addition, patients with a higher frequency of patient-physician meetings achieved their hemoglobin A1c, blood pressure, and cholesterol level goals faster and had higher success rates compared with patients who had less frequent contact with their general practitioner [37,38]. Finally, mobile health interventions can change hemoglobin A_{1c}–levels more often in patients with T2DM and type 1 diabetes mellitus compared with patients receiving care as usual [39].

Lack of reimbursement has been mentioned as one of the main barriers to using apps for diabetes control and self-management. Hence, reimbursement of apps (eg, by health insurance companies) may have a positive effect on the acceptance and implementation of apps, as well as on health outcomes. To date, there are no or minimal reimbursement options in the Netherlands for apps or technological equipment if patients with T2DM are not insulin dependent. Financial issues in terms of reimbursement have been described as a major challenge in the adoption of digital health for diabetes care [40].

Patients with T2DM struggle to select relevant apps based on their personal preferences and needs. They need structured information and instructions to guide them from their first use. In addition, they prefer the integration of different apps and functionalities to limit the use of multiple apps side by side. Ideally, such apps will be compatible with electronic health records and remote data sharing when adjustments in diabetes care are required [17].

Strengths and Limitations

The strengths of this study are its collaboration with coresearchers (ie, experts in their disease). All coresearchers actively participated in the preparation of the study, data collection, and data analysis as citizen scientists who were enthusiastic about participating in this study and being coresearchers. They showed interest in the apps selected from different manufacturers. The coresearchers in this study all had years of experience with T2DM. They also had extensive experience collaborating with various professionals in the field of T2DM. Citizen science can be used to exploit existing experiences and ideas. Another strength is that coresearchers were free to choose 1 of the 4 selected apps that matched their personal preferences. Furthermore, this study provides an in-depth understanding of the perceptions of patients with T2DM before use (acceptability) and after use (acceptance). The limitations of this study include its characteristics of the study population. Coresearchers are more likely to have higher digital literacy and motivation compared with other patients with T2DM (response bias). All participants were interested in technology in relation to T2DM and had a higher-than-average level of education. There was a certain degree of acceptance and adoption of technology among the respondents, with all having a great discipline in the field of self-management in relation to T2DM. Most of the coresearchers were early adopters of technology and had extensive experience using different technologies for diabetes control and self-management.

Recommendations

Research has shown that mobile health apps provide support for diabetes control and self-management in patients with T2DM. Coresearchers have suggested that the benefits are higher when app use is combined with support from an HCP. The preferred functionalities of apps for T2DM control and self-management differ among coresearchers. Therefore, it is important that functionalities and visualizations in apps can be customized to personal preferences and needs. Developers should collaborate with patients with T2DM and experts during the development to optimize apps, for example, reducing the number of actions to enter data. Integration of app use in care as usual and guidelines for HCPs are therefore recommended. In particular, HCPs use the data obtained from patients for follow-up treatment. Future research is needed on how to increase technology implementation in the current care pathways. In addition, HCPs need to improve their digital skills, and lifelong learning is recommended.

Conclusions

Personal health was the main driver to start using apps to improve diabetes control and self-management. Before using the apps, coresearchers expected limited effort to use the apps, did not feel anxious and were not concerned about data security. However, after the initial phase, coresearchers needed more guidance and information on how to use the apps, and based on coresearchers' perceptions, both HCPs and relatives played an important role in app use and compliance. Acceptance and adoption of apps can increase if users can personalize functionalities, reimbursements are available, the number of data entry operations is reduced, and if different functionalities are combined in one app.

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Authors' Contributions

All authors contributed to the design and preparation of the study. MB, CMvL, and TJJO conducted the interviews and focus groups and analyzed and compared the findings. Peer debriefing took place at weekly meetings with the project team when

scientific and organizational aspects were discussed. At the end of the data collection, a summary of the findings was shared with the coresearchers. All authors contributed to writing the manuscript and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Example of flower associations.
[DOCX File , 312 KB - diabetes_v8i1e41076_app1.docx]

Multimedia Appendix 2
Topic list semistructured in-depth interviews.
[DOCX File , 18 KB - diabetes_v8i1e41076_app2.docx]

Multimedia Appendix 3
Topic list focus groups.
[DOCX File , 14 KB - diabetes_v8i1e41076_app3.docx]

Multimedia Appendix 4
Coding tree.
[DOCX File , 73 KB - diabetes_v8i1e41076_app4.docx]

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Abbreviations

HCP: health care professional
T2DM: type 2 diabetes mellitus
UTAUT: Unified Theory of Acceptance and Use of Technology

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Original Paper

App Design Features Important for Diabetes Self-management as Determined by the Self-Determination Theory on Motivation: Content Analysis of Survey Responses From Adults Requiring Insulin Therapy

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Abstract

Background: Using a diabetes app can improve glycemic control; however, the use of diabetes apps is low, possibly due to design issues that affect patient motivation.

Objective: This study aimed to describes how adults with diabetes requiring insulin perceive diabetes apps based on 3 key psychological needs (competence, autonomy, and connectivity) described by the Self-Determination Theory (SDT) on motivation.

Methods: This was a qualitative analysis of data collected during a crossover randomized laboratory trial (N=92) testing 2 diabetes apps. Data sources included (1) observations during app testing and (2) survey responses on desired app features. Guided by the SDT, coding categories included app functions that could address psychological needs for motivation in self-management: competence, autonomy, and connectivity.

Results: Patients described design features that addressed needs for *competence*, *autonomy*, and *connectivity*. To promote *competence*, electronic data recording and analysis should help patients track and understand blood glucose (BG) results necessary for planning behavior changes. To promote *autonomy*, BG trend analysis should empower patients to set safe and practical personalized behavioral goals based on time and the day of the week. To promote *connectivity*, app email or messaging function could share data reports and communicate with others on self-management advice. Additional themes that emerged are the top general app designs to promote positive user experience: patient-friendly; automatic features of data upload; voice recognition to eliminate typing data; alert or reminder on self-management activities; and app interactivity of a sound, message, or emoji change in response to keeping or not keeping BG in the target range.

Conclusions: The application of the SDT was useful in identifying motivational app designs that address the psychological needs of *competence*, *autonomy*, and *connectivity*. User-centered design concepts, such as being patient-friendly, differ from the SDT because patients need a positive user experience (ie, a technology need). Patients want engaging diabetes apps that go beyond data input and output. Apps should be easy to use, provide personalized analysis reports, be interactive to affirm positive behaviors, facilitate data sharing, and support patient-clinician communication.

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KEYWORDS

diabetes app; mobile health; mHealth; diabetes; diabetic; health app; self-management; motivation; competence; autonomy; connectivity; self-determination theory; insulin; glycemic control; glucose; blood sugar; design; user need; qualitative; randomized trial

Introduction

Background

Achieving treatment goals for patients with diabetes requires sustained behavioral lifestyle changes such as meal planning, monitoring carbohydrate (carb) intake and blood glucose (BG), and exercising. Diabetes apps can function as electronic care plans by helping patients plan and incorporate healthy behaviors into their daily routines [1]. The apps have been shown to lead to the improvement of glycemic control, with hemoglobin A_{1c} (a blood test measuring average BG over the past 3 months) reduction typically in the range of 0.4% to 1.9% [2-7]. The most common app functions include the documentation of BG reading, diet, and medication use; BG analysis report; data export; and email capability [8]. Visual displays of BG readings help patients link this data to their behaviors, thus facilitating behavior changes to improve glycemic control [9]. Systematic reviews have found that the effectiveness of the apps increased with greater interactivity [10,11]. Interactive feedback could be an automated message from an app algorithm [5] (eg, "you have met your BG goal setting five times this week"), a text message from a dietician who reviewed data and customized a meal plan, [3] or an alert message whenever a BG reading is out of range compared to the goal [3,4,8,12].

Despite more than 1100 apps available on the market, their adoption and use vary, possibly due to design issues [13,14] and variations in technology development [15]. To date, only a few rigorous evaluation studies of app designs have involved patients [16], and most have evaluated the quality of all available apps in the market without involving end users such as patients and clinicians [17,18]. A recent systematic review showed that patient adoption of diabetes apps weighs heavily on patient perception of benefits, ease of use, and clinician recommendation to use diabetes apps [19]. Thus, the Agency for Healthcare Research and Quality stressed the need to understand the patient perspective on the use of diabetes apps [20]. Our research question focused on adults with type 1 or 2 diabetes on insulin therapy: What diabetes app functions are helpful as explained by a theory on motivation, called the Self-Determination Theory (SDT), to promote self-management behaviors? The purpose of this study, therefore, was to describe how patients with diabetes perceive diabetes apps to address the 3 psychological needs of competence, autonomy, and connectivity as described by the SDT [21]. Our analysis also allowed us to provide evidence that would refine this theory on motivation as it applies to the use of mobile apps in the population with diabetes requiring insulin.

Theoretical Framework

Motivation is an important factor in user experience with technology [22,23]. The SDT [21] on motivation, as expanded by Szalma [24] for motivational design on effective human-technology interaction, guided this study. The SDT posits that people are driven to engage in behaviors because they believe those behaviors will personally benefit them [25]. According to the theory, humans have 3 basic psychological needs that influence behaviors [21]. *Competence* is the need to master tasks and learn skills [26]. *Autonomy* is the need to feel in control of one's behaviors and goals [27]. *Relatedness* or *connectivity* is the need to feel attached to other persons [26,28]. The SDT has been used in educational, business, and health care settings [29-31]. It is used to explain the human-technology interaction [24]. Ryan et al [32] reported that the ease of technology use directly and positively affected the satisfaction of psychological needs. This theory thus provides the basis for this study as we organized participant responses according to the 3 psychological needs outlined in the theory.

Methods

Design

This study was part of a crossover randomized laboratory trial [33] to test 2 top-rated, free commercial apps (*OnTrack* and *mySugr*), identified as the "the Best Diabetes Apps 2016" by *Healthline* [34]. The within-subject design helped control for patient characteristics because the same individual tested the 2 apps in random order. Quantitative measures of these diabetes apps' usability, including user satisfaction, time, success, and accuracy rates, have been reported elsewhere [33]. The data for the analysis presented here include field notes of observations during app use, audio recordings taken during the tests, and participant responses to an electronic survey with open-ended questions that queried what app functions patients perceived as being the most useful and most important in supporting diabetes self-management.

Ethics Approval

This study was approved by the University of Minnesota Institutional Review Board (MOD00001221).

Participants

Using a flier posted on a bulletin board or on the web, 92 participants were recruited from the following venues: Facebook (n=46); participant referrals (n=8); Federally Qualified Health Center clinic (n=7); university campus (n=6); public housing (n=6); Craigslist (n=5); veteran's clinic (n=4); diabetes support groups (n=3); and miscellaneous sites from a state fair, church, and library (n=7). Inclusion criteria were (1) aged ≥18 years; (2) having type 1 or type 2 diabetes; (3) having used an Android phone for 6 months or longer; (4) having used insulin therapy for 6 months or longer; (5) adequate English proficiency; and (6) smartphone proficiency (ie, they used the device for more than phone calls, emails, texting, or taking pictures). Exclusion

criteria were (1) inability to read or speak English and (2) prior use of the *OnTrack* or *mySugr* app or use of any diabetes app in the past 6 months. Individuals were screened for eligibility on the phone, and written informed consent was obtained prior to the start of each study session.

Procedures

From July to November 2017, we conducted 92 sessions of in-person tests of the apps that lasted an average of 1 hour. The testing took place in a private meeting room inside a public library or building. Participants viewed a YouTube training video posted by each app developer. They then practiced using the apps by the following protocol: (1) enter a carb intake; (2) enter an exercise activity; (3) enter an insulin dose; (4) enter a BG reading; (5) locate a BG report for specific days of the week; (6) locate a BG report for each meal; and (7) email a BG report. Then, each participant tested the 2 apps in a randomized order to carry out the same tasks listed in the practice protocol. Each participant received a US $50 gift card upon study completion.

Data Collection

The first author (HF) kept field notes detailing her observations of participant reactions during the test of the apps and audio recorded the tests. The field notes and audio recordings were transcribed verbatim in a Microsoft Word file by a research assistant. The survey was administered on an iPad (Apple Inc.) and included questions on demographic characteristics, technology use, and diabetes history. In addition, based on the SDT [21], the survey also included questions about motivation for self-management and psychological needs for competence, autonomy, and connectivity. Details of these measures are reported in prior publication [33]. To explore participant responses to the app, the survey queried participants about their perceptions of app usability and satisfaction, preferences for a "dream" app and indications of what function(s) would be the most useful, and identification of the most important functions in a diabetes app.

Data Analysis

Field notes, audio recordings, and survey responses were analyzed based on key constructs from the SDT [21]. The analytic team, consisting of 4 members (HF, JFW, CJP-M, and TJA), analyzed the transcripts with the aid of Dedoose [35], a web-based, qualitative data analysis software. Directed content analysis, as described by Hsieh and Shannon [36], was used. With this approach, an existing theoretical framework (SDT) was used to organize data according to predetermined categories that are aligned with key constructs in the theory: competence, connectivity, and autonomy. Data that failed to contribute to the categories were coded and used to suggest modifications or extensions of the theory. A codebook was developed based on the initial reading and updated with independent coding from an analysis team. The team reached consensus on the code definition that were clear and mutually exclusive (see Table 1 for conceptual and operation definitions for codes used).

Competence was conceptually defined as app features to help patients gain skills to keep BG in the target range [24]. *Competence* was operationalized as app functions to help patients understand the meaning of their data. This refers to how the app records data, analyzes data, and provides reports on which numbers are not in the target range and why. *Autonomy* was conceptually defined as app features that help patients set safe goals on diet, insulin dose, or activity level based on personal trends of BG and carb intake [24]. *Autonomy* was operationalized as app data visualization to help patients identify abnormal highs or lows, which are important for setting up reasonable targets to change behaviors associated with those abnormal readings. *Connectivity* was conceptually defined as app features to facilitate interactions between persons and the technology involved, which means enabling the sharing of home-monitored data and communicating with clinicians [24]. *Connectivity* was operationalized as app print report options, exports of data and analysis reports, and reports sent to clinicians or others through email.

Analysis occurred in several steps consistent with content analysis procedures as described by Miles et al [37]. First, based on the SDT [21], the team reviewed the conceptual definitions of the 3 main categories (eg, *competence*, *autonomy*, and *connectivity)* and, through discussion and consensus, developed operational definitions of each that were clear and mutually exclusive. See Table 1 for the conceptual and operational definitions of each of the categories. Second, a codebook was developed that outlined rules for coding data to each of the categories. The codebook was refined through several iterations of coding. Third, a table was developed that included each of the 3 categories as column headings and a column heading labeled "other" for codes that did not align with any of the categories. Data from each participant were placed on a row that was identified with the participant's ID number. Fourth, all data were read by all team members and divided into text units (eg, coherent phrases or sentences relevant to the study purpose). The text units were coded with a label that captured the essence and, based on the coding rules, placed in the appropriate cells on the table. Fifth, the analytic team met to gather similar codes from each column into subcategories through a process of discussion and consensus. The subcategories in the 3 main columns (ie, competence, autonomy, connectivity) were described.

The team used several procedures to enhance the trustworthiness of the study findings based on criteria outlined by Lincoln and Guba [38]. First, participants were carefully chosen based on comprehensive inclusion criteria that ensured they had sufficient backgrounds to fully engage with the app testing. Second, expert consensus was achieved with a 4-member research team experienced in diabetes self-management, the SDT [21], and app use, working together to reach consensus in the interpretation and grounding of the theory of the SDT. Third, transferability was enhanced with detailed descriptions of the study population and context. Fourth, auditability was ensured with a detailed audit trial maintained in the Dedoose software chronicling all analytic decisions of the study. Finally, research bias was addressed through frequent team discussions that encouraged researcher reflexivity.

Table 1. Codebook on definitions of app design features.

Conceptual definition and code	Operational definition
Help gain skill to keep BG[a] in-target-range to promote *competence*	
Carb[b] counting	• App feature to have carb counting help, search a food database, link carb content, and planned how much carb to eat
Help planning	• App use to plan meal or plan behavior change in diet, meds, activity, or lifestyles as well as medication and diabetes supply due for refill. - planning action - different from alert/ reminder that is reminding a behavior
Monitor or track BG, carb intake, physical activities, medication use, and others	• App use to monitor, track, record, or log BG, BG testing frequency, carb, activity, medication use, mood, emotional status, stress, or pain • The convenience of recording data on the go or app with built in glucometer function to test and record
Report summary	• Report or records to help understand home-monitored data as a benefit for app use, including BG averages and hemoglobin A1c statistics
See BG out-of-range	• App analysis of BG in-target-range and out-of-range
Set safe and practical short- and long-term goals to promote *autonomy*	
Trends of frequent high or low BG	• Data analysis to see the trends and pattern of BG including consistency of the changes (fluctuation)
BG or carbs trends by time	• Able to see data BG or carb in relation to time of the day
BG or carbs trends by days or months	• Able to see BG or carb in relation days of the week, or one week - a specific format to see which day of the week • Able to see BG or carb with a monthly average to give a grand overview
Facilitate supportive interaction between persons and technology involved to promote *connectivity*	
Share data or reports to get feedback from clinicians on home-monitored data	• Enable data upload, export, or email to send data or reports to clinicians • Print reports to bring to clinic visit with clinicians
Support from other	• Sharing with app reports with family, friend, or other non-clinician involved in their diabetes care
General app design to promote *positive user experience*	
Automatic	• Automatic upload data which includes sync with glucose meter, insulin pump, continuous glucose monitoring, or another medical device
Alert or reminders	• App feature to set up alarm or reminder alert for BG testing, exercise, diet change, etc.
Color	• Color as an important design element
Cost	• Financial expense to use the app
Icon, emoji, button	• Design element for app screen or app functions
Interactivity	• Interactive feedback or response such as a sound
Patient-friendly	• Easy to use • Simple and understandable terms/icons
Tutorial or self-help	• Tutorial, help function, or resource to help users learn to use the app
Voice over	• Respond to voice, eliminate typing or taping of icon

[a]BG: blood glucose.

[b]Carb: carbohydrates.

Results

Sample Characteristics

In all, 92 persons participated in the study. Their mean age was 54 (range 19-79) years. The majority were female (54/92, 59%), White (57/92, 62%), and college educated (61/92, 66%; Table 2).

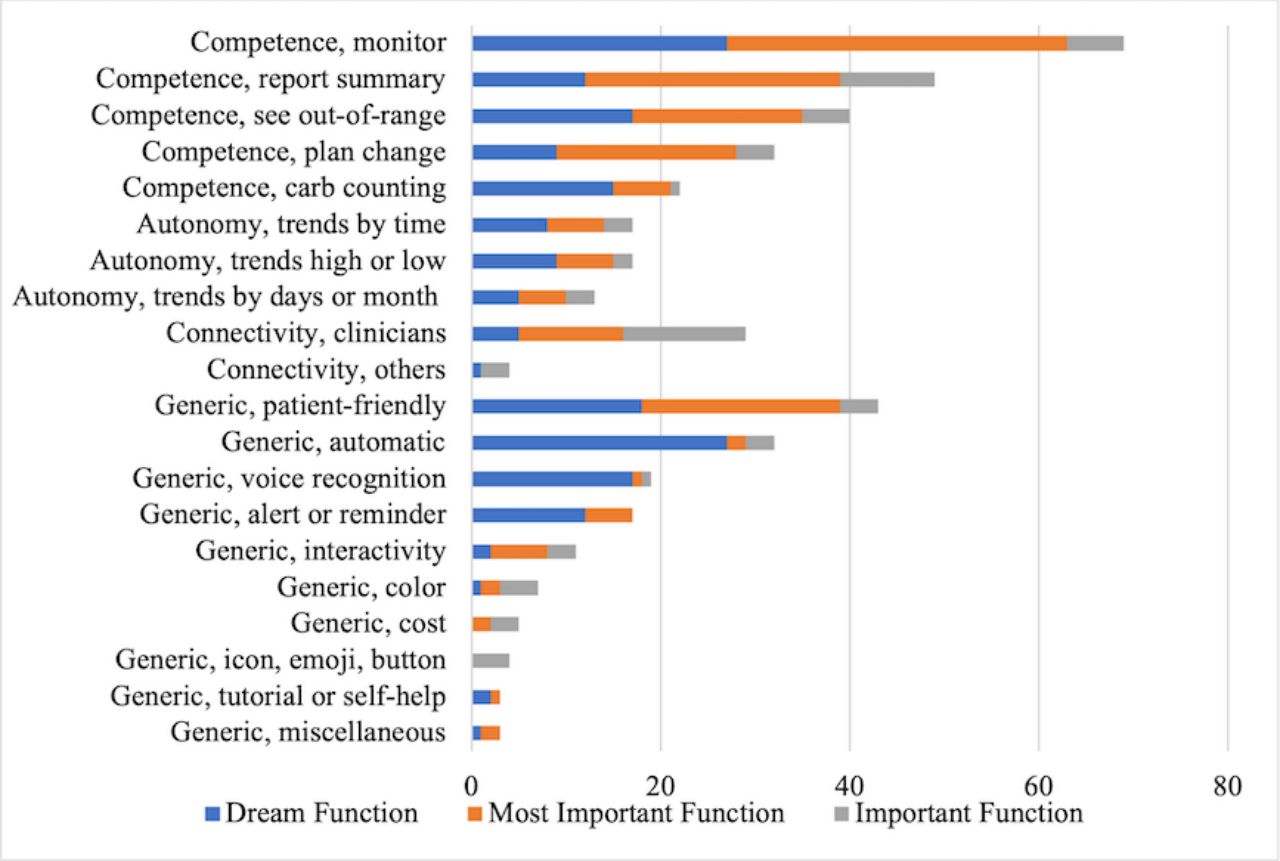
Most (64/92, 70%) participants had type 2 diabetes and had used insulin for an average of 12 (SD 12) years. The participants reported a wide variety of diabetes complications including short-term memory loss; retinopathy; mobility impairment with the use of a cane, walker, or wheelchair; hemiparesis related to stroke; hand tremor; and peripheral neuropathy affecting hand dexterity. The majority (57/92, 62%) were comfortable or very comfortable using a smartphone. Additionally, 60 participants reported whether they were working (n=35) or not working (n=25)—student (n=3), retired (n=13), homeless (n=2), and disabled (n=7). Participants reported the most important app functions related to promoting competence as described by the SDT; on the other hand, what they reported as dream app functions were general app designs unrelated to the SDT (Figure 1). Of the 436 text units that were highlighted, 292 (67%) were coded to 1 of the 3 categories of needs based on the SDT [21]: competence (n=212, 48.6%), autonomy (n=47, 10.8%), and connectivity (n=33, 7.6%). The remaining 144 (33%) text units were not aligned with any of the 3 categories. The categories are discussed below.

Table 2. Sample characteristics (N=92).

Characteristics	Value
Age (years), mean (SD)	54 (13)
Men, n (%)	38 (41)
Race, n (%)	
Alaska Native or American Indian	10 (11)
Asian	2 (2)
Black or African American	23 (25)
White	57 (62)
Highest completed education, n (%)	
Elementary	4 (4)
High school or equivalent	27 (29)
2 years of college	31 (34)
4 years of college	19 (21)
Graduate school	11 (12)
Device brand, n (%)	
Samsung	44 (48)
LG	19 (20)
iPhone	8 (9)
ZTE	7 (8)
Motorola	6 (6)
Other	8 (9)
Smartphone comfort level, n (%)	
Very uncomfortable	23 (25)
Neither	12 (13)
Comfortable	33 (36)
Very comfortable	24 (26)
Diabetes	
Type 1, n (%)	28 (30)
Type 2, n (%)	64 (70)
Duration years, mean (SD)	17 (11)
Insulin use years, mean (SD)	12 (12)
Insulin use types, n (%)	
Insulin pump	14 (15)
Long- and short-acting injection	46 (50)
Long-acting injection	28 (30)
Short-acting injection	2 (2)
None (stopped use)	2 (2)
BG[a] testing per day, mean (SD)	6.2 (1.4)

[a]BG: blood glucose.

Figure 1. Comparison of dream function versus the most important function versus important functions in diabetes apps listed by major coding categories supportive of the Self-Determination Theory (SDT) on psychological needs (competence, autonomy, and connectivity), as well as those unsupportive of the SDT on technical needs.



Competence

Participants found that the apps could improve their sense of competence by helping them monitor data (ranked 1st), create analysis reports (ranked 2nd), gain knowledge about reasons for out-of-range BG (ranked 4th), and plan behavior changes in self-management activities (ranked 5th), including counting carbs linked to a food library (ranked 7th; see Table 3).

Some appreciated receiving information that guided them in adjusting their insulin doses. One participant stated, “It helps me know my high and low blood sugar reading so I can adjust insulin dose. If it is real high in the morning, then at night I take more insulin. Now I do trial and error. My way is not the best.” Participants liked the automatic carb counting function. One said, “[You] take a picture [and let it] analyze for you and tell you how many carbs and everything it is.”

Table 3. Themes of motivational app design features as postulated by the Self-Determination Theory reported by adults with type 1 or 2 diabetes requiring insulin therapy.

Motivational design and app design features	Rank (ranged from 1-15)	Frequency (N=436), n (%)	Quotes
Help gain skill to keep BG[a] in-target-range to promote *competence*			
Help record, monitor, or track BG, carb[b] intake, physical activities, medication use, and others conveniently on a smartphone	1	69 (16)	• "Ability to track sugar and foods without relying on memory" • "Ability to enter as much information regarding the event (meal, exercise, etc.) as I possibly can. If I've exercised prior to meal or if I am sick, I want to be able to note that along with the medication or meal entry. -- tagging information to an event"
See a report with convenient view	2	49 (11)	• "Tracking my glucose readings, having at-a-glance reports and comparisons" • "See blood sugar report and diet report in the apps - that way helps you maintaining your diabetes and keeping it in control"
See out-of-range BG and explanations for abnormal readings	4	40 (9)	• "The app should let you know that you are doing good or bad in any given time" • "BG report when high, you can tap on it - lead you to see what you eat made it high."
Plan changes in diet, exercise, BG testing, and medication use	5[c]	32 (7)	• "Telling me how much insulin to use with what food and exercise" • "Fix your not normal readings of BG before going to see doctor"
Carb count and provide a food library	7	22 (5)	• "Adding carbs and being able to find food items with. The carbs planned out"
Set safe and practical short- and long-term goals to promote *autonomy*			
Trends of frequent high or low BG	9[d]	17 (4)	• "Tracks your diabetes - system going up and down" • "Blood glucose Trends on the home page"
BG or carbs trends by time	9[d]	17 (4)	• "Tell you when your blood sugar had a big jump" • "Recording all records of bs testing, tracking foods eaten around those reading times"
BG or carbs trends by days or months	10	13 (3)	• "Ability to easily see patterns throughout the day over a period of the past 30 days" • "Glucose levels compare to other hours and days. Want to know if this week, if any meal BG readings are in range."
Facilitate supportive interaction between persons and technology involved to promote *connectivity*			
Quicker feedback from clinician	6	29 (7)	• "Let my doctor know instead of waiting 3 months, and doctor tell me what to do to improve my diabetes" • "Able to send report to doctor or print at home a paper copy to bring to an appointment"
Support from other	14	4 (1)	• "Talk with loved one [about their] data" • "Within the app – meet each other weekly, get together, video, message, phone call, more secure too"

[a]BG: blood glucose.

[b]Carb: carbohydrates.

[c]Same rank as automatic feature.

[d]Same rank as set up alert or reminders.

Autonomy

Participants found that the apps improved their sense of autonomy. They felt more self-sufficient because the apps showed if their BG was trending high or low in relation to the time (ranked 9th) and in relation to the day of the week (ranked 10th). Being provided with a data visualization of these personal patterns increased their sense of empowerment and assisted them in identifying short- and long-term goals for changing behaviors. One participant explained, "a function that easily helps me find when I most commonly have hypoglycemia." Information provided by the apps aided their decision-making regarding how and when to change behaviors to keep BG in the target range. This could be done with data visualization; one participant stated the benefit to see "how my trends are changing."

Connectivity

Participants found the apps enhanced a sense of *connectivity* because the clinicians could receive emails or print reports on home-monitored data to better understand patients' self-management behaviors (ranked 6th). One participant said, "An app that can send my numbers directly to [the doctor] if there is a concern [about frequent] lows or highs." Participants also felt connected because of the bidirectional messaging functions of the apps. These functions supported monitoring of BG, and readings could be compared to hemoglobin A_{1c} laboratory readings in the clinic. Connectivity was also enhanced by informal coaching support from others (ranked 14th). One patient stated, "help people share what other people not understanding. (1) report, (2) sharing - support for other patients with diabetes."

Top General App Design

Most participants reported the necessity for a diabetes app to save time regardless of functions. They described that the app needs to be efficient and "easy," requiring minimal user effort. They desired the app to use patient-friendly terminology and display easy-to-understand reports (ranked 3rd; see Table 4).

Automatic features (ranked 5th, same as to plan behavior change) is the integration between devices so that their data are interoperable. One participant explained, "Have this app be able to read my pump and. An app I reason I don't use app, having an orange and apple that they don't talk to each other. An app that easy and talk to my pump." Voice recognition (ranked 8th) is the elimination of typing text, which was best described by one participant: "speaking function to record all data." App alerts (ranked 9th) are helpful to remind users to do activities such as retest BG and repeat insulin for elevated BG after eating a meal. App interactivity (ranked 11th) is giving behavior confirmation as one participant explained: "You did it, completed 1 entry." Other app designs (ranked from 12th to 15th)—color; cost; icon, emoji, or button options; tutorial or self-help; and fun, technical support, and link to pharmacy—were of interests to participants.

Table 4. Themes of top general app design features unsupportive of the Self-Determination Theory reported by adult with type 1 or 2 diabetes requiring insulin therapy.

App design features	Rank (ranged from 1-15)	Frequency (N=436), n (%)	Quotes
Patient-friendly	3	43 (10)	• "To put language that patients could understand - small words - for example blood sugar instead of glucose." • "I like the pick and choose option but maybe more screens so there's less congestion. (Less busy screen) simple screen shot that leads to new screens. Don't like scrolling." • "Easy to read and understand the report and information you put in it - make numbers bigger"
Automatic: integration of devices plus easy view of data	5[a]	32 (7)	• "Pump, and meter integration that also downloads my CGM readings to form a graph with minimal interaction from me." • "A graph to be able to connect with my meter"
Voice recognition	8	19 (4)	• "Voice command to record my BG reading and carb intake" • "App talks to me that my blood sugar is too high or too low"
Set up alert or reminders	9[b]	17 (4)	• "Track carb, when went over the amount, it alarms you to don't eat any more carb." • "Reminder for to check your blood and make sure exercise (tell you exercise, a schedule) - like to tell you to go a walk at what time"
Interactivity	11	11 (3)	• "For the app to show me the cravings for the carb, to motivate you not to eat the carb, when I eat carb, the app should go off" • "Interactive apps. I really like when 'slimy' congratulated me or said it happens, when my sugars were not good."
Color	12	7 (2)	• "Color to differentiate functions." • "Tap in red color to give your time and more detail."
Cost	13	5 (1)	• "Don't have to buy a meter for it." • "Willing to pay for the app if it works"
Icon, emoji, button	14	4 (1)	• "More icon per se where a picture would be used instead." • "The activity (have emoji) hit emoji when you start jogging and hit emoji again to stop."
Tutorial or self-help	15	3 (1)	• "Help function - no paragraph, video to see how to use this function." • "Help function to help you use the app (like to email in the app)."
Miscellaneous: fun, link to pharmacy, technology support	15	3 (1)	• Link to pharmacy order within the app and "your pharmacy deliver to you." • "For people to have a hot line, get stuck to get help technical support, a live person to help with the app. If I did not go back to last app that she showed him how to send and get gmail to send report."

[a]Same rank as plan behavior change.

[b]Same rank as see BG (blood glucose) trends and carbs (carbohydrates) trends.

Discussion

Principal Findings

The aim of the research question and purpose of the study was to investigate how adults with diabetes requiring insulin therapy perceive diabetes apps based on the 3 key psychological needs described by the SDT [21]: competence, autonomy, and connectivity. Our findings provide evidence on the usefulness of the SDT in mobile health technology and describe specific app functions that address psychological needs. The results are consistent with Szalma's [24] description of a theoretical model of motivational design based on the extension of the SDT. Newly identified categories about general app design did not fit with the SDT's psychological needs, but they addressed the technology needs for patients to use an app with minimal effort.

Competence

App functions help patients to record and understand data and plan behaviors as skill to keep BG in the target range. First, the convenience to track electronically whether BG is in the target range (80-130 mg/dL before eating and <180 mg/dL after eating) [39] is highly valued [40]. This is consistent with patient surveys that found diabetes apps are important for BG monitoring [41]. Understandable "Glucose Diary View" is the most practical [42]. Abnormal BG readings should be color-coded [39] and

summarized into a 1-page standardized report [43]. An electronic report can increase patient knowledge to plan behavior changes such as eating right (making it easier to count carbs and plan meals) and calculating short-acting insulin dose to lower elevated BG readings due to excessive carb intake. These features are all valuable to patients because they help them to gain insight and understanding about abnormal BG readings so they can achieve competence in diabetes care, which is consistent with a study on the requirements of diabetes apps for underserved patients [44].

Carb counting is a commonly desired app function, where a smartphone takes a picture of the food; analyzes the portion size, carb content, and corresponding insulin dose; and suggests a time for insulin administration. This finding broadly supports app use to improve adherence of medical nutrition therapy [2-4,45]. Currently, many diabetes apps have low-carb diet recipes, multidevice integration, and automatic features, but the cost can be expensive. For example, *Glucose Buddy* Premium has a subscription cost ranging from US $19.99 to US $59.99 per month to access the full food database [46,47]. Future research should be undertaken to investigate ways to offset the cost of app technology such as subsidizing the expense while the health system could bill insurance for remote patient monitoring, given that the Centers for Medicare and Medicaid Services can reimburse the transmission of home-monitored data and summary report by clinic staff [48]. Offering analysis tool to count carbs and calculate insulin dose is a form of "virtual dietician." Research is in progress to develop and test apps that leverage machine learning to perform image recognition and automate recommendations of behavior change [49].

Autonomy

App functions of trend analysis help set safe and practical short- and long-term goals by time, day of the week, and month, which aids personalizing options to change. Participants reported the need to visualize the trends or patterns of frequent high or low BG (ie, what) by day of the week and time (ie, when). This finding is consistent with prior research showing that diabetes apps helped patients identify and incorporate healthy behaviors into their daily routine [1]. Seeing demarcations of BG changes between months, weeks, days, and time of the day is very important to show patients when dangerous BG levels occur and to set reasonable goals to change behaviors [50]. Goal or target setting helps patients plan behaviors and provides a warning when they are outside the target [51,52]. Personalizing options should include tracking mental health factors such as mood, stress, and illness, because these factors are associated with hyperglycemia and poor glycemic control. Effective self-management is important economically, since many adults diagnosed with diabetes are not able to maintain work. They exit the work force earlier (30% higher) compared to those without diabetes [53].

Connectivity

App functions can facilitate supportive interaction by sharing data or app reports with clinicians and "loved ones" to gain support for behavior change. This is consistent with several studies that showed data sharing or showing data from the mobile devices with their clinicians during a medical visit is highly valuable for patients [50,54,55]. Greater app interactivity with a clinician appears to improve glycemic control [11,56]. A simple explanation for this finding may be that successful diabetes self-management takes teamwork [54,55]. Informal coaching support by other people or even a virtual coach in an app is valuable. Artificial intelligence could provide confirmation of positive behavior change, such as reaching a BG value in the target range, to provide immediate feedback to patients. A trial of an artificial intelligence virtual coach with 187 adults with type 2 diabetes, unfortunately, did not demonstrate a difference in changing hemoglobin A_{1c} but did improve health-related quality of life [57]. Very few long-term studies of diabetes apps have been conducted [58]. However, due to the COVID-19 pandemic, telehealth visits had an unprecedented increase in use from 0.3% in 2019 to 29.1% in 2020 among a 2019 cohort (n=1,357,029) versus a 2020 cohort (n=1,364,522) [59]. Leading companies in web-based diabetes care—*Livongo*, *One Drop*, *mySugr*, *Cecelia Health*, *Steady Health*, and *Virta Health*—noted a rise in subscribers during the pandemic [60]. Future studies using the mobile health platform for telehealth, including a diabetes app, should be undertaken.

Top General App Functions or Features

Themes unsupportive of the SDT emerged that focused on the acceptability of general app design features. These themes did not support the SDT, but they described patients' technology needs. The theme of being patient-friendly is highly relevant for user-centered app design. A patient-friendly app implies a match between the app and the patient's real world [61,62], and icons and wording need to speak the users' languages and concepts. For example, "blood sugar" is preferred to "blood glucose." Eliminating medical jargon would decrease barriers and make it easy for patients to understand knowledge gained from using apps [50]. Automatic features to integrate devices that test BG and upload results into apps ranked in the top 5, which is consistent with a survey study among patients with type 1 diabetes, 91.6% of whom agreed that it is the most important function (n=167) [51]. Voice recognition decreases the user's need to type data. Alert notifications can remind patients who are on multiple insulin injections and need frequent BG testing (>4 times a day). Patients desired app alerts to remind them of behavior (eg, repeat BG testing) [63]. An interactive app is about giving the patient a response to promote user interaction, not just data in and data out. A change in emoji, an app message of "good job," or a sound are ways of interaction between the user and the technology. Color can help customize user experience. An app tutorial or technology support is an important resource to increase user confidence to interact with the app. Overall, these themes around acceptable design features are important for patient engagement to promote a positive user experience and boost patient confidence to use the technology.

Limitations

Three major limitations in this study were (1) the laboratory setting, (2) only 2 top-rated, commercially free apps being tested, and (3) the urban population. The first weakness is that participants only used the apps once in a research visit rather

than in their home setting with real data. It is possible that using the apps in the home setting would have changed participants' opinions about the desired app features. Future work is required to establish the viability of actual app use at home and in other settings (eg, use an app for 2 weeks and attend focus groups to discuss the facilitators and barriers of app use). A second weakness is testing only 2 top-rated free apps, which may not be representative of the diabetes apps on the market. However, *mySugr* has remained in *Healthline*'s 2022 list of best diabetes apps [45], and *OnTrack* has been recommended by educators from the American Diabetes Association [46] and the University of Michigan [47]. Apps requiring payment were not included in this study. Payment for increased functionality may increase patient engagement and potentially create bias to use the app to get a return on the investment [64]. A third weakness is that the results may not be applicable to a rural population who may have no or inadequate internet service. App responsiveness may depend on the type of internet connection. Notwithstanding these limitations, this study offers valuable insight to addressing behavior needs for self-management by adults with diabetes requiring insulin therapy. Several strengths of this study include the diverse sample of racial or ethnic minority participants and a variety of diabetes complications, which increase study generalizability. Additionally, this study had a sample of 92 participants, which is much larger than most usability study sample of 30 participants.

Conclusions

The SDT helped to explain patient perspectives on the roles of diabetes apps as an electronic tool to address their psychological needs of competence, autonomy, and connectivity in diabetes care. Our findings also validated that the 3 concepts of the SDT guided the initial coding, further analysis, and development of operational definitions. Using an app can promote competence in keeping BG in the target range through electronic monitoring of BG, creating analysis reports, and gaining knowledge about reasons for out-of-range BG to plan behavior. The app can promote autonomy to set safe and practical BG goals by showing trends of high and low readings in relation to time, day of the week, and months. An app can promote connectivity by printing reports for clinic visits or emailing reports to a clinician, thereby helping patients receive feedback from clinicians. Patient technology needs, such as being patient-friendly and requiring minimal user effort, are also important. Continued efforts are needed to understand long-term adoption of diabetes apps to support self-management by patients, as well as the integration of diabetes apps in the telehealth setting for clinicians.

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Authors' Contributions

HF, JFW, CJP-M, and TJA researched the data and contributed to the general discussion before writing, reviewing, and editing the manuscript. HF, JFW, CBD, and TS wrote, reviewed, and edited the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BG: blood glucose
Carb: carbohydrate
SDT: Self-Determination Theory

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Review

The Clinical Impact of Flash Glucose Monitoring—a Digital Health App and Smartwatch Technology in Patients With Type 2 Diabetes: Scoping Review

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Abstract

Background: Type 2 diabetes has a growing prevalence and confers significant cost burden to the health care system, raising the urgent need for cost-effective and easily accessible solutions. The management of type 2 diabetes requires significant commitment from the patient, caregivers, and the treating team to optimize clinical outcomes and prevent complications. Technology and its implications for the management of type 2 diabetes is a nascent area of research. The impact of some of the more recent technological innovations in this space, such as continuous glucose monitoring, flash glucose monitoring, web-based applications, as well as smartphone- and smart watch–based interactive apps has received limited attention in the research literature.

Objective: This scoping review aims to explore the literature available on type 2 diabetes, flash glucose monitoring, and digital health technology to improve diabetic clinical outcomes and inform future research in this area.

Methods: A scoping review was undertaken by searching Ovid MEDLINE and CINAHL databases. A second search using all identified keywords and index terms was performed on Ovid MEDLINE (January 1966 to July 2021), EMBASE (January 1980 to July 2021), Cochrane Central Register of Controlled Trials (CENTRAL; the Cochrane Library, latest issue), CINAHL (from 1982), IEEE Xplore, ACM Digital Libraries, and Web of Science databases.

Results: There were very few studies that have explored the use of mobile health and flash glucose monitoring in type 2 diabetes. These studies have explored somewhat disparate and limited areas of research, and there is a distinct lack of methodological rigor in this area of research. The 3 studies that met the inclusion criteria have addressed aspects of the proposed research question.

Conclusions: This scoping review has highlighted the lack of research in this area, raising the opportunity for further research in this area, focusing on the clinical impact and feasibility of the use of multiple technologies, including flash glucose monitoring in the management of patients with type 2 diabetes.

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KEYWORDS

type 2 diabetes; flash glucose monitoring; digital health; smartwatch; scoping review; app; smartphone; mobile phone; mHealth; digital; application; technology; effective; management; glucose; monitoring; database; wearable; diabetes; diabetic; glucose monitoring

Introduction

Overview

The rapid growth of easily accessible technology in the management of diabetes mellitus (DM) is undeniable, with the introduction of more sophisticated monitoring devices, including home-based self-monitoring glucometers [1], and more recently, continuous glucose monitoring (CGM) devices [2]. In the 2000s, real-time interstitial CGM (RT-iCGM) was introduced, although it still requires regular calibration (except for Dexcom G6 or G5 devices). A recent advance in commercial use is interstitial glucose monitoring through flash glucose monitoring (FGM) technology in the form of devices such as Abbott's FreeStyle Libre [3,4].

As with most technological advances in DM, their impact is first noted in those patients who are most vulnerable for complications. Thus, typically RT-iCGM and FGM often find early clinical implementation in patients at high risk for complications, such as patients with type 1 DM and pregnancy [5]. More recent studies have supported RT-iCGM and FGM using cost-benefit models compared to self-monitoring glucometers in type 1 DM [6,7]. These technologies, often in conjunction with web-based analytic applications, have shown significant improvements in glycemic control during insulin initiation [8,9], routine care [10,11], and enhanced safety through the reduction of hypoglycemic events [12]. This has been particularly evident with severe hypoglycemia, variably defined in the literature as a blood glucose level ranging from <3.3 mmol/L to <2.8mmol/L [13].

In patients with type 2 DM, the use of RT-iCGM and FGM is less well defined [14]. In type 2 DM, the risk of hypoglycemia is related to the duration of diabetes and the use of hypoglycemic agents, particularly insulin [15]. Although the risk of hypoglycemia is considered to be lower than that in type 1 DM [16], the significantly higher rates of poor cardiovascular outcomes in the Action to Control Cardiovascular Risk in Diabetes Study Group (2008) and the Veterans Affairs Diabetes Trial [17] suggest that hypoglycemia in type 2 DM is not a benign phenomenon.

Evidence suggests that intensive insulin regimens in patients with type 2 DM carry the highest risk for severe hypoglycemia, with nocturnal hypoglycemia episodes having a particularly high burden of risk [18]. CGM has shown that hypoglycemia is more common than both the patient and their treating clinician anticipate [17]. A recent study of CGM showed 1.74 episodes per patient over a 5-day period, with 75% experiencing at least one asymptomatic episode and 64% of patients undergoing treatment modification as a result of the information gathered [19]. Closed-loop glucose monitoring technology has also been used in an inpatient type 2 DM setting to improve control without any increase in hypoglycemia [20-23].

A desired outcome of any glucose monitoring modality is the use of real-time data to promote positive behavior and therapeutic changes. Systems that provide immediate feedback to patients and decision support tools for patients and providers have demonstrated positive outcomes [24]. Furthermore, RT-iCGM and FGM provide additional information in the form of comprehensive data on the 24-hour glucose profile, current glucose trend, glucose variability, detection of periods of hypoglycemia and hyperglycemia, and estimated HbA_{1c} [25]. FGM has the additional advantage of factory calibration and interstitial blood sampling, thus avoiding the risk and discomfort of frequent subcutaneous sampling, significantly increasing its utility [26].

CGM or FGM usually consists of 3 components: a wearable sensor, a transmitter that wirelessly transmits glycemic data, and a receiver nearby that displays such readings to the user. This is further augmented by mobile health (mHealth) diabetic management systems. The World Health Organization defines mHealth as a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices. This may include proprietary commercial cloud-based app portals for the purpose of more complex analysis, such as glycemic trend analysis by either the patient, their treatment team, or an authorized carer [27].

A separate technological development is the sharp increase in both free and commercial mobile apps for the self-management of diabetes [28,29]. These apps are designed to assist patients in behavior change. Common features of these apps include the ability to track blood glucose, HbA_{1c}, medications, physical activity, and body weight. Although apps for diabetes self-management can improve short-term outcomes, support from health care providers cannot be undervalued [30].

As a result of advances in information and communication technology, mobile phones and the internet technology are playing a growing role in interventions for health promotion and those aimed at preventing and managing diseases [31]. The largest burden of type 2 DM is not in high-income countries; given the high proportion of smartphone use in low- and middle-income countries, this could be a potential way of mitigating the small number of diabetes specialists in these regions.

With the most recent introduction of 5G networks, mHealth innovation continues to develop with the introduction of wearable devices [32]. One of the more easily accessible mHealth devices is the smartwatch with dominant global players such as Apple, Samsung, and Google expanding the market significantly. These wearable devices enable the application of smartwatches beyond traditional sectors [33,34] and their integration into daily management systems for diabetes.

Aim and Rationale

The research question was identified from a preliminary scan of the literature and by drawing on the expertise of the research team and additional stakeholders. The scoping review aims to study the interface between 3 emerging technologies in the field of diabetes: (1) FGM, (2) app-based mHealth diabetic systems, and (3) smartwatch technology in the management of patients with type 2 DM.

In particular, the scoping review explores their combined impact as an integrated platform intervention on the clinical parameters of glycemic control and behavioral parameters relevant to self-management in type 2 DM.

Scoping reviews are particularly useful in emerging fields where it is still unclear what additional specific questions could be answered through a more precise systematic review [35] and can be used to map the key concepts underpinning the research area as well as to clarify the conceptual boundaries of a topic. Arksey and O'Malley [36] introduced the principle of scoping reviews as a mechanism for mapping the literature in a field of interest, providing a mechanism for the dissemination of research findings where a systematic review is not feasible due to the dearth of evidence in these emerging fields [36].

Methods

Types of Studies Included

To capture a comprehensive list of potential sources, a preliminary search of Ovid MEDLINE and CINAHL databases was performed to identify keywords and related subject headings in consultation with research librarians at University of Newcastle. Keywords were identified and combined to address the 4 components of the research question: (1) FGM, (2) mHealth-based health care delivery, (3) smartwatch technology, and (4) type 2 DM.

The initial search is then followed by an analysis of the text words contained in the title and abstract of retrieved papers and of the index terms used to describe the articles. A second search using all identified keywords and index terms was performed on Ovid MEDLINE (January 1966 to July 2021; Multimedia Appendix 1). This search strategy was adapted for EMBASE (January 1980 to July 2021), Cochrane Central Register of Controlled Trials (CENTRAL; the Cochrane Library, latest issue), CINAHL (from 1982), IEEE Xplore, ACM Digital Libraries, and Web of Science databases. No language or publication restrictions were applied. Reference lists of all included studies were checked for other potentially eligible papers that were searched in August 2021. All databases were then re-searched to ensure this review was updated to cover any recent titles and abstracts between July 2021 and July 2022.

Furthermore, ProQuest Dissertations and Theses Global (full text; 1997-present) were searched for relevant dissertations and theses; conference proceedings were searched via Scopus to capture any additional pertinent research, as this is an emerging field. Additional studies were identified by searching the reference lists of the included studies as well as the reference lists of related systematic reviews and meta-analyses. The rationale for including the breadth of literature formats is that, during a scan of the literature, a limited number of randomized controlled trials have evaluated the use of this combination of these technologies in the management of DM.

Context

No restrictions will be placed on the types of settings in which the interventions have taken place, and as such, different study settings (eg, primary care, outpatient, inpatient, or community settings) will all be considered.

Selection of Studies for Review

All search results were exported to Covidence systematic review management software (Veritas Health Innovation). Covidence is a web-based collaboration software platform that streamlines the production of systematic and scoping reviews. Two reviewers (AF and AC) independently searched the titles and abstracts of the retrieved literature via Covidence. Conflicts were resolved by a third reviewer (SDA) and through team consensus. Articles that met the inclusion criteria through abstract screening were reviewed in full. Both inclusion and exclusion criteria were revised in an iterative process as the search evolved, to best address the research question (Textbox 1).

Textbox 1. Inclusion and exclusion criteria.

Inclusion criteria

- Diagnosis of type 2 diabetes mellitus at any age.
- mHealth interventions, including digital health apps and smartwatch technology.
- The following study types: randomized clinical trials, quasi-experimental, controlled before and after studies, and observation (eg, cohort, case-control, cross-sectional) studies.
- No language restrictions.

Exclusion criteria

- Type 1 and gestational diabetes mellitus.
- Conference abstracts or protocols only.
- If continuous glucose monitoring (CGM) or mHealth interventions could not be adequately separated and efficacy determined.

Extraction of Results

A data extraction form was first prepared by SDA and AC. The data extraction process and assurance of the quality of data was iterative with frequent updates of the extraction form and the data collected from the studies. The data extraction process is shown in Table 1.

Table 1. Descriptive information for included studies.

Study	Population, sample, or context	Study design	Aim or objectives	Technologies used	Outcome measures	Results	Limitations
Kim et al [37]	29 adults with type 2 diabetes mellitus. Seoul National University Hospital, South Korea	12-week feasibility pilot study. One-arm group.	Test the feasibility of HbA_{1c} reduction using a patient-centered, smartphone-based, diabetes care system.	(1) Android-based app with four modules: glucose, diet, physical activity, and social network system; (2) Bluetooth glucometer; and (3) Bluetooth activity tracker	HbA_{1c}, fasting plasma glucose, body weight, blood pressure, and various cholesterol measures (summary of diabetes self-care activities was used to evaluate the overall self-management activities for diabetes)	After 12 weeks participants had significantly decreased HbA_{1c} and FPGs. Reduction in HbA_{1c} were correlated with the number of daily glucometer inputs. Inputs were generally higher in older patients. Body weight and cholesterol measures were not statistically significant after 12 weeks.	No control group. Short observation time. Small sample size.
Shaw et al [38]	60 adults with type 2 diabetes mellitus. Southeastern United States.	6-month cohort prospective study.	To determine feasibility and acceptability of using multiple mHealth technologies in patients with T2DM[a] and to also examine trajectories and patterns of diabetes-related variables.	(1) Glucometer "iHealth," (2) Fitbit, (3) self-report mobile text messaging, and (4) cellular enabled scale by body trace	(1) Blood glucose; (2) physical activity—daily steps, distance travelled, and activity intensity; (3) medication adherence; and (4) weight	mHealth interventions not used to improve outcomes listed. Most used technology was the Fitbit. Participants who were younger had higher HbA_{1c} levels, and those who identified as Black were less likely to be engaged with their mHealth devices.	Only observational study; did not use control group for interventional impact. Small sample size.
Zahedani et al [39]	665 participants: healthy (448); prediabetic (25); and type 2 diabetic (192)	10-day observational study.	Investigating combined use of CGM[b] and mobile app (Sugar AI) on glucose tracing, heart rate, and physical activity.	(1) Abbott FreeStyle Libre, (2) Xiaomi Mi Band 3 or Garmin watch, and (3) Sugar AI app	(1) Blood glucose, measured as time in range (TIR): 54-140 mg/dL for being healthy and prediabetes and 54-180 mg/dL for T2D[c].	Authors concluded that a subgroup of those showing poor TIR (combined participants with T2DM and before diabetes) demonstrated an average of 22.7% improvement in TIR; 62.9% of participants with diabetes who showed an improved TIR had greater improvement in their daily variation.	Only observation study. Not randomized clinical trial. Short follow-up. Limited results provided on use of Garmin watch or MiBand 3 to improve outcome measures such as blood glucose levels or heart rate.

[a]T2DM: type 2 diabetes mellitus.

[b]CGM: continuous glucose monitoring.

[c]T2D: type 2 diabetes.

A descriptive-analytical narrative method was used to extract and chart the data from the selected articles [40]. Two reviewers (SDA and AF) independently collected the data using the extraction form. Charts were used to collate, summarize, and share data for team review and decision-making. The reliability and quality of the extracted data was also ensured through subsequent meetings, cross-checking of the collected data, discussions to resolve disagreement in data extraction, rereading

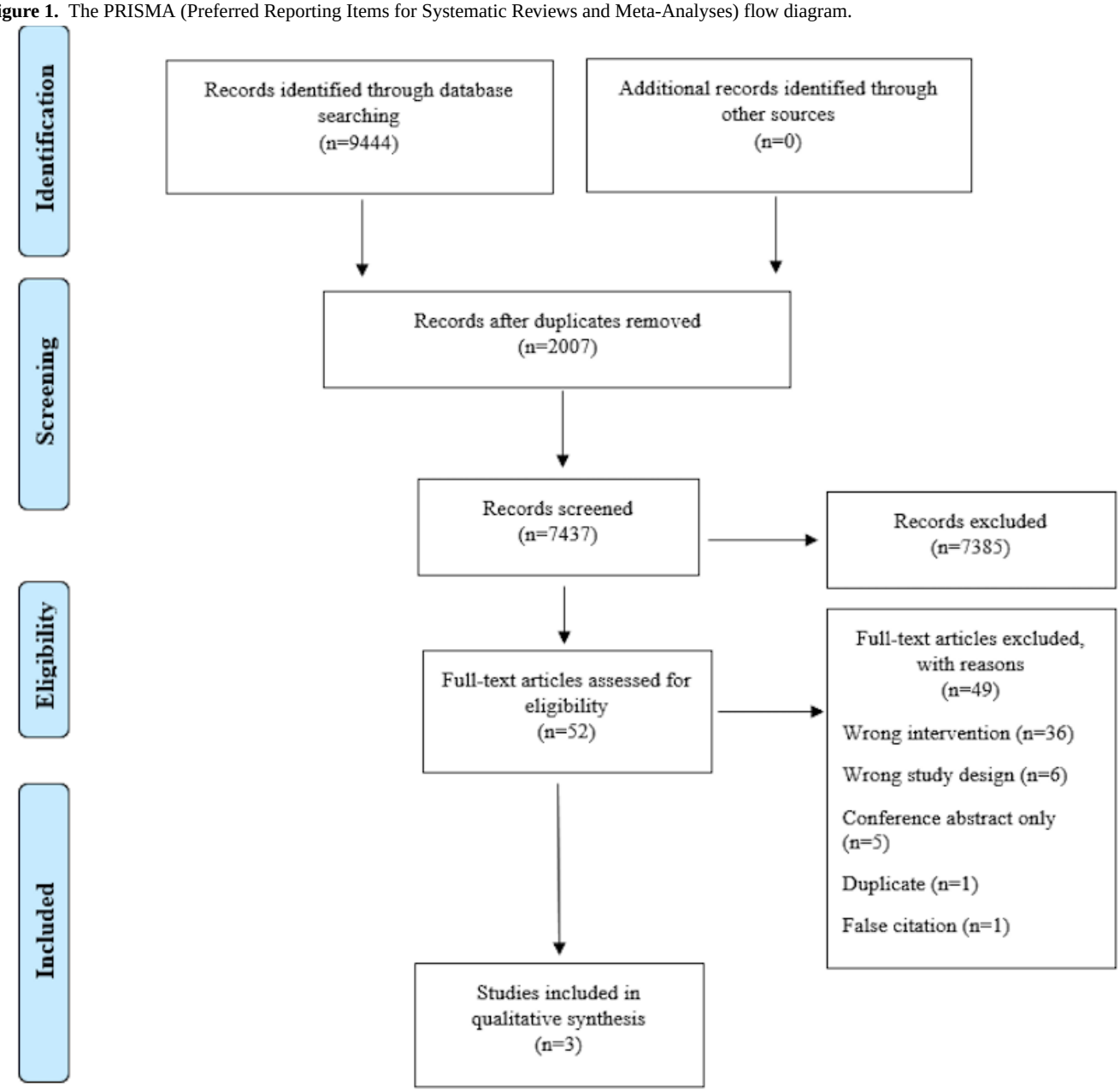
of the full texts of the papers, refining the extraction form, and revising the collected data.

Results

Overview of Included Studies

Figure 1 depicts the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram. After duplicate removal, 7437 articles were individually screened; 52 full-text articles were screened for eligibility, and 36 articles were excluded because they were labelled as having the wrong intervention. These studies were closely examined by 2 independent reviewers (AF and DS) confirming they did not contain smartwatch technology and were therefore excluded for synthesis. Six studies were excluded due to wrong study design, as their overall objectives and approach was not to test smartwatch technology and also did not contain the right intervention. Five studies were excluded, as they were conference abstracts and full-text versions of these studies could not be retrieved from corresponding authors. The final 2 potentially eligible papers were excluded, as one was a duplicate and the other was a false citation. Ultimately, 3 studies were included for qualitative synthesis [37-39]. All included studies investigated a combined mHealth approach in participants with type 2 diabetes and included the use of a wearable device. Table 1 highlights the details of each study included. Some of the main findings from each study are presented in the next sections.

Figure 1. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.



Kim et al (2016)

In this paper [37], the authors introduced a patient-centerd smartphone–based diabetes care system (PSDCS) for patients with type 2 DM. They were instructed to use the PSDCS, which integrates a Bluetooth-connected glucometer, a digital food diary, and a wearable physical activity monitoring device. The

primary end point was the change in HbA_{1c} from baseline after a 12-week intervention.

The application of the PSDCS to patients with inadequately controlled type 2 diabetes resulted in a significant HbA_{1c} reduction (from 7.7% to 7.1%) with tolerable safety profiles. There was no comment on the usability or durability of the intervention.

Shaw et al (2020)

In this 6-month longitudinal feasibility study [38], the authors sought to examine the use of multiple mHealth technologies to generate and transmit data from diverse patients with type 2 DM in between clinic visits.

The study found that it was feasible for participants from different socioeconomic, educational, and racial backgrounds to use and track relevant diabetes-related data from multiple mHealth devices for at least six months. The study seemed to suggest that engagement with activity tools (eg, Fitbit technology) had the most success, while other technological engagements seemed to wane over time with some different demographic patterns in the engagement with these tools (eg, weight and glucose engagement tools).

Zahedani et al (2021)

In this study [39], the authors sought to explore the potential benefit of CGM combined with a mobile app that links each individual's glucose tracing to meal composition, heart rate, and physical activity in a cohort of people without diabetes and noninsulin- treated people with type 2 diabetes. The primary end point was the change in time in range (TIR), from the beginning to the end of a 10-day period of use of the FreeStyle Libre CGM.

Of those with suboptimal baseline TIR, 58.3% of participants with type 2 diabetes and 91.7% of healthy or prediabetes participants improved their TIR by an average of 22.7% and 23.2%, respectively. Predictors of improved response included no prior diagnosis of type 2 diabetes and lower BMI. There was no commentary on the usability or durability of the intervention.

Discussion

Principal Findings

In an increasingly technology-enabled world, strategies that harness the benefits of technology have the potential to address gaps in health care provision and address some of the most vexing clinical problems with concomitant improvements in the management of common chronic conditions across a broad population of patients. This scoping review sought to explore the evidence for the use of technology in the management of type 2 diabetes. The focus was on emerging yet increasingly available technologies in this field, such as smartphone apps and web applications, FGM, and smartwatch technology. Doupis et al [41] explored the peer-reviewed literature and found inconsistent benefits from applications that are automated for individualized feedback, such as Diabeo, Diabetes Pal and Blue Star with only Diabeo, using a telehealth-facilitated model showing benefits in HbA_{1c} reduction [41]. The addition of smartwatch technology to help change patient behaviors and enhance health literacy introduces the opportunity to explore real-time use of technology in this field. There is increasing interest from both the private healthcare industry and the technology sector as well as state sponsored providers due to the possibility of providing health care at scale with the continuously reducing cost of some of the technology. This scoping review focused on the use of FGM, as it is gaining momentum as an emerging technology in continuous glucose monitoring with early evidence of benefits in the management of type 2 diabetes [42-44]. Castellana et al [45], however, highlight in their meta-analysis that FGM did not show benefits in HbA_{1c} in patients when compared with traditional home-based glucose monitoring. There are several explanations for this outcome, including the lack of hypoglycemia and hyperglycemic alarms and a negative bias at low glucose concentrations, possibly resulting in the patient inadvertently adapting to higher glucose concentrations and thus higher HbA_{1c}.

Smartwatch and Its Potential to Support Diabetes Care

In 2020, 21% of Australians had a smartwatch and the wearables market is expected to grow by 14.5% annually from 2021 to 2026 [46]. Consumer smartwatches have grasped health research across a broad range of chronic diseases [34]. This scoping review highlights the limited studies that have explored the effect of smartwatch technology and its integration with continuous glucose monitoring in patents with type 2 diabetes. Most of the literature looking to integrate technology platforms has focused on popular lifestyle applications and associated technology, such as Fitbit [38]. The early studies by Kim et al [37] and Shaw et al [38] did not have control groups and had small sample sizes undermining the validity of the results. Zahedani et al [39] showed that the integration of data from FGM and a smartphone-based app is a feasible and multimodal data collection, with synthesis and feedback to participants provided by an mHealth app, and can significantly improve glycemic control, although the participants used the technology for only 10 days. Furthermore, the study is a nonrandomized observation study opening it to the risk of bias.

Implications for Research

This scoping review clearly highlights the need for high quality studies exploring the effect of emerging technologies in an integrated fashion on the management of patients with type 2 diabetes. The research into the impact of both FGM and smartwatches, which are arguably more recent additions to the technological toolbox in health care provision for patients living with diabetes, needs further exploration.

Implications for Practice

The provision of mHealth-supported, FGM-enhanced diabetic care can provide opportunities to improve health literacy and promote self-management for patients with type 2 DM and their treating teams through the data sharing of real-time glucose control. The impact of this and newer technological interventions such as web-based applications and mobile phone or smartphone apps that monitor a wide range of self-efficacy parameters need to be explored in a broader cohort of patients with type 2 diabetes. There is a great opportunity to influence health literacy,

self-efficacy, and overall control of type 2 diabetes and its complications if these interventions can be delivered in a sustainable, cost-effective fashion.

Limitations

There are several limitations to the use of emerging technologies in the management of diabetes. From the patient and clinician perspective, there are usability and affordability limitations to much of the proprietary technology available [47]. From a technology perspective, there is a need for accurate measurements of physiological parameters, full access to raw data in real time, and all technological tools on a compatible platform [48].

This scoping review sought to link the impact of these 3 technological developments as a bundle on behavior- and lifestyle-related diabetic self-management. Wu et al [49] showed that in patients with type 2 diabetes, mHealth apps can have a measurable impact on lifestyle modification, but this was measured mainly in regard to its impact on HbA_{1c} rather than other measures of self-efficacy and self-management behaviors [49]. Keller et al [50] showed that structured digital behavior change interventions infrequently have high-level evidence data to support their status as guideline base [50], and only one study by Quinn et al [51] showed a significant improvement in diabetic control in intervention versus the control group. As mentioned, the focus was mainly on HbA_{1c}, and broader measures of health self-promotion were not measured. There seems to be a significant gap in the literature exploring the feasibility and usability of the use of the multipronged technological interventions and exploring the concept of technological fatigue in those whose condition is chronic, and thus, the interventions are expected to be lifelong.

Conclusions

This scoping review highlights that there is scant peer-reviewed literature on the clinical impact of integrated emerging technologies used for the management of type 2 DM. As these technologies become more affordable, it is crucial that safe and validated digital health devices are increasingly available as part of the multimodal care for patients with type 2 diabetes. These emerging technologies have the potential to provide quantifiable and reliable data that can assist health professionals and hopefully prevent costly health complications. High-quality research needs to ensure that these interventions do not have unintended consequences of health care fatigue in an already at-risk population and that they deliver on the potential for improved control both in the short term and the longer term with the appreciation that diabetes is a chronic condition.

Conflicts of Interest

None declared.

Multimedia Appendix 1
OVID Medline Search Strategy.
[DOCX File , 21 KB - diabetes_v8i1e42389_app1.docx]

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Abbreviations

CGM: continuous glucose monitoring
DM: diabetes mellitus
FGM: flash glucose monitoring
mHealth: mobile health
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSDCS: phone-based diabetes care system
RT-iCGM: real-time interstitial continuous glucose monitoring
TIR: time in range

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Original Paper

Integration of the Vision of People With Diabetes Into the Development Process to Improve Self-management via Diabetes Apps: Qualitative Interview Study

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Abstract

Background: Diabetes is a major global epidemic and serious public health problem. Diabetes self-management is a 24/7 challenge for people with type 1 diabetes that influences their quality of life (QoL). Certain apps can support the self-management of people with diabetes; however, current apps do not meet the needs of people with diabetes appropriately, and their safety is not ensured. Moreover, there are a multitude of hardware and software problems associated with diabetes apps and regulations. Clear guidelines are required to regulate medical care via apps. In Germany, apps must undergo 2 examination processes to be listed in the *Digitale Gesundheitsanwendungen* directory. However, neither examination process considers whether the medical use of the apps is sufficient for users' self-management.

Objective: This study aims to contribute to the technology development process of diabetes apps by exploring individual perspectives on desired features and content of diabetes apps among people with diabetes. The vision assessment conducted is a first step toward creating a shared vision among all relevant stakeholders. To ensure adequate research and development processes for diabetes apps in the future, guiding visions from all relevant stakeholders are required.

Methods: In a qualitative study, 24 semistructured interviews with patients with type 1 diabetes were conducted, among whom 10 (42%) were currently using an app. To clarify the perceptions of people with diabetes regarding the functions and content of diabetes apps, a vision assessment was conducted.

Results: People with diabetes have concrete ideas of features and content in apps to improve their QoL and allow them to live as comfortably as possible, such as informative predictions through artificial intelligence, improvements in signal loss and value delay through smartwatches, improved communication and information-sharing capabilities, reliable information sources, and user-friendly and discreet messaging options through smartwatches. In addition, according to people with diabetes, future apps should show improved sensors and app connectivity to avoid incorrect values being displayed. They also wish for an explicit indication that displayed values are delayed. In addition, personalized information was found to be lacking in apps.

Conclusions: People with type 1 diabetes want future apps to improve their self-management and QoL and reduce stigma. Desired key features include personalized artificial intelligence predictions of blood glucose levels, improved communication and information sharing through chat and forum options, comprehensive information resources, and smartwatch alerts. A vision assessment is the first step in creating a shared vision among stakeholders to responsibly guide the development of diabetes apps. Relevant stakeholders include patient organizations, health care professionals, insurers, policy makers, device manufacturers,

app developers, researchers, medical ethicists, and data security experts. After the research and development process, new apps must be launched while considering regulations regarding data security, liability, and reimbursement.

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KEYWORDS

people with type 1 diabetes; self-management; diabetes apps; vision assessment; anticipated stigma; qualitative research; Digitale Gesundheitsanwendungen; DiGA; mobile phone

Introduction

Background

Diabetes mellitus is a major public health issue [1]. In 2045, a total of 700 million people worldwide will be affected by diabetes [2], whereas currently, 10% of the world population has type 1 diabetes (T1D) [3,4]. In particular, T1D care largely depends on self-management, which is a 24/7 responsibility that persists for 365 days per year [5,6]. The continuous challenge of monitoring blood glucose levels, correcting them with insulin, and finding metabolic balance reduces the quality of life (QoL) of people with diabetes [2,7]. Owing to the different pharmaceutical and supportive needs of people with diabetes [8], it is one of the most challenging health problems for the health care system and also a burden for people with diabetes themselves [7]. Numerous apps have been developed in the past years to support people with diabetes in managing their disease [6], and the importance of this topic has been confirmed by a growing body of literature [6].

Germany is the first country in which physicians can prescribe digital health apps [9]. In 2019, the Digital Supply Act entered into force in Germany. It allows physicians to prescribe apps that are listed in the *Digitale Gesundheitsanwendungen* (DiGA) directory by the *Bundesinstitut für Arzneimittel und Medizinprodukte*. Although there are 341,000 T1D cases [10] in Germany, no diabetes apps were registered in the DiGA directory while the study was conducted. The *Bundesinstitut für Arzneimittel und Medizinprodukte* decides via a fast-track procedure whether an app will be accepted into the DiGA [11]. However, whether the content and features of the app have sufficient medical benefits for the users is often still questionable. The legal conditions under which DiGAs are integrated into the DiGA directory place too little value on patient benefits [12]. A further prerequisite to be accepted into the DiGA directory is a Conformité Européenne medical product certification [12,13]. However, in this certification process, the completeness of the app is also not reviewed [14].

Despite the reported rapid growth of diabetes apps on the market [6], no diabetes apps were registered in the DiGA while the study was conducted, and numerous hardware and software problems need to be solved. First, apps do not fit into the daily activities of people with diabetes as most diabetes apps do not integrate the most important diabetes management tasks, such as physical activity, education, and health feedback [15]. In addition, the apps do not meet the needs of people with diabetes, such as user-friendly apps that provide actionable reminders and consolidate data across peripheral health devices [16]. Second, patient safety is not guaranteed as apps that manage the health of people with diabetes are mostly unregulated, do not ensure evidence of accuracy and clinical validity, show poor interoperability and standardization, and offer insufficient data security [6]. Therefore, the implementation of proper regulations is needed to ensure the medical use of apps and the security of the sensitive personal data of people with diabetes. They are highly interested in using diabetes apps that facilitate their self-management [17].

The main app features focus on nutritional intake, insulin injection, and physical activity [18], for example, via functions such as (1) diary of blood glucose measurements, (2) food database of carbohydrates, (3) bolus calculators for insulin dosage, (4) warning of too high or too low blood glucose levels, and (5) fitness trackers.

To avoid apps being certified and included in the DiGA directory whose features and content do not ensure medical use and are not optimally adapted to the needs of people with diabetes, this study aimed to contribute to the technology development process of apps by focusing on the perspective of people with diabetes. This should ensure that future apps that become available on the market and are possibly listed in the DiGA directory are optimally adapted to users' needs and, thereby, to their self-management.

Contribution of This Study to the Body of Literature

This study's specific approach focused on the perspective of people with T1D and the improvement of their self-management via apps. The study responded to a research gap described in the literature: only a limited number of studies exist that have explored the use and feature preferences of people with diabetes concerning apps [16]. Furthermore, it is crucial to involve patients in defining the most important functions of apps [19] and have a better understanding of the potential of apps concerning self-management [15,20]. Future apps need more features to improve diabetic self-management [21,22] and must be tailored more to diabetic needs [23]. Thus, further research is needed on future diabetes app development [24].

Contribution of This Study to a Wider Context

This qualitative study aimed to contribute to the technology development process of diabetes apps by exploring perspectives on the desired content and features of diabetes apps among people with T1D. This study was embedded in a complex and iterative process involving research, technology development, and implementation of new technologies in the health care sector. The specific objective was to contribute to the technology development process of diabetes apps by making explicit which features and content of apps can improve the self-management and QoL of people with diabetes.

In the context of health care, this study aimed to provide needs-based care for people with chronic diseases while ensuring maximum security (physical safety and data security). In the context of health economics, the aim was to reduce the costs of care for people with T1D by ensuring that optimized self-management results in fewer acute metabolic disorders with the need for hospitalization. The long-term goal was cost reduction via reduced and delayed comorbidities.

Methods

Overview

An exploratory study enabled the assessment of the perspectives of people with diabetes on self-management using diabetes apps [25]. In addition, a qualitative research study design fit the purpose of exploring the visions of people with diabetes concerning how diabetes apps can improve the diverse aspects of diabetes self-management. Qualitative semistructured interviews were conducted with patients with T1D who used an app and those who did not. Semistructured interviews offered the opportunity to gain a deep and contextualized insight into the content and features that participants would like to see in future apps.

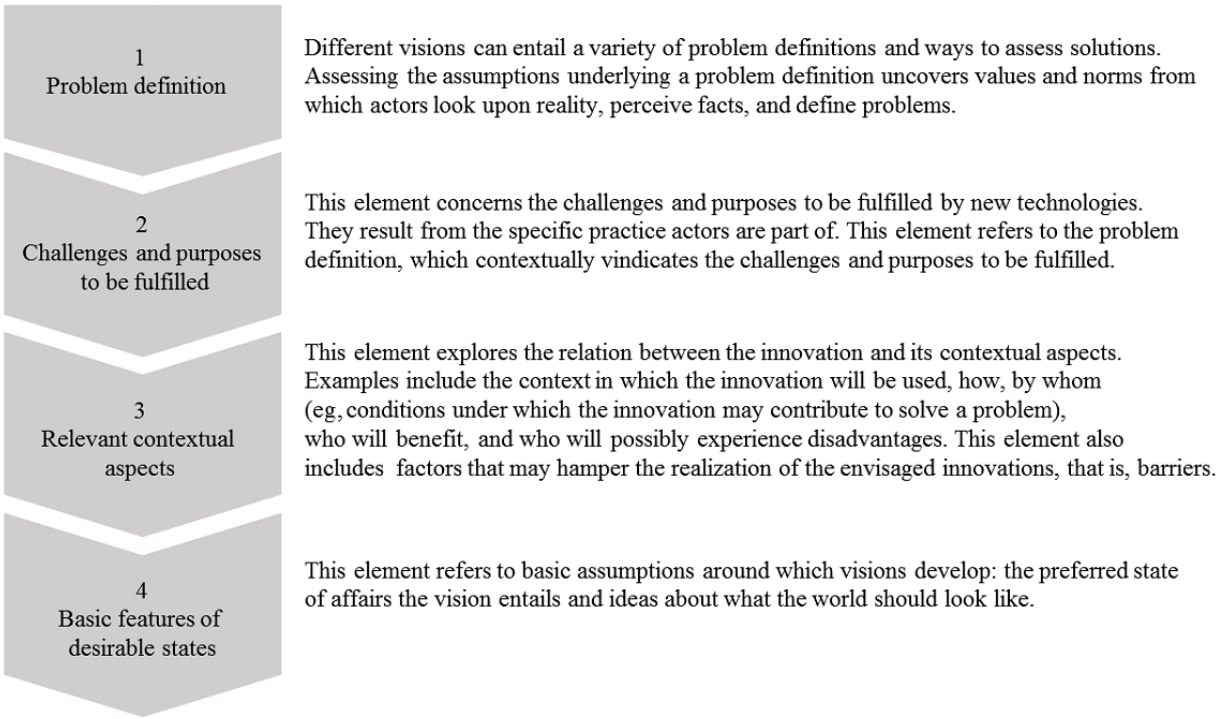
Theoretical Framework

To obtain people with T1D's perspectives on the features and content of future diabetes apps, the Responsible Research and Innovation (RRI)—part of the European Framework Programmes—was chosen as the research approach. A vision assessment was used for this purpose.

The RRI approach aims to open up the research and innovation process to a wider group of stakeholders to "anticipate and assess potential impacts and societal expectations about research and innovation" [26]. In doing so, "all stakeholders involved should work together throughout the research and innovation process" [26].

In line with the RRI, a vision assessment is used to actively include users' perspectives in the technology development process. This can be done by making their visions explicit before the technology is developed. By opening up the technology development process to all relevant stakeholders and including their visions, important contributions can be made to this process [27]. By considering a wider set of facts and values associated with the technology in the making, its development process is rendered more likely to yield a responsible product. In this study, a vision assessment was conducted with people with T1D as, until now, their visions have not been sufficiently integrated into the research and technology development process of diabetes apps. A vision assessment provided an opportunity to explore the underlying assumptions about the expectations and concerns of people with diabetes. Moreover, it allowed for the early anticipation of potential negative unintended consequences. To date, only the vision of app developers has been considered in app development. Integrating the visions of people with T1D into the awareness-raising process opens the technology development process to a wider set of relevant stakeholders. Only when a vision assessment has been carried out with all relevant stakeholders can the guiding vision be merged into a shared vision [28]. A shared vision guiding technology development is more likely to attain societally beneficial products as it takes into account multiple perspectives. This study followed the 4 elements for a vision assessment developed by Arentshorst et al [28] (Figure 1) based on the studies by Fischer [29,30] and Chilvers and Kearnes [31].

Figure 1. Vision assessment in the style of Arentshorst et al [26].



The 4 elements provide insight into people with T1D's views on what features and content of apps are necessary to optimize their self-management. The model has been validated for emerging technologies (sources). However, when applying this model in the context of diabetes, it is important to keep in mind that this study was not about the initial development of apps but about improving existing apps by adding new features and content. Therefore, the focus of this report was to identify a future guiding vision based on the perspective of people with diabetes that contributes to the technological development process of diabetes apps. Thus, the main research question was as follows: What are the perspectives of people with diabetes on the features and content of future diabetes apps?

The 4 elements of a vision assessment are translated into 4 subquestions: What is the problem definition in terms of relevant values and norms according to people with diabetes? What challenges and purposes are related to apps according to people with diabetes? What are the relevant contextual aspects of diabetes apps according to people with diabetes? What are the ideas of people with diabetes on what their world should look like?

Procedure

The recruitment of participants took place from February 2021 to March 2021. A diabetologist was contacted to connect the researcher with potential interviewees among their patients. A purposive sampling strategy helps identify and select individuals who are especially knowledgeable about or experienced with the phenomenon of interest, in this case, diabetes self-management using apps [32]. Participants were included if they mastered the German or English language, had T1D, used or did not use a diabetes app, and were willing and able to agree to a voluntary consent form. Contact with potential participants was initiated with a personalized email request for a recorded interview with a short description of the research purpose and central topic. To explore a range of perspectives of people with diabetes, a large number of people with diabetes were interviewed, composed as heterogeneously as possible in terms of the apps, age, and sex. Table 1 shows the sociodemographic data (sex, age, and app) assessed through the questionnaire.

Table 1. Sample characteristics.

ID	Sex	Age (years)	Use of app
R01	Male	44	CGM[a] but would prefer an app
R02	Female	32	CGM; prefers it over an app
R03	Female	43	FreeStyle Libre app
R04	Male	81	CGM; has no smartphone
R05	Male	65	CGM; has no smartphone
R06	Female	36	Blood glucose self-monitoring; will switch to FreeStyle Libre app
R07	Female	78	Transplanted
R08	Female	32	FreeStyle Libre app
R09	Male	61	CGM; waits for a new sensor that can be connected to an app
R10	Female	47	CGM
R11	Female	40	FreeStyle Libre app
R12	Female	51	Transplanted; could not use sensor because of work condition
R13	Male	26	Blood glucose self-monitoring
R14	Female	42	FreeStyle Libre app
R15	Female	43	CGM but would like to use an app
R16	Male	25	FreeStyle Libre app
R17	Male	25	FreeStyle Libre app
R18	Female	24	No app but the patient gets a new insulin pump and then uses app
R19	Male	26	Dexcom app
R20	Male	23	FreeStyle Libre app
R21	Male	25	CGM; Dexcom has no compatibility with a phone but the patient wants to use the app
R22	Male	29	FreeStyle Libre app
R23	Male	28	CGM
R24	Female	24	FreeStyle Libre app

[a]CGM: continuous glucose monitoring.

In total, 24 individual semistructured interviews were conducted with people with diabetes based on a vision assessment until data saturation was attained. The decision on data saturation resulted from a consensus among the researchers. A total of 42% (10/24) of the participants used an app for their diabetes management. In total, 29% (7/24) wanted to use an app but were unable to do so because of circumstances beyond their control. The remaining 29% (7/24) of respondents did not want to use an app or had not considered it. Half of the participants (12/24, 50%) were female, and half (12/24, 50%) were male. Overall, participants were aged between 23 and 81 years. One-third of the participants (8/24, 33%) had experience with continuous glucose monitoring, and another third (9/24, 38%) had experience with the FreeStyle Libre app. Overall, 62% (15/24) of the interviews were conducted at a diabetologist practice face to face, and 38% (9/24) of the interviews were conducted via videoconference because of the restrictions of COVID-19. A data management plan was created and served as a guide for this research and the data collection process.

Analysis

Qualitative analysis was performed by IK in an iterative and nonlinear manner using the general steps of qualitative data analysis described by Creswell [32]. This was supported by ATLAS.ti (ATLAS.ti Scientific Software Development GmbH), a specialized computer software for qualitative research [33]. First, inductive content analysis was applied to organize and analyze the raw data through an open coding process (Multimedia Appendices 1 and 2). Subsequently, these codes were checked against the codebook and deductively created from the theoretical framework displayed in Figure 1 (deductive coding). Newly emerging codes were added, or existing codes were amended to allow for the inclusion of new insights. Axial coding was carried out to make connections between codes, determine relationships, and form a hierarchy among codes. Through this process of categorization, the final broader analytical themes were formed. The inductive coding process did not expand the broader analytical themes of the theoretical framework used (Textbox 1). Overall, the coding procedure used a combination of emerging and predefined codes [34].

Textbox 1. Definitions of the final analytical themes.

- Problem definition: underlying problems that people with diabetes experience with their disease
- Challenges: problems that people with diabetes experience in self-management using apps
- Purposes: features that future apps need to entail to solve these problems
- Relevant contextual aspects: app characteristics [3] and technical aids such as apps [28]
- Desirable states: the ideas of people with diabetes about what the world should be like

Ethical Considerations

Before starting the recruitment of participants, a research ethics self-check provided by the Vrije Universiteit Amsterdam Faculty of Science [35] was conducted that stated that this study did not require approval from a medical ethics committee.

Before the interviews, participants were informed about the study's purpose and the right to withdraw at any time. They received information from the diabetologist or via email regarding the research objectives and the confidentiality of their personal information. Written or verbal voluntary consent for the recorded interviews was asked for and obtained before the interviews began. Interviewees were allowed to refuse to answer questions or provide sensitive information and end the interview at any time. The interview design was based on the operationalization of the 4 subquestions. The interview guide included a topic list with possible probing questions. The duration of the interviews ranged from 45 minutes to 1 hour. Notes were taken during and after the interviews.

The interview recordings were transcribed verbatim with the participants' permission. To ensure the privacy of the interviewees, the researcher was the only one with access to the recordings. The audio recordings were deleted after transcription, and the anonymized transcripts are stored securely for 5 years.

Results

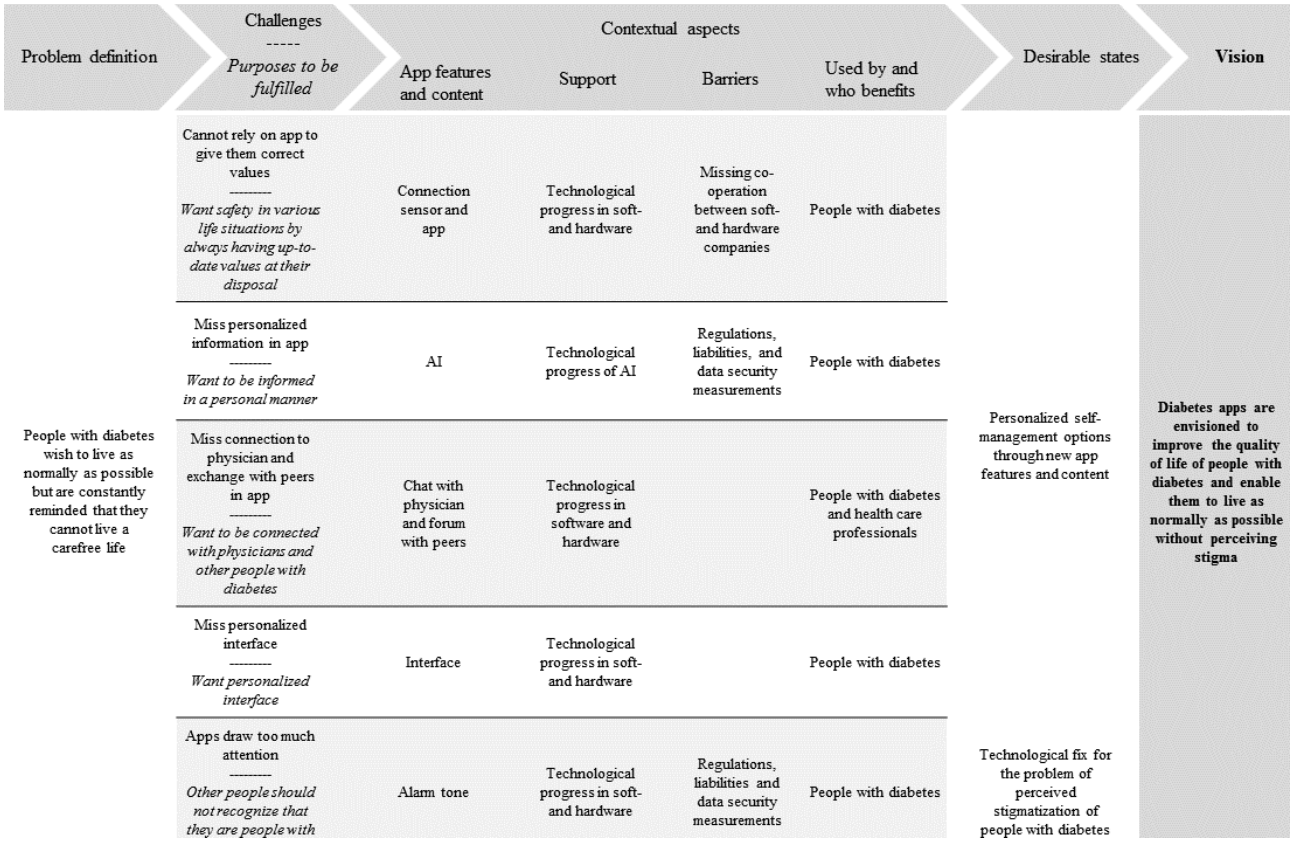
Overview

Henceforth, a distinction will be made between *users* (current app users) and *interviewees* (all interviewed participants). The collected data showed that the main reason why people used an app for their diabetes management was to improve daily self-management. Within the interviews, age, technical understanding, usability of the sensor (which is attached to the upper arm), work conditions, and compatibility with the physician's practice could be identified as factors influencing the current use of apps. There were no identified differences in the answers from participants of different sex.

Analysis of the interviews resulted in the identification of one guiding vision on diabetes apps from the perspective of people with diabetes. Diabetes apps are envisioned to improve people with T1D's QoL and enable them to live as normally as possible without anticipating stigma.

An overview of the results is presented in Figure 2. The *Results* section is structured in line with the elements displayed therein.

Figure 2. Results of the vision assessment: elements constructing the vision on diabetes apps from the perspective of people with diabetes. AI: artificial intelligence.



Problem Definition and Underlying Values

The main problem that people with T1D experience with their diabetes is that they wish to live as normally as possible but they are constantly reminded that they cannot live a carefree life:

> *I think as a person with diabetic you are always between the two poles of absolute control, and I do not care, I always oscillate between these two poles, and you never reach one of them, you are always in between.* [R10; female; aged 47 years]

This is related to the ambivalence that people with diabetes must endure every day concerning their health. People with diabetes reported not feeling sick yet having to manage a chronic disease 24/7:

> *Diabetes is not a real disease in comparison to cancer or dementia, because you can do everything you want.* [R22; male; aged 29 years]

Values such as self-determination, individuality, privacy, and safety, as well as associated norms, are subject to the aforementioned ambivalence between feeling healthy and constantly managing their diabetes. For people with diabetes, the value of *self-determination* means that they can live a self-determined life in which they have freedom of decision and action. However, in everyday life, they face problems with their blood glucose levels that make it impossible for them to have complete freedom of decision and action. The value of *safety* is important as people with diabetes live with a constant fear of hypoglycemia, which can have deadly consequences. Thus, they need regular and reliable information on their current blood glucose levels. *Individuality* about diabetes means that people with diabetes do not feel individually supported by their apps as these are not tailored to their life circumstances. Moreover, people with diabetes attach great importance to the value of *privacy*. However, it is important to note that this value is related to the wish not to attract attention to their disease in everyday life situations rather than to concerns about potential access to personal health data generated through apps:

> *A more discrete sound would be great so not everyone notices it and it does not attract everyone's attention.* [R16; male; aged 25 years]

Challenges of Current Apps and Purposes to Be Fulfilled by New Apps

Challenges were reported when using apps for self-management. These challenges resulted in the purposes that people with diabetes would like to see in future apps. First, apps were found to attract too much attention from other people. Therefore, future apps, or rather the use of these apps, should not attract the attention of other people so that people with diabetes do not have to anticipate stigmatization:

> *During n school exam, it is very annoying when the App makes sounds because the professors might think you are cheating.* [R18; female; aged 24 years]

Second, people with T1D could not rely on the reality of the values displayed in the app. Therefore, people with diabetes wished that future apps display real-time values that they can rely on without any delay. Third, people with diabetes missed

reliable, solid, and personalized information in the apps. Thus, they wanted to be informed in a personalized and high-quality manner by future apps continuously. Fourth, they missed personal exchange options with physicians and other people with diabetes. Hence, they desired the opportunity to communicate with physicians and other people with diabetes via apps:

> *It would be great to quickly get the information you need from your doctor or other people with diabetes, especially in tricky or new situations.* [R21; male; aged 25 years]

Relevant Contextual Aspects of Diabetes Apps

Interviewees reported that the following existing app features and content need to be improved to optimize their self-management: alarm tone, sensor, and app connection. Moreover, interviewees reported that the following new app features and content need to be developed to optimize their self-management: artificial intelligence (AI), information, and communication features.

Alarm Tone

Users reported ambivalence toward the alarm tone. It was reported to be both the most useful feature to prevent hyper- or hypoglycemia and the most annoying feature. Most users (9/10, 90%) reported missing features to individually select the alarm tone and decide when to turn it on and off. The alarms were reported to be the most indiscrete feature as they attract a lot of attention from other people, leading to anticipated stigmatization:

> *When I am at work, I do not want my colleagues to notice the sounds of the App. The App makes sounds when I hypoglycaemia. They might think that I am weak or that I cannot concentrate any longer.* [R14; female; aged 42 years]

The interviewees especially expressed this in situations such as being at work or at a restaurant or engaging in sports. In addition, waking up to a harsh tone every night was a reason why people with diabetes turned off the alarms at night, which means that they accepted the risk of hypoglycemia. However, other users said that the alarm during the night was the greatest feature of the app as it made them feel safe. Users reported appreciating a feature that would let them individually select the alarm sounds and time slots when it is on or off. Most interviewees (17/24, 71%) wished for an installation of an app on a smartwatch. A vibrating smartwatch was argued to be superior to an alarm tone. In this way, the potential of anticipated stigmatization would also be minimized:

> *I am already wearing a smartwatch and it vibrates when I get a message. It is inconspicuous and discreet, and not everyone notices it. Also, a quick look at the watch and briefly holding the watch in front of the sensor is more discreet.* [R15; female; aged 43 years]

Sensor and App Connection

Concerns regarding delayed value transmission and signal loss were widespread among interviewees. All users (10/10, 100%) stated that delayed value transmission hampered their self-management:

> *I always have to control the system and listen to my body and compare how I feel to what the App says. This is because the sensor measures the concentration of glucose in interstitial fluid which has a time lag of sometimes 20 minutes compared to blood glucose measurements.* [R16; male; aged 25 years]

Some interviewees (3/24, 13%) even reported not using an app as they could not handle the value delay. The delayed values reportedly made them insecure. Thus, they wished for clear information about value delay in the app:

> *If the values always have a delay of 20 minutes, then it should be written down for you like 20 minutes ago this was your value. But it is not displayed anywhere, you just have to know it.* [R17; male; aged 25 years]

Furthermore, missing values because of signal loss between the app and the sensor were mentioned repeatedly:

> *If you leave the phone somewhere then the value transfer from the sensor to the App does not work anymore, and you cannot see your values. This is very annoying.* [R2; female; aged 32 years]

Moreover, some interviewees (6/24, 25%) stated that an improved connection between apps and sensors from different providers would greatly increase individual self-management. Most interviewees (17/24, 71%) preferred an app installation on a smartwatch that diminished the problem of signal loss as the distance between the sensor and the watch is shorter. The combination of improved value display and reduced signal loss was said to increase the usability of the app and, thereby, highly improve the daily self-management of people with diabetes.

AI Features

Many users (7/10, 70%) stated that they adapted to the app and not the other way around:

> *The users adapt to the system and not the system to the user.* [R16; male; aged 25 years]

All users (10/10, 100%) indicated that apps lack sufficiency in ensuring good self-management that suits their daily activities. Concerning stressful situations at work, some interviewees (8/24, 33%) complained that they forgot to check their values and, thus, forgot to inject insulin for 2 reasons. First, they did not have their phone or blood glucose meter device with them (eg, when a phone is not allowed at work). Second, blood level measurement attracts too much attention from colleagues. Some users (3/10, 30%) stated that they turned the alarms off at work so that other people would not ask questions or notice them:

> *I am a teacher and during my break, I always leave the break room to check my glucose levels. I do not want other people to notice. Also, during meetings, I switch off the sound because I do not want others to think that I cannot concentrate any longer.* [R14; female; aged 42 years]

Interviewees expressed the wish for an AI on a smartwatch app that reminds them to check their values or shows them the prognosis of their blood glucose level.

In addition, during activities such as sports or eating at a restaurant, users reported that current apps are not well adapted to their needs. Some interviewees (5/24, 21%) stated that they did not try a new sport as they were afraid that they could not handle their self-management before, during, and after the new activity. Interestingly, most user (8/10, 80%) reported missing profound personal information about sports in the app (content). They suggested that algorithms and AI should provide hints or reminders regarding nutrition, insulin dosage, and sports. The AI should recognize patterns of body stature and fitness level to provide users with predictions, such as a graph in which one can see the predicted blood glucose level for a certain sport:

> *It could predict blood glucose level for sports. So that I can see how the values will change during the activity and I can adapt my eating behaviour and activity to it.* [R13; male; aged 26 years]

Furthermore, interviewees repeatedly reported that a prerequisite for that is that diabetes apps are connected to other apps:

> *Prediction is not working at all at the moment. They should connect the Apple Health App to the diabetes App and then tell me how much insulin I have to inject. Or when I do sport the App could give me the alarm a bit earlier and tell me that the values will go down quicker.* [R17; male; aged 25 years]

Some interviewees (3/24, 13%) said that, in the beginning phase, they took a scale with them to restaurants to calculate insulin injections, which was reported to be an uncomfortable situation in terms of anticipated stigmatization. Most interviewees (17/24, 71%) expressed that a photo AI calculating the bread unit (BU) would be easy to integrate into their daily lives and be more discrete at a restaurant. Newly diagnosed interviewees were unanimous in the view that this feature would be one of the best features to alleviate their daily lives.

Information and Communication Features

A recurrent theme in the interviews was that individually tailored, in-depth, and informative content was missing in the current apps. In unknown and challenging situations, most interviewees (17/24, 71%) reported missing well-founded sources offering reliable and individual information in apps, which could increase safety in everyday life. For example, interviewees expressed the wish for more information in the form of notifications for activities such as sports, traveling, or consuming alcohol:

> *It would be useful to enter interests in the App like Pinterest and thereby get individually tailored information via notifications.* [R17; male; aged 25 years]

In addition, communication was expressed to be important but still missing. Some interviewees (11/24, 46%) reported that information exchange and connection with peers were extremely important when they were first diagnosed. Communication features such as chats and forums were stated to enable enhanced information exchange possibilities. Most interviewees (13/24, 54%) preferred a direct chat with their physician over a chatbot to receive timely information in tricky situations. A chat function with their physician was preferred over a chat with peers:

> *I would only like to have a quick contact with my doctor. He knows my history and I trust him.* [R19; male; aged 26 years]

Half of the interviewees (12/24, 50%) considered a forum feature to be more suitable for their daily life than a direct chat with peers. Furthermore, some interviewees (5/24, 21%) were aware that it is difficult to ensure that the available information in forums is medically accurate, trustworthy, and up-to-date.

Supporting and Hampering Contextual Aspects

A range of contextual aspects were mentioned by most interviewees (18/24, 75%) that support or hamper the realization of future apps features. On the one hand, the main supporting aspects mentioned were fast technological innovation progress, digitalization, and AI. These were said to improve app features and their compatibility with other devices (smartwatches). On the other hand, interviewees perceived the lack of collaboration between software and hardware companies as a barrier to the implementation of innovations. In addition, many interviewees 10/24, 42%) mentioned that data security measures hamper physician practices in transferring data from the app directly into their professional software. This was reported as most likely to remain a barrier in the future. Interviewees were aware that integrating AI and the other aforementioned features into future apps will take some time as aspects such as regulations, liability issues, and data security measures are barriers to the implementation of medical devices.

Interestingly, interviewees did not attach high importance to the data security of the aforementioned new features. Most interviewees (17/24, 71%) stated that they did not care about data security, especially if this hampers the introduction of the features that would make their self-management easier:

> *When the added value of the feature outweighs the supposed disadvantages, I would like to use the new App features.* [R18; female; aged 24 years]

Moreover, most (10/17, 59%) assumed that they were the only ones thinking that way and stated that most likely others would give a higher priority to data security than they did:

> *I personally don't see blood glucose level as super sensitive data, but most likely other people may see it quite differently.* [R17; male; aged 25 years]

Some interviewees (8/24, 33%) stated that they believed that, if somebody wants to find out things about them, they will. Some respondents (7/24, 29%) also stated that they may not have an overview of the extent to which others could harm them by accessing their personal data.

Desirable States of People With Diabetes

The analysis revealed 2 desirable states, from which the guiding vision was developed. According to the interviewees, the combination of both states leads to an improvement in their QoL and the feeling of living a normal life. Thus, the interviewees formulated the following ideas about what the

technical solutions should look like: (1) personalized self-management options with new app features and content and (2) a technological fix for the problem of anticipated stigmatization of people with diabetes.

First, all the features and contents named by the interviewees optimized their self-management. Interviewees stated that all the mentioned features and contents could lead to a more personalized app that adapts to their personal and medical needs. In particular, algorithms and AI could provide them with individually tailored information in the form of tips, reminders, and predictions for a wide range of activities. Features and contents of future apps were reported to open up options to combine the app with a variety of hardware devices, receive individually tailored information, and communicate with health professionals and peers. According to interviewees, all these features and contents of future apps could lead to an optimized personalized self-management.

Second, some of the features that interviewees reported should be included in future apps to minimize anticipated stigma. These are features to individually select alarm tones and time slots when the alarm is on or off, as well as the possibility to install an app on a smartwatch that vibrates and does not make any noise and, therefore, cannot be perceived by others. The possibility to take a photo of the food to estimate BUs was also mentioned. These features make sure that others do not recognize them as people with diabetes and, thereby, reduce the belief of people with diabetes that others stigmatize them as sick.

From these 2 desirable states, the guiding vision was developed. According to the interviewees, only the combination of both leads to an improvement in QoL and living as normally as possible without anticipating stigma.

Discussion

Principal Findings

Overview

From the perspective of people with T1D, diabetes apps can improve QoL and enable them to live as normally as possible without anticipated stigma. This guiding vision is connected to two aspects: (1) the need for personalized self-management options through new app features and content and (2) the need for technological fixes regarding the issue of anticipated stigmatization generated through the sounds and visibility of self-management activities. In this regard, people with diabetes have a clear idea of which features and contents should be included in future apps to improve self-management. Overall, six main topics surfaced: (1) improvement of the sensor and app connection via smartwatch, (2) innovation of blood glucose measurement methods, (3) prediction via AI, (4) information and communication via forum and chat, (5) alarm tone reduction by using a smartwatch, and (6) data security.

Improvement of the Sensor and App Connection via Smartwatch

Signal losses when connecting the sensor and app can be reduced by using a smartwatch as an in-between solution. The distance between the sensor and the app when installed on the smartwatch is reduced. However, a lack of cooperation between companies, liability issues, and data security measures were mentioned as possible reasons why only a few companies offer this solution, which is also confirmed by Freckmann [36]. Participants named data security measures as the main reason hindering the realization of a sensor-smartwatch connection. This finding was also confirmed by Cohen [37], who further states that medical device regulatory procedures are a general barrier to implementing new technologies. Overall, few authors have mentioned smartwatches for diabetes management support. For example, Årsand et al [38] concluded that smartwatches make it easier for people with diabetes to record, monitor, and analyze their blood glucose levels in everyday life. However, so far, users still need a smartphone as an intermediary to receive the data on a smartwatch. Moreover, widespread adoption will only be possible when the aforementioned hindering measures and regulatory processes are alleviated.

Innovation of Blood Glucose Measurement Methods

App users demanded that apps note that the displayed values of blood glucose are delayed. Current sensors have a time lag of 5 to 20 minutes [39]. Aware of this issue, manufacturers are currently developing new ways to measure blood glucose levels to improve delayed value transmission, such as mini-sensors that can be implanted under the fingertip, sensor tattoos, or a tool that detects blood glucose levels in exhaled air [40]. Moreover, research is also being conducted on how smartwatches can directly measure blood glucose levels and transmit them in real time [41].

Prediction via AI

The research results show that predicting blood glucose levels through algorithms and AI might improve self-management of various daily activities. However, Kriventsov et al [39] argue that the challenge in AI prediction is the value lag. Nevertheless, Kriventsov et al [39] also state that it is possible to accurately predict blood glucose fluctuations using personalized machine learning models [39]. These findings are consistent with those of Fatehi et al [42], who found that machine learning algorithms and AI can provide personalized predictions based on data models from similar cohorts and patient histories. Therefore, using AI in future apps to accurately predict blood glucose levels would greatly improve the self-management of people with diabetes in everyday life.

In addition, Maharjan et al [43] proposed an AI-driven personalized diabetes virtual assistant to support people with T1D in their daily activities. The AI could then learn from the user's habits, inputs, or questions so that the user receives better support over time [43]. For example, Vettoretti et al [44] developed an AI algorithm that can predict future blood glucose levels based on past glitches and errors. The developed algorithms learn from the user's collected data (amount of exercise, sleep, and stress) and integrate them into the prediction models [44]. However, Kulzer [45] stated that the capacity of AI models for decision-making, data security issues, and liability issues are limited when using AI. This statement is consistent with the barriers identified by respondents in our study. Moreover, the intense societal debate on the opportunities and

risks of AI, including ethics, liability, and data protection, must be addressed [45].

Finally, the participants desired a photo AI function to help calculate their BUs. An AI currently in development by the start-up SNAQ, for example, performs an image-based nutritional analysis of meals and calculates the necessary insulin dosages [46]. Another example is an AI for insulin optimization that can predict the blood sugar level for the next 60 minutes developed by the start-up Hedia. This AI also detects eating habits over time and suggests an adjustment tailored to the individual [47].

Information and Communication via Forum and Chat

The interviewees appreciated the possibility of information exchange with peers via forums, although they were also aware that it might be difficult to ensure profound knowledge in these forums. In accordance with our findings, a study by Jeon and Park [48] showed that participants' self-care motivation significantly improved by offering a bulletin board in their app where people with diabetes could share their experiences and express empathy with others.

A cross-sectional study by Litchman et al [49] suggested that individuals who participate in web-based communities are more likely to have improved blood glucose levels and better QoL. Despite the proven positive effects, Eberle and Ament [50] state that social features such as forums are not yet present in many apps. Hence, additional research is needed to explore how forum use influences users' self-management [50]. Furthermore, research will be needed to determine how engagement in these forums may affect health outcomes [49].

Our research has also shown that people with T1D wish for a chat feature in the app to communicate with their physicians about certain or urgent problems. They did not want to communicate with other physicians or a chatbot. The findings of Zhang et al [51] are similar to our research. Moreover, the participants stated that the feedback has to be on time to be useful. However, surprisingly, a report by the Center for Advanced Hindsight found that people with diabetes accepted a chatbot as an expert in a certain domain, and over time, they became attached to the bot as a friend. The reason for this is that a chatbot can provide continuous and reliable support to the user in a tailored manner [51]. The outcomes of the report by the Center for Advanced Hindsight [52] are somewhat contrary to our findings. Therefore, more research is needed to assess whether people with diabetes would prefer a chat with their physician or a chatbot and how either of these solutions can be integrated into the apps to become a reliable source of information. In this regard, it is to argue whether the findings are not necessarily contradictory but complementary in the sense that, if a chat with a physician is not possible, people with diabetes will probably settle for a chatbot, which could be satisfying enough for them. For some people, it could also be a barrier to approaching a physician with a (more or less trivial) question concerning their health, and as a consequence, these people are more comfortable asking a chatbot.

Alarm Tone Reduction While Using a Smartwatch

App users criticized the sound of the alarm tone of apps while using the smartwatch, which easily attracts the attention of other people. Thus, they wanted a technological fix to minimize their fear of judgment from others (anticipated stigmatization). In this context, the study by Brazeau et al [53] confirms that noticeable equipment leads to the fear of being judged by others, which is more pronounced among young people and is associated with lower diabetes-related self-management and self-efficacy, severe hypoglycemia, and diminished sense of well-being. Furthermore, the cross-sectional study by Gredig and Bartelsen-Raemy [54] found that anticipated stigma has a negative impact on QoL, which is in line with our findings.

Moreover, participants of the studies by Gredig and Bartelsen-Raemy [54] and Liu et al [55] expressed the wish for education for the general public to reduce diabetes stigma. Furthermore, Gredig and Bartelsen-Raemy [54] concluded that health care professionals play a key role in changing the stigma about diabetes, and the authors suggested that health campaigns for diabetes could be developed similarly to HIV campaigns. However, to tackle stigma at its roots, a combination of education of the public, health campaigns, and technology development could be a holistic approach to tackle the fear of being judged by others.

Data Security

Another key aspect was data security, which involves safely managing the information of app users. However, interestingly, our interviewees did not attach high importance to the data security of new app features when the added value of a new feature was high for their self-management. The fact that interviewees did not attach high importance to data security is probably due to a lack of experience with adverse events such as security breaches or hacker attacks. Still, according to Britton and Britton-Colonnese [56], the safety of people with diabetes is at risk when cybersecurity is not achieved. Filkins et al [57] listed the implications that data breaches can have for people with diabetes. For example, malware can be installed, which leads to both loss of control of the device and corrupted data, with severe consequences for people with diabetes. In conclusion, people with diabetes have to be made aware of these dangerous consequences.

Moreover, Britton and Britton-Colonnese [56] and Fleming et al [6] revealed that people with diabetes are often unaware of what they authorize when they install an app. In addition, when they want to use a certain app, they have to accept how manufacturers gather, share, and use their data [56]. These findings support the need for more digital literacy.

Limitations

This study has limitations resulting from people with T1D and the apps that they currently use or used in the past. Only the guiding vision of 1 stakeholder group was assessed and not those of various other relevant stakeholders. This study was limited by the use of only interviews because of COVID-19 restrictions. Focus groups are more suited for the construction of a guiding vision as people do not develop visions or opinions

in isolation but through discussion and interaction with their surroundings. Focus groups are better able to mimic this process.

Although the interviewees who did not use apps only had limited imagination about the potential of apps, some interviewees (4/24, 17%) only used an app for some time as they had problems with the sensor app system and stopped using it (eg, an allergic reaction to sensor glue). This limited their imagination because of negative attitudes toward technological devices.

Furthermore, this report did not focus on all the systems that are available for diabetes self-management. Examples of what was not considered in this report are insulin pumps and automated insulin delivery systems. Finally, interviewees used different apps. Some used apps in connection with a sensor, and others used apps with a sensor and pump.

Conclusions

People with T1D have a specific idea of the features and content needed in future apps to improve their self-management—and, thereby, their QoL—and enable them to live as normally as possible without anticipating stigma. These include personalized predictions via AI, improvements in signal loss and value delay via smartwatch, improved communication and information exchange possibilities (chat and forum), profound information sources, and warning through a vibrating smartwatch.

The vision assessment conducted in this study is a first step toward creating a shared vision of all relevant stakeholders for the technology development process of diabetes apps. Therefore, the next step could be to assess the guiding visions of the relevant stakeholders included in the research and technology development process. Thereby, their visions are made explicit and can be integrated into a shared vision. The relevant stakeholders that should be included are patient organizations; health care professionals (diabetologists, diabetes advisers, and dieticians); insurers; policy makers; device manufacturers; app developers; researchers; medical ethicists; and medical data security specialists. This enables the development process of future apps to be guided by a rich and shared vision of all relevant stakeholders, thereby raising the likelihood of the apps being societally relevant and responsible. The research and development process is followed by the implementation of new apps. The implementation requires regulations regarding data security (AI), liability issues, and reimbursement (the Digital Supply Act).

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Authors' Contributions

IK conceptualized and conducted the qualitative study and analyzed and interpreted the data. MdJ and CD supervised the research process. IK, KJW, and JA drafted the manuscript. JA (MSc) and KJW supervised the drafting process in the role of senior authors. IK, KJW, LA, MdJ, CD, and JA revised the manuscript critically for important intellectual content. All the authors read and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Coding tree.
[DOCX File , 22 KB - diabetes_v8i1e38474_app1.docx]

Multimedia Appendix 2
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 481 KB - diabetes_v8i1e38474_app2.pdf]

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Abbreviations

AI: artificial intelligence
BU: bread unit
DiGA: Digitale Gesundheitsanwendungen
QoL: quality of life
RRI: Responsible Research and Innovation
T1D: type 1 diabetes

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Original Paper

Use of a Smartphone-Based Medication Adherence Platform to Improve Outcomes in Uncontrolled Type 2 Diabetes Among Veterans: Prospective Case-Crossover Study

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Abstract

Background: Medication nonadherence is a problem that impacts both the patient and the health system.

Objective: The objective of this study was to evaluate the impact of a novel smartphone app with patient-response-directed clinical intervention on medication adherence and blood glucose control in noninsulin-dependent patients with type 2 diabetes mellitus (T2DM).

Methods: We enrolled 50 participants with T2DM not on insulin with smartphones from a rural health care center in Northern Nevada for participation in this case-crossover study. Participants underwent a standard of care arm and an intervention arm. Each study arm was 3 months long, for a total of 6 months of follow-up. Participants had a hemoglobin A_{1c} (HbA_{1c}) lab draw at enrollment, 3 months, and 6 months. Participants had monthly "medication adherence scores" (MAS) and "Self-Efficacy for Appropriate Medication Use Scale" (SEAMS) questionnaires completed at baseline and monthly for the duration of the study. Our primary outcomes of interest were the changes in HbA_{1c} between study arms. Secondary outcomes included the evaluation of the difference in the proportion of participants achieving a clinically meaningful reduction in HbA_{1c} and the difference in the number of participants requiring diabetes therapy escalation between study arms. Exploratory outcomes included the analysis of the variation in medication possession ratio (MPR), MAS, and SEAMS during each study arm.

Results: A total of 30 participants completed both study arms and were included in the analysis. Dropouts were higher in participants enrolled in the standard of care arm first (9/25, 36% vs 4/25, 16%). Participants had a median HbA_{1c} of 9.1%, had been living with T2DM for 6 years, had a median age of 66 years, and had a median of 8.5 medications. HbA_{1c} reduction was 0.69% in the intervention arm versus 0.35% in the standard of care arm (P=.30). A total of 70% (21/30) of participants achieved a clinically meaningful reduction in HbA_{1c} of 0.5% in the app intervention arm versus 40% (12/30) in the standard of care arm (odds ratio 2.29, 95% CI 0.94-5.6; P=.09). Participants had higher odds of a therapy escalation while in the standard of care arm (18/30, 60% vs 5/30, 16.7%, odds ratio 4.3, 95% CI 1.2-15.2; P=.02). The median MPR prior to enrollment was 109%, 112% during the study's intervention arm, and 102% during the standard of care arm. The median real-time MAS was 93.2%. The change in MAS (1 vs –0.1; P=.02) and SEAMS (1.9 vs –0.2; P<.001) from baseline to month 3 was higher in the intervention arm compared to standard of care.

Conclusions: A novel smartphone app with patient-response-directed provider intervention holds promise in the ability to improve blood glucose control in complex non–insulin-dependent T2DM and is worthy of additional study.

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KEYWORDS

application; biguanide; blood glucose; case-crossover; diabetes management; diabetes; diabetic; digital health intervention; epidemiology; glucose monitoring; glucose; HbgA1c; hemoglobin A1c; hemoglobin; hyperlipidemia; hypertension; interquartile range; IQR; MAS; Medication Adherence Scores; medication adherence; mobile health intervention; mobile phone; odds ratio; paired t test; quasi experimental; SEAMS; Self-Efficacy for Appropriate Medication Use Scale; smartphone; sulfonylurea; T2DM; Type 2 Diabetes Mellitus; veteran

Introduction

Medication nonadherence is a problem that impacts both the patient and the health system. Medication nonadherence results in undesirable clinical outcomes, especially in patients with chronic diseases, as well as increases in health care resource consumption [1]. The International Society of Pharmacoeconomics and Outcomes Research (ISPOR) has identified that 33%-69% of medication-related hospitalizations are due to poor adherence, accounting for up to US $100 billion in annual health care costs [2,3].

Specifically, medication nonadherence has been identified as a major problem in the management of patients with type 2 diabetes mellitus (T2DM). Studies have shown only 40%-60% of patients maintain a proportion of days covered (PDC), defined as the proportion of days over a given period that a patient has medication available to take, of ≥80%, and only 45% of patients with T2DM are able to maintain glycemic control during treatment [1,4,5]. In patients with T2DM, nonadherence has been correlated with poor glycemic control, exposing patients to significant long-term complications of the disease [4]. Improvements in medication adherence in this population have been shown to improve clinical outcomes as well as reduce health care costs [6,7].

Specific to the "veteran" population, T2DM affects greater than 20% of veterans compared to 8% of the general population [8]. Studies have shown that 73% of veterans are nonadherent with their medications [8]. The number of medications and complexity of their medication regimen were associated with increased rates of nonadherence [8].

Thus, with the known importance of medication adherence in problems such as T2DM, considerable research efforts have been put forth to improve adherence and attendant health outcomes. Advances in technology have been shown to improve medication adherence in a wide range of disease states [9-20]. Automated alerts have been shown to improve medication adherence in patients with hypertension [10]. Smartphone apps have demonstrated increased patient awareness and improved medication adherence in T2DM [9,15,17]. Automated reminders, along with pharmacist intervention, have improved glycemic control as well as medication adherence in patients with diabetes [6,11]. A limitation of all these studies is the use of "medication possession ratio" (MPR), PDC, or "medication administration score" (MAS) as a surrogate marker for medication adherence. These measures have significant limitations and bias toward an overestimation of true adherence. Current measures also lack auditable information that could be reviewed by the patient care team in directing interventions. Due to such limitations with current technologies, many of these studies have failed to demonstrate clinically meaningful improvement in patients' control of chronic disease states [6,9,10]. Within the veteran population, continued challenges remain in improving medication adherence and the attendant morbidity of uncontrolled diabetes.

The purpose of this study was to operationalize a pragmatic study design to evaluate the impact of a novel smartphone app that provides customizable medication alerts, real-time auditable adherence data, and a novel engagement system on medication adherence and blood glucose control in a single-site health care system.

Methods

Study Design

In a pragmatic, quasi-experimental pilot study approach, we employed a case-crossover design where participants underwent both a standard of care arm as well as an intervention arm. Study participants were assigned in alternating blocks of 5 to either a standard of care arm followed by intervention or intervention followed by standard of care. Each study arm was 3 months long, for a total of 6 months of follow-up. Participants had a hemoglobin A_{1c} (HbA_{1c}) lab draw and MPR assessment at enrollment, 3 months, and 6 months. In addition to structured lab draws and MPR assessments, participants had the MAS and "Self-Efficacy for Appropriate Medication Use Scale" (SEAMS) questionnaires completed at baseline and monthly for the 6-month study duration. For additional information on trial design, medication adherence scoring measures, participant recruitment, and sample size determinations, see Multimedia Appendix 1.

Subject Recruitment

Participants were recruited from the Veterans Affairs Sierra Nevada Health Care System (VASNHCS) between March and November 2021. The VASNHCS is a Veterans Affairs (VA) medical center that provides care to more than 30,000 US military veterans across a large geographical area comprised primarily of rural and highly rural communities. The Veterans Health Administration (VHA) provides comprehensive health and pharmacy benefits to all enrolled veterans. Potential participants were identified and recruited using the VHA corporate data warehouse. Participants older than 18 years with uncontrolled T2DM on active treatment were identified and contacted for participation. Potential participants were recruited in descending priority according to the number of previous HbA_{1c} greater than 8.5% in the last 2 years and were excluded if they were on insulin or were initiated on insulin during the study period. Potential participants were also excluded if they did not own a smartphone or were unable to download the smartphone app and create a user account. There was no formal assessment of technology literacy.

Standard of Care

The VASNHCS provides comprehensive clinical, specialty, and pharmacy care to all enrolled veterans. Study participants enrolled in the standard of care arm were provided medication reconciliation counseling focused on adherence strategies. They were then instructed to continue to follow up with either their primary care provider or endocrinologist. Participants' primary care providers and endocrinologists were free to modify their medications, prescribe new medications, and discontinue medications in accordance with the VA national formulary and current clinical practice guidelines.

Intervention

In addition to medication reconciliation and counseling on medication adherence, participants were provided with a novel smartphone app, DayaMed Arthur (DayaMedicals Incorporated), configured with their current medications. The app provided accurate prompts and reminders to participants to take all medications as directed and paired with caregivers to notify them of medication administration status. The app medication reminders were set up so that they required a participant's response or action to be satisfied. See Multimedia Appendix 2 for additional information on app reminders and the digital incentivization program.

Clinical Outcomes

Our primary outcomes of interest were the change in HbA_{1c} compared between the smartphone app intervention arm and the standard of care. Secondary outcomes focused on the evaluation of the difference in proportion of participants able to achieve a clinically meaningful reduction in A_{1c}, defined as 0.5%, and the differences in the proportion of participants that required escalation of diabetes medication therapy. Therapy escalation was defined as the addition of a new therapy or an increase in the dose of an existing therapy to the participant's regimen for the treatment of diabetes. If a participant was converted from a dipeptidyl peptidase-4 inhibitor (DPP4-I) to a glucagon-like peptide-1 (GLP-1) agonist, this was also considered a therapy escalation. De-escalation was considered when a medication dose for the treatment of diabetes was decreased or discontinued. Exploratory outcomes included differences in visits for the management of T2DM as well as the analysis of the variation and changes in MPR, MAS, and SEAMS during each study arm.

Statistical Methods

We used a modified intent-to-treat approach to complete our analyses. Participants who did not undergo both study arms were excluded from the analyses. Participants were included in the analysis regardless of engagement with the study intervention and care team, provided all lab draws and surveys were completed. The primary end point of the difference in mean reduction HbA_{1c} between the intervention and control groups was evaluated using a paired *t* test. Secondary outcomes of the proportion of participants achieving a reduction of HbA_{1c} of greater than or equal to 0.5% and the proportion of participants requiring therapy escalation were evaluated using McNemar's test. Other exploratory outcomes included descriptive analysis evaluating the baseline and change in MAS and the change in SEAMS from baseline to completion of each study arm (intervention and standard of care).

Ethics Approval

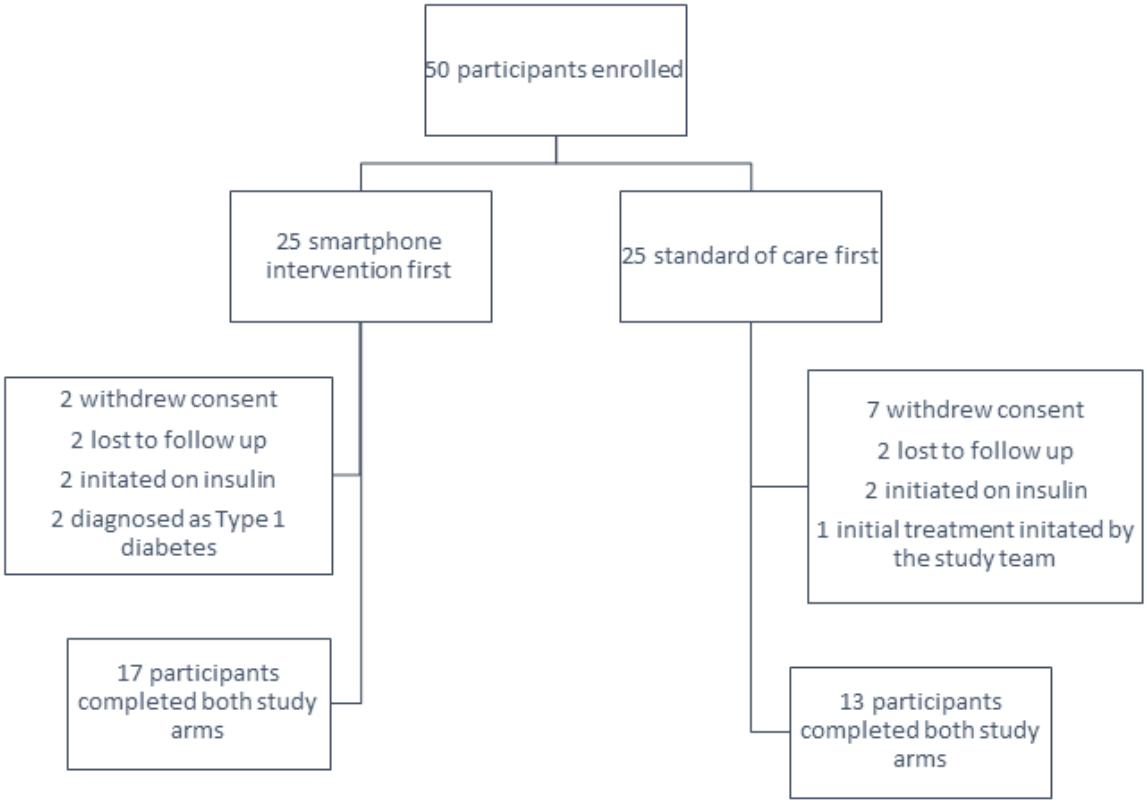
This study was reviewed and approved by the University of Nevada, Reno Institutional Review Board (1655381-2). All study participants provided written informed consent before the initiation of any study activities.

Results

Study Population

A total of 50 participants were enrolled over an 8-month period. Out of which 9 participants withdrew consent, 4 participants were lost to follow-up, 4 participants were initiated on insulin, 1 participant was initially diagnosed and initiated on treatment by the study team, and 2 participants were later identified as latent-onset type 1 diabetics. Resulting in 30 evaluable participants (Figure 1) who completed both study arms. Dropouts were twice as high in participants who were enrolled in the standard of care arm first compared to the intervention arm (9/25, 36% vs 4/25, 16%). Only 2 participants dropped out while actively on the app; both traveled frequently and struggled with alerts not adapting to changing time zones. All other participants withdrew during the standard of care arm, primarily due to unwillingness to continue monthly surveys and every 3-month lab draw.

Figure 1. Description of study enrollment and retention.



Participants had a median HbA_{1c} of 9.1% (IQR 8.6%-9.6%) and had been living with T2DM for 6 (IQR 3-10) years with a median BMI of 30.8 (IQR 28.2-36.3). Participants had significant comorbidities, most commonly hypertension and hyperlipidemia. The median age of study participants was 66 (IQR 56.25-73.25) years and all were male. Participants were on a median of 8.5 (IQR 6.3-11) medications and 3 (IQR 2-3) medications for the management of diabetes. The most common medication classes for the treatment of diabetes were biguanides (29/30, 96.7%) and sulfonylureas (19/30, 63.3%). New novel medications were also used by participants enrolled in the study, with 6/30, 20% on a GLP-1 agonist and 11/30, 36.7% on a sodium-glucose cotransporter-2 (SGLT2) inhibitor. Of note, all but 1 participant were prescribed statin therapy. Overall, the evaluable participants were similar to the population which dropped out or was excluded from analysis in regard to age, HbA_{1c} at baseline, BMI, MPR, time since first T2DM diagnosis, and comorbidities. The population that dropped out differed on the median number of total medications (5 vs 8.5; *P*=.01). The lower medication burden may have played a factor in participants' decisions to withdraw from the study. See Multimedia Appendix 3 for the complete study demographic table.

Review of Clinical Outcome Results

The average HbA_{1c} reduction was 0.69% while participants were in the smartphone app intervention arm versus 0.35% in the standard of care arm (*P*=.30) (Table 1). The SD in both groups was large (0.92% vs 1.30%), pointing toward significant variation in total HbA_{1c} change by participant, which was expected. A total of 21/30 (70%) participants achieved a clinically meaningful reduction in HbA_{1c} of 0.5% in the app intervention arm versus 12/30 (40%) in the standard of care arm (odds ratio 2.29, 95% CI 0.94-5.6; *P*=.09). A total of 16/17 (94.1%) participants in the intervention first arm achieved an HbA_{1c} reduction greater than or equal to 0.5% while on the smartphone app intervention, compared to only 4/13 (30.8%) in the standard of care first arm. A total of 8/13 (72.7%) participants sustained or improved reductions in HbA_{1c} when assigned to the intervention following the standard of care arm. Conversely, only 9/17 (56.2%) participants sustained or improved on HbA_{1c} reductions achieved during the intervention arm when switched to standard of care. Participants had statistically significantly higher odds of a therapy escalation while in the standard of care arm than while on the intervention (n=18/30, 60% vs n=5/30, 16.7%; odds ratio 4.3, 95% CI 1.2-15.2; *P*=.02). Additionally, 3 participants had therapy de-escalated while on the intervention, compared to 0 participants while on the control arm. Therapy escalation was split evenly between participants assigned to the intervention first and the standard of care first (8/17, 47.1% vs 7/13, 53.8%).

Table 1. Comparison of intervention outcomes in case-crossover study of a digital intervention versus standard of care.

	Intervention (n=30)	Standard of care (n=30)	*P* value
Primary effectiveness outcome			
Change in HbA_{1c}[a], mean (95% CI)	0.69 (0.36 to 1.02)	0.35 (−0.12 to 0.82)	.30
Secondary effectiveness outcome			
≥0.5% HbA_{1c} reduction, n (%)	21 (70)	12 (40)	.09
Therapy escalated, n (%)	5 (16.7)	18 (60)	.02
Therapy de-escalation, n (%)	3 (10)	0 (0)	—[b]
Visits for T2DM[c], median (IQR)	2 (1 to 3)	2 (1 to 3)	—
Medication adherence scores			
MPR[d], median (IQR)	112 (100 to 130)	102 (98.5 to 127)	.37
RMA[e], median (IQR)	93.2 (79.3 to 99.1)	—	—
Change in MAS[f], mean (95% CI)	1 (0.48 to 1.52)	−0.10 (−0.54 to 0.34)	.02
Change in SEAMS[g], mean (95% CI)	1.90 (0.86 to 2.94)	−0.20 (−0.56 to 0.16)	<.001

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

[b]Not available.

[c]T2DM: type 2 diabetes mellitus.

[d]MPR: medication possession ratio.

[e]RMA: real-time medication adherence score.

[f]MAS: medication administration score.

[g]SEAMS: self-efficacy of appropriate medication use scale.

The median MPR for the 6 months before enrollment was 109% for the study population. During the study intervention arm, MPR was 112% (IQR 100%-130%) and 102% (IQR 98.5%-127%) during the standard of care arm. Despite the MPR maintaining above 100% on average, the median real-time medication adherence (RMA) was estimated to be 93.2% (IQR 79.3%-99.1%). The average baseline MAS was 6 out of 8, defined as moderate adherence, and the baseline SEAMS was 41.5 out of 45, defined as high confidence. The change in MAS (1.0 vs −0.1; *P*=.02) and SEAMS (1.9 vs −0.2 *P*<.001) from baseline to month 3 was higher in the intervention arm compared to standard of care. Overall, there was significant variation between the different adherence scores, though most trended toward moderate to good adherence. MPR and SEAMs appear to report higher adherence rates, whereas MAS and RMA reported moderate adherence rates in study participants. The smartphone app intervention appeared to improve participant MPR, self-reported adherence rates through the MAS, and confidence around medication adherence, as reported by SEAMS. These changes were incremental, but they may represent more significant improvements in true medication adherence.

Discussion

Principal Findings

Under conditions of a pragmatic pilot study design, we were able to demonstrate that a novel smartphone medication adherence app demonstrated positive effects in improving medication adherence, patient confidence in their ability to adhere to their medication plan, and blood glucose control in a single-center study among veterans with chronically uncontrolled T2DM. While not achieving statistical significance for our primary end point, the reduction in HbA_{1c} while on the smartphone app trended toward significance, as did the proportion of participants who achieved a clinically meaningful reduction in HbA_{1c}. Additionally, participants in the intervention had 4 times lower odds of having an escalation of therapy compared to the standard of care. Given that the study was a cross-over design, therapy escalation in participants initially enrolled in the control arm could have skewed the HbA_{1c} reduction observed in the following intervention arm. However, the escalation of therapy was split evenly between the app first and standard of care first intervention groups. Additionally, HbA_{1c} reduction was consistently observed while participants were on the intervention in both groups. Finally, HbA_{1c} levels appeared to increase when the smartphone app intervention was removed in the app first group, while HbA_{1c} reductions were increased or sustained in the standard of care first group when the smartphone app intervention was added (Multimedia Appendix 4). Collectively, these data corroborate currently published data, suggest that the intervention has a positive impact on lowering blood glucose in patients with complex uncontrolled T2DM, and provide preliminary evidence to support a larger, more definitive study.

An interesting and unexpected finding in the analysis was the difference in therapy escalation and de-escalation between the smartphone app and standard of care observation periods. The

overall proportion of participants with an escalation of their diabetes medications during the 3 months of the standard of care arm was 60% (18/30), compared to 17% (5/30) in the intervention arm periods. We were unable to find comparative data with similarly complex participants over a similar duration of follow-up to compare our findings, though this would appear to be a clinically meaningful observation. In a posthoc analysis, we evaluated a matched retrospective cohort (N=60) in which medication escalation was observed in 35/60 58.3% of participants over a 3-month period (Multimedia Appendix 5). This data suggests that the smartphone app intervention may impact therapy escalation, which is meaningful in the management of chronic progressive disease states such as diabetes. A better understanding of the duration of this effect on therapy escalation needs to be evaluated in future studies of this and other adherence interventions.

In our exploratory objective to evaluate different measures of medication adherence, we found significant variation in reported adherence metrics. MPR consistently overestimated adherence and was not able to provide granularity on adherence patterns. RMA provided a more accurate review of medication adherence and an understanding of adherence patterns. Participants' self-reported adherence scores increased while on the app, which was reflective of patient self-reporting during study visits that the smartphone app increased their confidence in understanding their medication regimen. This finding supports the current literature, which has demonstrated that automated reminders improve participants self-reported adherence scores. In the intervention first cohort, the improvement in self-reported medication adherence scores during the intervention arm was not sustained during the standard of care arm, indicating that perhaps 3 months of app use are not sufficient to build long-lasting habits around medication adherence. It is possible that medication changes during the control arm may have also contributed to reductions in self-reported medication adherence scores. Future research is needed to evaluate the optimal duration of app engagement (or other medication adherence interventions) required to build lasting habits and the impact of new medication changes on established medication adherence habits.

Limitations

As this was a pilot study, inherent limitations included the small sample size, high rate of dropout, and quasi-experimental cross-over study design. For this pragmatic point-of-care pilot study, we successfully enrolled 50 participants over an 8-month period. Our dropout and exclusion rates were higher than anticipated, with only 30 participants completing the study and being included in the final analysis. We believe the complexity of the population and long-term history of uncontrolled diabetes contributed to the fact that engagement in the standard of care arm was minimal and resulted in 7 of 9 participants withdrawing from the study and 4 participants being lost to follow-up. It is possible that including a nominal incentive in future studies would increase sustained participation in the standard of care arm. Lack of patient engagement in care and commitment to lifestyle modification is a known challenge in the management of patients with chronic disease states, including T2DM. Of note, only 2 participants withdrew consent, and none were lost to follow-up while on the smartphone app. This difference in dropout and lost to follow-up may be due to participants feeling more engaged with their care and care team while using the app, which provides daily alerts, specific notifications, prompts calls from the study team, and a unique nonmonetary incentivization system. Additional research is needed to better understand this difference, as improved engagement using smartphone apps may provide meaningful improvement in health outcomes across populations. With the small sample size of this study, we planned to conduct a cross-over study to ensure comparison groups were balanced in subject complexity. The limitation of this approach is the lack of a truly independent intervention; however, we felt this trade-off was acceptable in this first pilot study and ensured groups were similar for analysis.

Other limitations in our analysis are that the study was conducted in a single center in northern Nevada and limited to the veteran population, and that the treatment and management of diabetes were managed by the participant's established primary care provider or endocrinologist. While our clinical care setting may not reflect more urban settings, our rural and highly rural population provides new insights into potential solutions for this population, which is significantly underrepresented in research. Deferring the management of diabetes to the care team allowed for variability in prescribing practice to potentially impact the results. The VA has a structured formulary and management guidelines that aim to ensure consistent quality care across the veteran population. We feel that this structure limits the potential impact of significant interprovider variability.

Conclusions

A novel smartphone app with patient-response-directed provider intervention holds promise in its ability to improve blood glucose control in complex noninsulin-dependent T2DM and is worthy of additional study. This system of intervention may be a viable solution to reduce the medication burden by being a noninvasive method of reducing the need for diabetes medication escalation. RMA provides more granular and actionable detail on patient medication adherence for the care team compared to MPR. A smartphone app with built-in medication alerts can improve patients self-reported medication adherence scores and confidence in taking their medications. However, a 3-month duration of use is not sufficient to build long-lasting improvements in medication adherence or patient confidence.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Additional detailed information related to study design, adherence scoring metrics, and sample size determinations.
[PDF File (Adobe PDF File), 278 KB - diabetes_v8i1e44297_app1.pdf]

Multimedia Appendix 2
Detailed information on application alerts and digital incentivization strategy.
[PDF File (Adobe PDF File), 636 KB - diabetes_v8i1e44297_app2.pdf]

Multimedia Appendix 3
Characteristics of study subjects enrolled in case-crossover study.
[DOCX File , 15 KB - diabetes_v8i1e44297_app3.docx]

Multimedia Appendix 4
Graph of median hemoglobin A_{1c} between study groups.
[PDF File (Adobe PDF File), 57 KB - diabetes_v8i1e44297_app4.pdf]

Multimedia Appendix 5
Matched cohort.
[DOCX File , 14 KB - diabetes_v8i1e44297_app5.docx]

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Abbreviations

DPP4-I: dipeptidyl peptidase-4 inhibitor
GLP-1: glucagon-like peptide-1
HbA_{1c}: hemoglobin A_{1c}
ISPOR: International Society of Pharmacoeconomics and Outcomes Research
MAS: medication adherence score
MPR: medication possession ratio
PDC: proportion of days covered
RMA: real-time medication adherence
SEAMS: Self-Efficacy for Appropriate Medication Use Scale
SGLT2: sodium-glucose cotransporter-2
T2DM: type 2 diabetes mellitus
VA: veterans affairs
VASNHCS: Veterans Affairs Sierra Nevada Health Care System
VHA: Veterans Health Administration

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Original Paper

Assessing the Content Validity, Acceptability, and Feasibility of the Hypo-METRICS App: Survey and Interview Study

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Abstract

Background: The Hypoglycaemia – MEasurement, ThResholds and ImpaCtS (Hypo-METRICS) smartphone app was developed to investigate the impact of hypoglycemia on daily functioning in adults with type 1 diabetes mellitus or insulin-treated type 2 diabetes mellitus. The app uses ecological momentary assessments, thereby minimizing recall bias and maximizing ecological validity. It was used in the Hypo-METRICS study, a European multicenter observational study wherein participants wore a blinded continuous glucose monitoring device and completed the app assessments 3 times daily for 70 days.

Objective: The 3 aims of the study were to explore the content validity of the app, the acceptability and feasibility of using the app for the duration of the Hypo-METRICS study, and suggestions for future versions of the app.

Methods: Participants who had completed the 70-day Hypo-METRICS study in the United Kingdom were invited to participate in a brief web-based survey and an interview (approximately 1h) to explore their experiences with the app during the Hypo-METRICS study. Thematic analysis of the qualitative data was conducted using both deductive and inductive methods.

Results: A total of 18 adults with diabetes (type 1 diabetes: n=10, 56%; 5/10, 50% female; mean age 47, SD 16 years; type 2 diabetes: n=8, 44%; 2/8, 25% female; mean age 61, SD 9 years) filled out the survey and were interviewed. In exploring content validity, participants overall described the Hypo-METRICS app as relevant, understandable, and comprehensive. In total, 3 themes were derived: hypoglycemia symptoms and experiences are idiosyncratic; it was easy to select ratings on the app, but day-to-day changes were perceived as minimal; and instructions could be improved. Participants offered suggestions for changes or additional questions and functions that could increase engagement and improve content (such as providing more examples with the questions). In exploring acceptability and feasibility, 5 themes were derived: helping science and people with diabetes; easy to fit in, but more flexibility wanted; hypoglycemia delaying responses and increasing completion time; design, functionality, and customizability of the app; and limited change in awareness of symptoms and impact. Participants described using the app as a positive experience overall and as having a possible, although limited, intervention effect in terms of both hypoglycemia awareness and personal impact.

Conclusions: The Hypo-METRICS app shows promise as a new research tool to assess the impact of hypoglycemia on an individual's daily functioning. Despite suggested improvements, participants' responses indicated that the app has satisfactory content validity, overall fits in with everyday life, and is suitable for a 10-week research study. Although developed for research purposes, real-time assessments may have clinical value for monitoring and reviewing hypoglycemia symptom awareness and personal impact.

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KEYWORDS

hypoglycemia; diabetes; ecological momentary assessment; smartphone app; content validity; mobile phone

Introduction

Background

Hypoglycemia, or low blood glucose, is a common complication of insulin treatment among people with type 1 diabetes mellitus (T1DM) and insulin-treated type 2 diabetes mellitus (T2DM). Hypoglycemia can result in neurocognitive impairment [1] and can be debilitating, adversely affecting multiple aspects of quality of life (eg, work life and relationships) for people with diabetes and their family members [2-4].

The Hypoglycaemia – MEasurement, ThResholds and ImpaCtS (Hypo-METRICS) app was developed for research purposes and uses ecological momentary assessments (EMAs) to capture the impact of hypoglycemia on daily functioning in adults with T1DM or insulin-treated T2DM [5,6]. EMA refers to the repeated assessment of experiences and behavior in real time and in the usual environment of the participants [7]. The Hypo-METRICS app is currently being used for the first time in the Hypo-METRICS clinical study, a European multicenter observational study conducted under the Hypoglycaemia - REdefining SOLutions for better liVEs (Hypo-RESOLVE) project [8]. One aim of the Hypo-METRICS study was to investigate participants' experiences and the impact of hypoglycemia via a smartphone device 3 times per day (morning, afternoon, and evening *check-ins*) for 70 consecutive days. In addition to their usual method of glucose monitoring, participants wore a blinded continuous glucose monitor (CGM) to record their glucose levels in real time for research purposes. The Hypo-METRICS app enables researchers to investigate the impact of hypoglycemia temporally closer to the occurrence of the episode or episodes, reducing the risk of recall bias and confounding variables. Furthermore, by using smartphones, responses are captured during the participants' day-to-day lives, not in a hospital or research laboratory setting, thereby optimizing ecological validity [7].

The app was designed iteratively, informed by an independent group of adults with diabetes and a multidisciplinary team of psychologists, diabetologists, health economists, industry partners, and members of the Hypo-RESOLVE consortium patient advisory committee. All stakeholders provided feedback on the content (questions and response options). Content validity is "the degree to which the content of an instrument is an adequate reflection of the construct to be measured" and can be considered in terms of relevance, comprehensiveness, and comprehensibility [9]. Although the content validity of the Hypo-METRICS app was addressed during its development, the COSMIN (Consensus-based Standards for the Selection of Health Measurement Instruments) guidelines for exploring the quality of person-reported outcome measures [9] recommend that new instruments be subjected to additional content validity studies in independent samples.

Objectives

The first aim of this study was to explore whether the app is "fit for purpose" by investigating its content validity. The second aim was to explore the use of the app in the Hypo-METRICS clinical study in terms of both acceptability (eg, ease of use) and feasibility (eg, completion multiple times per day over 10 wk). The third aim was to explore participants' suggestions for future versions of the app.

Methods

Design

This study was conducted as part of the European Hypo-METRICS clinical study, initiated in October 2020. The

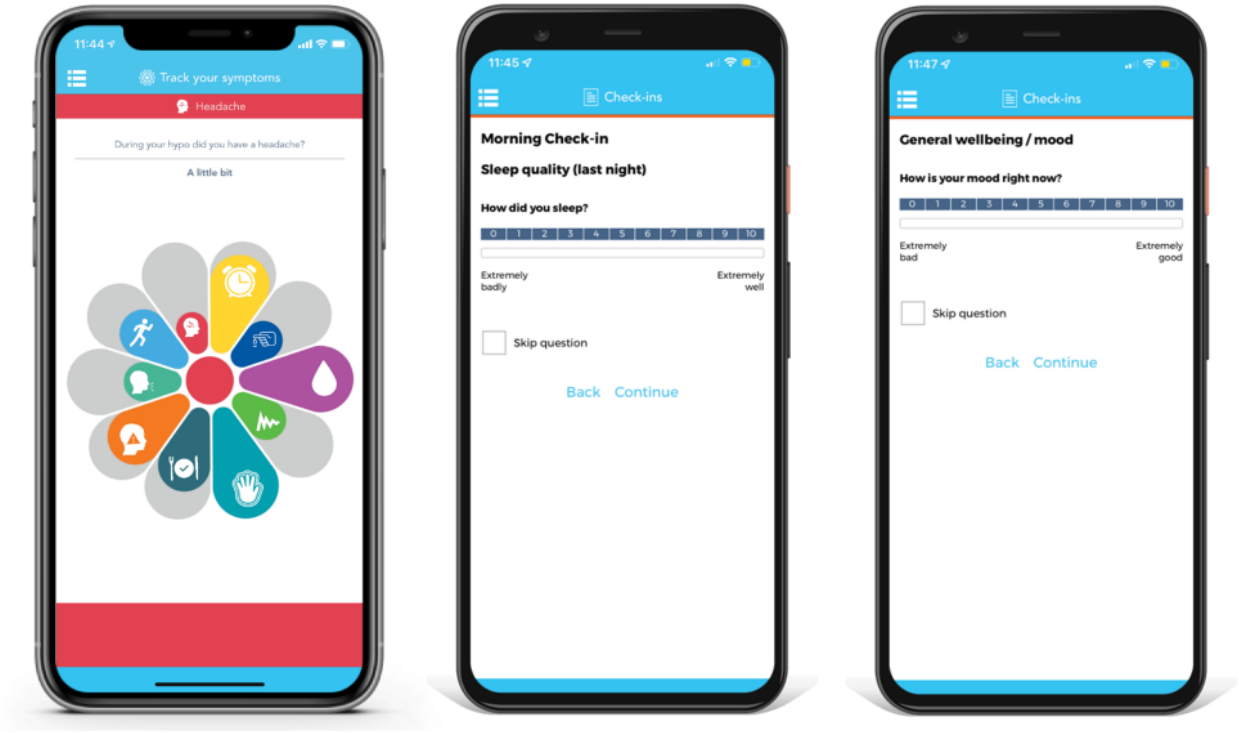
study consisted of a short web-based survey (quantitative data) followed by an interview (qualitative data). This combined-method design was used to address the research question. This manuscript followed the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist [10] (Multimedia Appendix 1). Details of the overall 10-week Hypo-METRICS study have been published previously [5,8].

The Hypo-METRICS App

The Hypo-METRICS app comprises 29 unique items, forming 7 modules, and uses EMA to examine how hypoglycemia affects daily functioning among adults with T1DM or insulin-treated T2DM [5] (content available in Multimedia Appendix 1). The app was administered via the uMotif Limited platform [11]. Daily functioning includes sleep quality, overall mood, energy levels, negative affect, cognitive functioning, fear of high and low glucose levels, social functioning, and work-related questions. Additional questions capture details of each episode of hypoglycemia (including how it was detected and managed; Multimedia Appendix 1). Participants could only complete each of the check-ins within predefined time intervals (morning: 6 AM to noon; afternoon: noon to 6 PM; evening: 6 PM to midnight). Notifications were sent to remind participants to complete each of the 3 daily check-ins (at 7 AM, 3 PM, and 9 PM). The full details of the Hypo-METRICS app development have been described previously [5].

In addition to the check-ins, other features were included in the app for other research purposes, including the *Motif*, which participants were asked to complete after each hypoglycemic episode—and which was used to document hypoglycemic symptoms—by moving the Motif slider to record their response (Figure 1 and Multimedia Appendix 1).

Figure 1. Screenshots of the Hypo-METRICS app on the uMotif Limited platform (left: Motif for recording symptoms; middle and right: check-ins for describing daily functioning and hypoglycemia).



Study Participants and Recruitment

Participants from clinical sites in the United Kingdom were eligible to participate if they (1) had completed the 70-day Hypo-METRICS clinical study (key inclusion criteria were having T1DM or insulin-treated T2DM and at least one episode of hypoglycemia in the past 3 months [8]), (2) had access to a computer and internet, and (3) were willing to complete a web-based survey and a semistructured interview. Participants were approached (via email or telephone or at the clinic) by the research team and invited to take part. Purposive sampling was used to recruit a heterogeneous subsample of participants (eg, across sexes, types of diabetes, age groups, and check-in completion rates). Participants were not compensated for taking part in the interviews.

Data Collection

Participants who expressed interest in the interview study received an email including the participant information sheet and provided written consent for participation. Participants' sociodemographic and clinical characteristics were collected from the Hypo-METRICS REDCap (Research Electronic Data Capture; Vanderbilt University) database. Typically, a few days before their interview, participants completed a brief web-based survey via Qualtrics (Qualtrics International Inc) reflecting on their overall experiences with the Hypo-METRICS app, including (1) motivation to fill in the check-ins, (2) relevance of the check-in questions, (3) understandability of the check-in questions, (4) ease or difficulty of learning how to use the check-ins, (5) design or look of the check-ins, and (6) overall ability to capture the true impact of hypoglycemia (see questions

and scales in Multimedia Appendix 1). Each of these questions could be rated on a scale of 0 to 10, with higher ratings indicating a more positive experience. The survey was developed by a core group of the investigators (US, NZ, MB, CH, JS, PC, and FP) and assessed by the remaining coauthors to confirm its face validity.

A semistructured interview guide was developed to explore (1) the content validity of the app and (2) acceptability and feasibility (Multimedia Appendix 1). The interview guide was developed based on similar studies [12], the Mobile App Rating Scale [13], and the COSMIN content validity manuals [9]. All interviews were conducted in English via Zoom (Zoom Video Communications) and audio recorded with the participants' permission. During the interviews, the participants viewed the app items via a shared screen to help them remember the content. The researcher (US) who led the interviews was a Doctor of Philosophy student (University of Southern Denmark, Odense) at the time of the interviews and received additional training on conducting qualitative research as part of his Doctor of Philosophy training. He had previously conducted cognitive debriefing interviews as part of the translation of the Hypo-METRICS app [5] and received communication training as part of his medical degree. No participants had any previous interactions with US, only knowing that he was a member of the Hypo-METRICS team. The second researcher (NZ), who was present during the interviews, is an experienced qualitative researcher and has had training in qualitative research throughout her Master of Science in Health Psychology and has received further training in qualitative research through the University of Oxford Medical Sociology and Health Experiences Research Group.

In line with the aims and deductive methods of the proposed analysis, the authors followed the procedure recommended by Halcomb and Davidson [14], which consists of extensive field note taking in lieu of full verbatim transcription [15-17]. Researcher US interviewed the participants while NZ took field notes and assisted with prompt questions. After completing the first 2 interviews, NZ and US amended the interview guide based on the initial field notes. After each interview, NZ reviewed the field notes and added to them. Next, US and JLA listened to the audio-recorded interviews one or more time or times to ensure that the field notes represented the interactions in the interview. They added verbatim quotes that were useful to illustrate participants' feedback and amended the notes if necessary. Recordings and notes were saved on a code-secured external hard drive. The notes and findings were not returned to the participants for comments. During the data collection period, US and NZ met with the wider research team to discuss preliminary findings and amendments to the interview guide. Most of the conversations during the interviews were centered on the 3 check-ins, but participants also shared their experiences with the Motif. If not specified, the descriptions in this paper refer to the check-ins.

Data Analysis

Descriptive statistics were used to summarize participants' demographic and clinical characteristics as well as their responses to the web-based survey. These data were presented as numbers and percentages or means and SDs. The notes from the semistructured interviews were uploaded to NVivo (version 11; QSR International) to perform coding and thematic analysis. A deductive approach (theory driven using the research aims described previously) for the initial analysis was followed. Despite this deductive approach (in particular for aim 1), an inductive process to identify themes was used following general principles of the iterative process outlined by Braun and Clarke [18]. An initial coding framework was agreed upon by US and NZ and followed by independent double coding of 20% of the interview notes. Candidate themes were discussed and revised by all authors, and a consensus was reached on the themes to include. Developers' perspectives on the suitability of the proposed changes were drafted by US and reviewed and amended by the remaining coauthors.

Ethical Considerations

Ethics approval was obtained from the South Central–Oxford B Research Ethics Committee (20/SC/0112).

Results

Overview

Of the 49 participants from the Hypo-METRICS study who were approached, 18 (37%) adults with diabetes were interviewed (T1DM: n=10, 56%; 5/10, 50% female; mean age 47, SD 16 years; T2DM: n=8, 44%; 2/8, 25% female; mean age 61, SD 9 years; Table 1). The interview duration ranged from 29 to 81 (mean 53, SD 15) minutes. All participants completed the brief web-based survey before the interviews.

A total of 8 themes were derived from the interview data and organized by study aim (Textbox 1).

Table 1. Participant characteristics.

Characteristic	Type 1 diabetes (n=10)	Type 2 diabetes (n=8)
Sex (female), n (%)	5 (50)	2 (25)
Age (years), mean (SD)	47 (16)	61 (9)
Recruitment site, n (%)		
Cambridge	1 (10)	0 (0)
King's College London	3 (30)	4 (50)
Dundee	0 (0)	1 (12)
Sheffield	6 (60)	3 (38)
Employment, n (%)		
Full time	5 (50)	3 (38)
Part time	1 (10)	1 (12)
Unemployed (but not actively looking for work)	1 (10)	0 (0)
Retired	3 (30)	4 (50)
Impaired awareness of hypoglycemia (Gold score of >4), n (%)	5 (50)	1 (12)
Diabetes duration (y), mean (SD)	26 (16)	16 (8)
HbA_{1c} (mmol/mol), mean (SD)	58.06 (13.54)	57.19 (20.77)
HbA_{1c} (%), mean (SD)	7.46 (1.24)	7.38 (1.90)
Glucose monitoring modality, n (%)		
Flash	5 (50)	2 (25)
Finger prick	5 (50)	6 (75)
App check-in completion rates (%), mean (SD)		
Morning check-ins	85.14 (9.48)	86.43 (10.66)
Afternoon check-ins	75.29 (11.35)	86.79 (11.16)
Evening check-ins	85.00 (7.66)	94.64 (5.70)
Total completion rate	81.81 (8.37)	89.29 (8.76)
Web-based survey ratings[a], mean (SD)		
Motivation to use the check-ins	7.80 (1.62)	8.88 (1.13)
Relevance of the check-in questions	7.20 (1.93)	8.50 (1.41)
Understandability of the check-in questions	7.80 (2.15)	8.75 (1.28)
Ease or difficulty of learning how to use the check-ins	7.40 (2.22)	9.38 (0.74)
Design or look of the check-ins	7.50 (1.43)	8.75 (1.16)
Overall ability to capture the true impact of hypoglycemia	6.60 (1.65)	7.38 (1.60)

[a]Possible ratings: 0 to 10. Higher ratings indicate more positive experiences. The full questions and response options are available in Multimedia Appendix 1.

Textbox 1. Themes by study aim.

Aim 1: exploring content validity

- Theme 1.1: hypoglycemia symptoms and experiences are idiosyncratic
- Theme 1.2: easy to select ratings on the app, but day-to-day variation was perceived as minimal
- Theme 1.3: instructions could be improved

Aim 2: exploring the feasibility and acceptability of using the Hypo-METRICS app

- Theme 2.1: helping science and people with diabetes
- Theme 2.2: easy to fit in, but more flexibility wanted
- Theme 2.3: hypoglycemia delaying responses and increasing completion time
- Theme 2.4: design, functionality, and customizability of the app
- Theme 2.5: limited change in awareness of symptoms and impact

Aim 3: suggestions for future versions of the app

Exploring Content Validity

Overview

The mean responses to the web-based survey questions were all >6.50 on the scale from 0 to 10 (Table 1), with individual scores ranging from 3 to 10. Multimedia Appendix 2 provides an overview of the web-based survey topics, together with suggested changes by participants (mentioned during the interviews), followed by the Hypo-METRICS app developers' comments on the suitability of implementing the suggested changes.

Hypoglycemia Symptoms and Experiences Are Idiosyncratic

The quantitative data from the cognitive debriefing survey showed that participants with T1DM and T2DM generally found the check-in questions relevant (mean rating 7.20, SD 1.93 and 8.50, SD 1.41, respectively) and easy to understand (mean rating 7.80, SD 2.15 and 8.75, SD 1.28, respectively).

In terms of daily functioning, participants' views regarding the relevance of the questions varied. Although some participants could pinpoint certain areas that were not relevant to them (eg, "I certainly have no fear of having a hypo" or "I rarely feel anxious"), generally, they "could see why the questions were being asked" and appreciated their potential relevance to others. Some expressed that relevance was context specific:

[The questions] *weren't necessarily relevant to me at that particular moment, but they could be if I were* [having], *or had just had a hypo.*

Participants expressed that it was "important" that the app "covered both mental well-being and physical well-being" and generally that the app "acknowledged" how hypoglycemia can "cause other symptoms like grumpiness or forgetfulness" instead of focusing only on whether it happened. Although most participants mentioned that some of the listed symptoms in the Motif were not personally relevant to them, generally, they considered its content relevant. Most participants could mention at least some symptoms listed on the Motif that they had when experiencing hypoglycemia, but others explained that "it just didn't capture very many" of their symptoms. One participant explained that some of the symptoms on the Motif seemed quite "severe" and less common.

Overall, when asked about the understandability of the questions, participants found that the questions were "clear," "easy," "straightforward," "self-explanatory," and "made sense." A few questions were considered more difficult to interpret or difficult to differentiate, and some participants expressed how they had to use their "gut feeling" or "guess what we mean" and how they felt "worried" that their interpretation was giving the wrong data (see examples in Multimedia Appendix 2). Regarding the Motif, participants generally understood what the symptoms were, but some expressed difficulties in judging whether they experienced a certain symptom—"heart palpitations...I didn't know if I had them"—and also whether an experienced symptom was due to hypoglycemia or another underlying condition.

When asked whether there were other areas of daily life that were affected by hypoglycemia according to the participants' own experiences, several participants indicated that the app covered all the relevant areas. For example, a participant stated the following:

> *I could not think of anything [else], I thought it pretty well covered it. Just saying "how bothersome was it today"...that's a really good question that sort of covers everything.*

Examples of changes suggested by participants to improve content validity are presented in Multimedia Appendix 2.

Easy to Select Ratings on the App, but Day-to-Day Variation Perceived as Minimal

For most participants, selecting a score (to represent the impact of hypoglycemia on their daily functioning) was perceived as a "pretty easy" and "quick" task, and they felt "fairly certain" in selecting their responses:

> *I don't think it was difficult to choose the answer...there is no right or wrong answer, there is only a personal answer.*

The scale from 0 to 10 was described as appropriate. One participant explained their approach to scoring as follows:

> *I think there was [a] slight tendency to just record how I felt, rather than trying to analyze why I felt like that. But that is probably okay, because it's for the medical professionals to analyze.*

Others had reservations about whether they had understood the meaning of the question sufficiently when providing their scores:

> *...it was easy enough to put a number in, it was more about what the questions was getting at.*

Regarding the following question—"How anxious do you feel right now?"—1 participant said the following:

> *I'm just not very good at monitoring that myself.*

In terms of how the hypoglycemic episode was detected, several participants mentioned how the "I just knew" option was really useful:

> *That is exactly how you feel, even if you don't have symptoms.*

Participants described difficulties with questions requiring the exact time of day or length of time to be reported.

Participants described that their responses "were fairly similar" and "consistent" and would not necessarily "change from one time to the other" and they just "put the same numbers in." However, despite responses generally being perceived as "all quite the same," participants also explained that they could experience small changes if they had hypoglycemia and how episodes could make them "feel more tired" and "irritable" and make it "harder to concentrate," indicating that they experienced changes in relation to hypoglycemia. A participant explained how they thought they "came to understand the questions better" with time:

> *...what do you mean by anxiety becomes clearer in your head after doing it for 3 or 4 weeks than it is at day one.*

When asked about what would generally reflect a meaningful change on the response scales from 0 to 10, participants expressed that a 1-point change was probably not a substantial change, but it was described that "it might have subconsciously reflected that I was more worried one day or the other." Although participants generally attempted to answer all questions, the "skip question" option was described as "important" for questions that were not applicable, such as questions related to work for those who were retired.

Instructions Could Be Improved

Participants expressed mixed views on the instructions (both verbal and written) given at the study sites. Some found them to be "beneficial" and good "to make sure you knew what was what" and that the instructions had just the right amount of detail without "leading the witness;" others found that they were "left with it" or the instructions were given "quite quickly" and they had to rely on a "trial and error approach." Some explained that they probably could have "figured out the app eventually" and it was quite "self-explanatory" but that, if no introduction was given, it would have taken longer to become familiar with the app. Several participants explained that more detailed instructions or examples, either given at the study sites or directly provided in the app, would be beneficial to understand the purpose behind the questions more clearly:

> *In some ways I wasn't too sure what you would actually get from the information I was giving you—it didn't seem very sort of precise to me.*
>
> *I think sometimes I was second guessing what you were getting at.*

A participant explained how they would have liked some instructions on when to fill out the Motif:

> *...should I do it as I'm coming out of the hypo...or when I'm fully recovered?*

In addition, several participants did not seem aware that a zoom function was available to ease the use of the slider in the Motif flower.

An overarching point was that, despite most of the questions being generic, that is, asked without a specific reference to hypoglycemia (eg, "How anxious do you feel right now?"), several participants described that they thought they were supposed to answer with hypoglycemia in mind:

> *...you don't necessarily know what is due to a hypo and what is due to something else.*
>
> *..."what is your mood now?" well, it's so difficult...there are so many external factors...how do I think about that in relation to hypos...and it also depends on where you are in your life.*

Exploring the Feasibility and Acceptability of Using the Hypo-METRICS App

Helping Science and People With Diabetes

Participants expressed that their motivation to take part in the study and use the app was driven by their desire to help science, researchers, or other people with diabetes:

> *I am always interested in taking part in research, because I think it is what you should do.*

Some found that their motivation to report details was higher after experiencing hypoglycemia. Using the blinded CGM was mentioned as a motivating factor as it offered participants who did not use it as their usual method of glucose monitoring the opportunity to obtain a more detailed overview of their glucose variations after completing the study. The voucher and Fitbit (given to study participants for taking part in the 10-week Hypo-METRICS study) were not key motivators but considered a nice gesture.

Easy to Fit in, but More Flexibility Wanted

Although motivation to use the app over the course of the study generally seemed high, variations occurred. Work or other commitments could make it challenging to find time for every check-in. The afternoon check-in was more frequently mentioned as challenging to fit in when "being busy with the day." Some found it useful to structure a "routine" around completing the app assessments (eg, "before getting out of bed" or "with meals"). Generally, people who worked from home or

who were retired found it easier to find the time to complete the assessments compared with those who worked outside the home or with more variable schedules. This was also supported by the fact that scores on the brief web-based survey were, on average, higher among adults with T2DM (a higher proportion of whom were retired).

Some participants found the check-in timings too "rigid," and missing a check-in could be associated with "guilt" and "pressure." A participant expressed that it would be beneficial to make it clearer that it "was not a crime to miss a check-in." Adding some more flexibility around the timings and a bit of a "buffer beyond the cut-off time" was described as having potential to improve engagement with the app. In contrast, other participants suggested reducing the check-in timings (ie, shortening the time intervals) to increase motivation for timely completion as longer intervals made it "easier to put it off."

In terms of study duration, some "missed it when it stopped" (ie, when the study ended) and could have continued for longer; particularly, retired participants generally seemed to find it easy to fit in as part of their day. Others reported finding it a bit "monotonous" or becoming "bored" and starting to fill it out in a more "automatic" manner. However, they were still able to "persevere" as they "could understand the sense of why we were doing it." Most reported that they spent a few minutes completing each check-in (maximum 15 min), which they found acceptable.

Hypoglycemia Delaying Responses and Increasing Completion Time

Hypoglycemia could extend the time spent completing check-ins because of the direct effects of the episode (eg, "your brain is working a bit slower") and because there were more details to report. Many participants expressed that it was necessary to delay the completion of the Motif "maybe 20 minutes" or longer before adding details about symptoms, either because they were "busy trying to treat" their hypoglycemia or because of feeling "disoriented" or "confused" from the hypoglycemic episode itself.

Design, Functionality, and Customizability

In terms of functionality and design, the quantitative data (scale from 0-10) showed that participants generally found the check-in functionalities easy to use (T1DM: mean rating 7.40, SD 2.22; T2DM: mean rating 9.38, SD 0.74) and liked the design (T1DM: mean rating 7.50, SD 1.43; T2DM: mean rating 8.75, SD 1.16).

Participants described the design of the app and its functions as "positive," "straightforward," "easy," "fine," "pretty simple," "readable," and "well designed." Participants who did not consider themselves "particularly tech savvy" said the following:

> *...even I could manage the app and the check-ins...Assuming someone is able to read and write, I think they are actually very easy to use.*

However, some expressed that they did not like the "touch technology" and that a computer keyboard would be easier for them. When asked if they had any suggestions for changes to the design of the check-ins, one participant said the following:

> *No, I would keep it exactly as it is—it is very simple to use. It's literally one question on each page, so you don't get confused by anything and you're not distracted by anything else...I really liked the design of the app.*

Some technical issues were raised, although these were considered minor and did not seem to cause major disruptions to check-in completion, for example, experiences of being asked to complete check-ins that the participants had already submitted and a longer loading time (ie, time to load each page) as the study progressed. Some participants explained how important it was to have study site contacts:

> *Initially I didn't know how to do the settings...I'm not a tech man. So, I had to call them and get this thing sorted out. Once I was on the move, I was fine.*

Several participants liked the design of the Motif flower, that it "wasn't just tick boxes," describing it as "engaging," "very eye catching," and "clever." Some preferred the Motif to the check-ins, particularly when they had multiple hypoglycemic episodes to record. However, several participants described the slider on the Motif as "fiddly" and "chunkier." One participant commented that they tried to avoid hypoglycemia so they would not need to complete the Motif. Those finding the Motif slider problematic did not seem to know that a zoom option (that made the slider larger) was available. Several participants explained how the Motif setup was very "innovative" and, as the sliders were easy to use, it allowed them to fill out details in the Motif at the time of the episode despite still feeling affected by it.

Participants generally expressed how customizability would be beneficial in terms of both functions (eg, customizing notifications and time intervals) and content (eg, option to remove content that would never be applicable to the individual, such as work productivity for retired participants).

Limited Change in Awareness of Symptoms and Impact

Most participants did not report any change in either their perception or experiences of symptoms of hypoglycemia (physical and emotional) or routine treatment of hypoglycemia from using the app. However, some participants experienced changes, both positive and negative. Some of these changes were related specifically to physical symptoms:

> *...it made me reflect on if I was experiencing symptoms.*
>
> *...it did make you think "oh goodness yes, actually I did not realise I also had that symptom."*

For some, using the app led to increased awareness of how hypoglycemia affected their emotional well-being:

> *I thought it was quite nice it was talking about mood and how well you got on with other people and things like that...I know I do get really annoyed and really grumpy, and I would think "oh it's just me, I'm just a really grumpy person," but actually...a few times, it is because I'm a bit low or a bit high, so it was really nice "oh, I'm not such a horrible person."*

For others, the change in awareness also extended into how hypoglycemia could affect significant others:

> *It did make me think about the impact of hypos, not just on me, but on my friends and family as well.*

One participant explained a negative emotional impact of using the app and highlighted the importance of informing participants of opportunities for support services if needed:

> *...doing constant questionnaires about it [diabetes] and thinking about it regularly, I think I got really upset about the long-term health complications. It did really start to get to me over the 10 weeks, and I had to remind myself that was because I was constantly thinking about it due to the app.*

Suggestions for Future Versions of the App

Across each theme, participants made several suggestions for improvements. Multimedia Appendix 2 summarizes them and includes the app developers' perspectives on the suitability of the proposed changes. The summary follows the structure of the interview guide (ie, within the topics in which they were discussed).

Discussion

Principal Findings

This study investigated users' experiences with the Hypo-METRICS smartphone app, a tool developed for research purposes to explore the impact of hypoglycemia on daily functioning in real life among people with T1DM and insulin-treated T2DM. The app allows for the collection of data during daily life and temporally closer to the hypoglycemic episodes as they occur. Overall, participants seemed to find the content relevant, understandable, and comprehensive, suggesting satisfactory content validity. Responding to questions was generally considered easy, and the response options were appropriate. Some participants indicated that they experienced only minimal fluctuations in ratings over time, querying how useful the thrice daily check-ins would be to the researchers. Some participants suggested that the instructions could be improved to aid their general understanding of the purpose of the study and the meaning of certain questions. Overall, the interviews suggest that participants had a positive experience using the app as part of a research study, and the interviews support the feasibility of investigating the impact of hypoglycemia on daily functioning with multiple daily assessments and use of smartphone technology. The time investment (a few minutes for most participants) required to complete the check-ins was considered acceptable. A few additional functionalities were suggested to further increase motivation and minimize the potential for automatic responses. The interviews also revealed a potential, although limited, intervention effect, with some participants reporting greater awareness of hypoglycemic symptoms as well as greater awareness of the impact of hypoglycemia on their own emotional well-being and on other people.

The interviews yielded suggestions for how to improve the user instructions given by the research staff at the study sites or provided within the app itself. A total of 5 examples of insufficient instructions are highlighted in this paragraph. First, most of the app questions were designed to be generic (eg, "How is your mood right now?") as it was expected that people would find it challenging to know whether their mood was attributable to hypoglycemia or to other factors (eg, work or sleep [5,19]). However, some participants indicated that they thought the question asked about the impact of hypoglycemia specifically, likely as they knew they were taking part in a study on hypoglycemia. In-app instructions, for example, a brief video when loading the app for the first time, could be considered to instruct participants to respond without reference to hypoglycemia. Second, participants who expressed difficulties in understanding certain questions also indicated that they had to rely on their own interpretation of the questions. A more thorough briefing of the questions, including a statement that a participant's own interpretation of their thoughts and emotions when answering the questions was expected (ie, that there is no right or wrong answer), could potentially have increased participant trust in their responses. Third, participants expressed concerns about the value of their data as they perceived minimal changes from one check-in to another. Future iterations of the app could include advice to reassure participants that all data are valid and useful regardless of the between-check-in variations in responses (eg, "Please select the score that best describes your experience in the moment. For some questions, you may have experienced little or no change over time, whereas for others, there may be larger changes in experiences. All experiences are valuable, and there are no right or wrong answers"). Fourth, informing participants that the check-in intervals were selected to minimize recall bias and missing occasional responses was okay could potentially have reduced the frustration that participants experienced from the "rigid" time intervals. Previous studies using eye-tracking technology have shown that some participants do not read instructions in detail [20]; thus, future versions of the app could explore the use of in-app videos or more examples in relation to the questions or embedding instructions into the questions or response options as alternative ways of including more guidance to support participants and minimize participant frustration instead of only providing lengthy instructions at study start. Fifth, comments from participants also revealed that, if they understand why the data are being collected and how the data can help them or others, participants will be motivated to put in the effort even for a longer time. As participants described higher motivation to complete the check-ins on days with hypoglycemia, the risk of reporting bias should be explored further (eg, comparing completion rate based on the presence or absence of hypoglycemia).

The interviews also addressed the challenges of relying on self-report when assessing the impact of a condition that acutely affects cognitive functioning. Participants explained difficulties concentrating or focusing on completing the Motif during hypoglycemic episodes. Future iterations of the app could consider exploring cognitive functioning using more objective (ie, not self-report) tasks, as done in other EMA studies [21] (eg, assessing visual-spatial attention and processing speed by selecting matching cards shown on the screen). The cognitive impairment described by participants further suggests that reducing the recall period even further is difficult as the person with diabetes needs to prioritize treatment over answering questions in the Motif. Future studies could consider using

CGM-prompted assessments with varying durations from the onset of the hypoglycemic episode to assess the durational effects of both symptomatic and asymptomatic hypoglycemia.

The design of the Hypo-METRICS study was observational, but interviews with users revealed some potential intervention effects of completing the app assessments multiple times daily for 70 consecutive days. Participants explained how being asked about hypoglycemia symptoms made them reflect more on the symptoms they experienced. This effect will be further assessed using the quantitative Hypo-METRICS data collected. These observations align with those of previous pilot studies that used apps to capture hypoglycemic symptoms [22,23]. Existing hypoglycemia awareness training and educational programs [24,25] could consider implementing app-based assessments, such as the Motif, to explore the Motif's additive effect on restoring awareness. Participants' descriptions of more atypical symptoms of hypoglycemia suggest a need for customizability in assessing hypoglycemia symptoms. The importance of customizability for participants' acceptability in EMA studies, in terms of both functions (eg, timing of assessments) and questions (eg, hypoglycemia symptoms), has been similarly described in other EMA studies [26].

Participants in this study described how using the app gave them more insights into how hypoglycemia affects them (eg, their mood) and how it can affect other people, including family and friends. A recent systematic review described how hypoglycemia can negatively affect family members' emotional well-being and their relationship with the person with diabetes and how greater involvement of family members in clinical care could prevent or reduce conflicts [3]. Participants using the app not only reflected more on but also had more opportunities to discuss the daily impact of hypoglycemia with significant others. For future studies, researchers could consider developing a "family member" version of the app or ask family members to actively take part in responding to the app to explore the potential value for the person with diabetes or the family member.

A recent qualitative study with people with T1DM explored the areas most important to an individual's quality of life and described how hypoglycemia affects the following domains: relationships and social life, work and studies, leisure and physical activity, everyday life, sleep, sex life, physical health, and mental health [27]. Although some of these may not be suitable to include in an app focused on daily assessments (eg, the subdomain "employment prospects"), others could be considered as amendments for future versions of the Hypo-METRICS app either as separate questions or as changes to or examples within existing questions, including driving, dietary freedom, spontaneity, and relationships or social life. Interestingly, participants in this study made no mention of their "sex life" in the context of hypoglycemia during their interviews. This is generally a topic that people can find uncomfortable or embarrassing to talk about [28,29] and suggests the importance of also exploring the comprehensiveness of questionnaires in written and anonymous formats.

Some interview participants described the importance of studying the impact of hypoglycemia on both physical and psychological aspects, whereas others found the impact of hypoglycemia on aspects of their daily functioning to be limited (eg, "I certainly have no fear of having a hypo"). Past research has consistently shown that severe episodes (requiring assistance from others for recovery) have negative physical and psychological impacts, whereas the findings for self-treated episodes are mixed [2]. Mixed evidence for self-treated episodes might be due to between-person variation, as was also expressed by interview participants in this study. This aligns with recent discussions regarding how some people with diabetes can experience that their mental health is closely related to their glucose fluctuations, whereas for others, they seem unrelated, and therapeutic approaches need to be considered based on individuals' unmet needs [30]. Longitudinal monitoring of behavior, glycemic values, and mental health could be used to identify individuals' needs. Although implementation of eHealth in clinical practice has previously proved challenging, app-based tools have the potential to improve self-management, guide scheduling of in-person visits (ie, triage and prioritizing those who need more frequent visits or a referral to psychologists), and reduce costs [31-33]. Furthermore, some people can be hesitant to address mental health issues directly with their health care professionals, and apps might provide a safe opportunity for people to describe their experiences [34].

Recent systematic reviews have concluded that more work is needed to better understand how self-treated hypoglycemia affects the person with diabetes, including domains such as anxiety, mood, and sleep quality [2,35]. Furthermore, the accuracy of effect sizes has been questioned because of recall bias and lack of ecological validity [2,35]. Other app-based studies have focused on the impact of hypoglycemia on domains such as cognitive functioning, physical activity, mood, and diabetes distress [21,36-38]. However, to our knowledge, the Hypo-METRICS app is a unique tool for enabling (1) multiple daily assessments of the impact of hypoglycemia on a broad range of daily functioning domains; (2) detailed daily assessments of person-reported hypoglycemia (including how episodes were detected and managed); and (3) an intensive multiweek (eg, 10-wk) investigation of hypoglycemia awareness and impact, which can be matched to CGM traces. Earlier findings have shown high completion rates and satisfactory psychometric properties of the Hypo-METRICS app [39], and this combined-method approach further supports the content validity, acceptability, and feasibility of the app, enabling innovative future research studies of personalized, real-world, detailed assessments of awareness, management, and impact of hypoglycemia among adults with T1DM and T2DM.

A key strength of this study is that experiences were assessed among participants who had used the Hypo-METRICS app for an extensive period and in the context of their day-to-day lives rather than only in short-duration piloting. The detailed interview guide developed before the interviews ensured overall uniformity in the questions and topics addressed across all the interviews. The purposive sampling strategy enabled balanced representation across sex, age, and type of diabetes; however, as expected, fewer participants with lower app completion (<168/210, <80% check-ins; ie, the participants could complete 3 daily check-ins for 70 days) were recruited. Only participants

from the UK sites of the Hypo-METRICS study were included in the interviews, and the transferability of the findings to other non–English-language sites included in the Hypo-METRICS study is limited. Although verbatim transcripts, compared with the notes used in this study, can help other researchers assess the data analysis, others argue that the cross-checking should be from the audio recordings and not from transcripts that may include errors [14]. As participants were answering other questionnaires during the study period in addition to the Hypo-METRICS check-ins and Motif, this may have biased participants' overall experience. Despite participants perceiving limited variation in their ratings over time, this needs to be examined empirically, and work is required to determine the minimal important differences in app ratings [40].

Conclusions

This study explored users' experiences with the Hypo-METRICS app. Overall, the findings suggest that participants had positive experiences using the app; that the content was relevant, understandable, and comprehensive; and that the app is a feasible and acceptable tool to assess the impact of hypoglycemia on daily functioning. For future versions, some modifications and customizability of functions and content could be implemented to increase engagement and content validity. The interviews further revealed a potential intervention effect, suggesting some improved awareness of hypoglycemia symptoms and impact, which warrants further investigation for future research and clinical care. Meanwhile, these data suggest that the Hypo-METRICS app in its present form provides a relevant, acceptable, and feasible new tool for assessing the impact of hypoglycemia on people's daily lives.

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Authors' Contributions

US, NZ, MB, CH, JS, PC, and FP designed the study and developed the interview guide and plan for the manuscript. US, NZ, and JLA conducted the interviews and wrote the field notes, relistening to the audio recordings and amending the notes. US and NZ coded and conducted the thematic analyses of the data and discussed with all the authors. US produced the first manuscript draft with contributions from NZ, MB, JS, CH, PC, and FP. All the authors reviewed the manuscript and provided critical feedback. All the authors approved the final version of the manuscript.

Conflicts of Interest

US works for Novo Nordisk A/S (the work for this manuscript was undertaken before this employment). SAA has served on advisory boards for Novo Nordisk and Medtronic and has spoken at educational events sponsored by Novo Nordisk and Sanofi. FP has received unrestricted funding for research from Novo Nordisk, Eli Lilly, and Sanofi. JS has served on advisory boards for Insulet, Janssen, Medtronic, Roche Diabetes Care, and Sanofi Diabetes; received unrestricted educational grants and in-kind support from Abbott Diabetes Care, AstraZeneca, Medtronic, Roche Diabetes Care, and Sanofi Diabetes; received sponsorship to attend educational meetings from Medtronic, Roche Diabetes Care, and Sanofi Diabetes; and received consultancy income or

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Multimedia Appendix 1
Hypoglycaemia – MEasurement, ThResholds and ImpaCtS app content, web-based survey, interview guide, and COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[DOCX File , 53 KB - diabetes_v8i1e42100_app1.docx]

Multimedia Appendix 2
Participants' suggestions for future versions of the app by topic and developers' perspectives on their suitability.
[DOCX File , 21 KB - diabetes_v8i1e42100_app2.docx]

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Abbreviations

CGM: continuous glucose monitor
COREQ: Consolidated Criteria for Reporting Qualitative Research
COSMIN: Consensus-based Standards for the Selection of Health Measurement Instruments
EMA: ecological momentary assessment
Hypo-METRICS: Hypoglycaemia – MEasurement, ThResholds and ImpaCtS
Hypo-RESOLVE: Hypoglycaemia - REdefining SOLutions for better liVEs
REDCap: Research Electronic Data Capture
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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Viewpoint

An Evidence-Based Framework for Creating Inclusive and Personalized mHealth Solutions—Designing a Solution for Medicaid-Eligible Pregnant Individuals With Uncontrolled Type 2 Diabetes

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Abstract

Mobile health (mHealth) apps can be an evidence-based approach to improve health behavior and outcomes. Prior literature has highlighted the need for more research on mHealth personalization, including in diabetes and pregnancy. Critical gaps exist on the impact of personalization of mHealth apps on patient engagement, and in turn, health behaviors and outcomes. Evidence regarding how personalization, engagement, and health outcomes could be aligned when designing mHealth for underserved populations is much needed, given the historical oversights with mHealth design in these populations. This viewpoint is motivated by our experience from designing a personalized mHealth solution focused on Medicaid-enrolled pregnant individuals with uncontrolled type 2 diabetes, many of whom also experience a high burden of social needs. We describe fundamental components of designing mHealth solutions that are both inclusive and personalized, forming the basis of an evidence-based framework for future mHealth design in other disease states with similar contexts.

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KEYWORDS

personalization; mobile health; mHealth; pregnancy; pregnant; maternal; personalized; diabetic; algorithm; diabetes; rule-based algorithms; social determinants of health; inclusive; inclusivity; design

Introduction

Mobile health (mHealth) apps have the potential to be an evidence-based approach to improve health behavior and outcomes. Some research studies have demonstrated that mHealth can improve health care access and delivery, adherence to care regimens, and patient self-management and behavior modifications for various chronic conditions, including type 2 diabetes (T2D), asthma, obesity, and hypertension [1-3]. A recent systematic review of mHealth use for diabetes (both type 1 diabetes and T2D) and obesity concluded that mHealth had a beneficial effect on outcomes, including hemoglobin A_{1c}

(HbA_{1c}) reduction (–0.3% to –0.5%). The review, however, noted that personalizing different components of mHealth to end users was particularly an unaddressed need [4].

An app, for example, can personalize educational content to a patient based on their clinical severity, lifestyle preferences, and social needs (eg, safe housing). Personalization can be abstractly defined as a "process which changes the functionality, interface, content, or distinctiveness of a system to increase its personal relevance" [5]. Prior research and theoretical frameworks have emphasized that personalization is an important determinant of engagement, which in turn is a determinant of health outcomes [6-8]. We define engagement in the context of this paper as patient interaction and behavior with a mHealth app and their care, including actions such as time spent with the app and using information from the app to communicate with care team members.

There are important theoretical and practical knowledge gaps existing in the link among mHealth personalization, engagement, and health outcomes for pregnant individuals living with diabetes. Evidence gaps exist in how these 3 areas could be aligned when designing mHealth apps for populations that experience significant adverse social determinants of health (SDoH) burden, including Medicaid-insured pregnant individuals with poor glycemic control [9,10]. In the spirit of Eyles et al [11], our paper collectively integrates various aspects of user-centered design (UCD) in mHealth tools that have been previously studied in silos. We use our ACHIEVE (successfully achieving and maintaining euglycemia during pregnancy for type 2 diabetes through technology and coaching) solution as the basis to address these knowledge gaps by proposing an evidence-based framework for designing mHealth apps that is both inclusive and personalized. This framework demonstrates how the design, implementation, and evaluation of such tools, driven by the principles of UCD, can be collectively undertaken for any digital health tool.

The ACHIEVE solution focuses on the development of a mHealth solution to improve glycemic control for Medicaid-eligible pregnant individuals with uncontrolled T2D. Briefly, our ACHIEVE solution is a multicomponent system, including a mHealth app, provider dashboard, continuous glucose monitoring (CGM), and care team coaching for medical and social needs [12]. This solution empowers Medicaid-eligible pregnant individuals with T2D to achieve glycemic control, improve access to care, and acquire patient education and support. Each subcomponent of the proposed solution is grounded in Social Cognitive Theory, and emphasizes an individual's skills, knowledge, beliefs, and self-efficacy to achieve glycemic control [13,14]. Current mHealth apps designed for individuals with T2D outside of pregnancy perform well on education and information functions, but poorly on engagement [4,15]. Few existing apps in both pregnancy and diabetes provide comprehensive evidence-based educational content, tracking tools, UCD, and integration with electronic health records or CGM data to support care team monitoring [15,16].

The novelty of our approach with the ACHIEVE mHealth solution addresses 2 specific areas: personalization with a clinically high-risk population and closing digital health inequities that exist among specific underserved populations, such as pregnant individuals who experience a high burden of unmet social needs. Our experiences with designing a personalized mHealth solution with a diverse high-risk patient population could be adapted to similar populations and contexts. Based on our approach, we describe individual components of designing mHealth solutions that form the basis of an evidence-based framework for future mHealth apps that are both inclusive and personalized. We first provide background information on the ACHIEVE solution and then describe its components within the context of the study population.

Background

Pregnancy With T2D

Poorly controlled T2D increases the risk of adverse pregnancy outcomes for the mother and the infant, including severe maternal morbidity, fetal growth abnormalities, preeclampsia, preterm birth, and neonatal intensive care unit admission [17-20]. Glycemic control decreases the risk of these complications [17-19]. The increasing insulin resistance during pregnancy in addition to experiencing a high burden of social needs (eg, inadequate transportation, food insecurity, and lack of access to quality health) care make it difficult to maintain glycemic control in pregnancy [20]. Medicaid-insured pregnant individuals with T2D are less likely to access preconception care and have worse glycemic control as measured by HbA_{1c}, and hence, are more likely to experience adverse pregnancy outcomes [21]. The clinical management of T2D in pregnancy includes strict and maintained pharmacotherapy and lifestyle changes to maintain glycemic control [22]. Medicaid-insured pregnant individuals with T2D experience significant barriers to successful diabetes management, including self-monitoring of blood glucose (SMBG), frequent changes in insulin dosing, inadequate resources to adhere to prescribed treatment plans, and a high burden of unmet social needs [23-25]. Disparities arising from these challenges manifest through inadequate glycemic control, lack of attendance at prenatal visits, insufficient engagement with care plans, and treatment nonadherence [26,27].

Multimodal Data Integration for Pregnant Individuals Who Have Social Needs and Are Living With T2D With Poor Glycemic Control

Patient-reported outcomes (PROs) that capture both physical and psychological symptoms can support the delivery of more patient-centered care [28]. The collection of PROs allows for ecological momentary assessment, which facilitates repeated assessments of patients [29,30]. Our prior research has indicated that most patients in our study population do not adequately and accurately complete their glucose logs based on SMBG [12]. Integration of PROs into prenatal care delivery has the potential to improve glycemic control for Medicaid-eligible pregnant individuals with T2D [31]. Such an approach can elucidate problems in achieving and maintaining glycemic control, allow for monitoring T2D self-care, improve patient-care team communication, and enable successful T2D self-management. Many of these tasks can be seamlessly

performed by a CGM device that can be linked to a mHealth app and provider dashboard. Advances in CGM can better characterize the glycemic response of pregnant individuals with T2D by identifying individualized glycemic patterns [32,33].

T2D in pregnancy disproportionately affects Medicaid-eligible individuals who are more likely to experience a high burden of social needs [34]. Outside of pregnancy, individuals with T2D who experience more social needs are at higher risk of complications resulting from inadequate glycemic control [35,36]. T2D management in pregnancy is expensive, with >US $7000 in excess pregnancy-related costs alone [37]. Over 40% of pregnant individuals in the United States receive prenatal care through public health insurance such as Medicaid [38,39]. Early and maintained prenatal care improves pregnancy outcomes for T2D [40]. Medicaid-eligible pregnant individuals encounter multiple barriers including unmet social needs that preclude timely diabetes and prenatal care [24,41]. Based on the determinants of health model, clinical care alone for this high-risk population is not sufficient, given the extent to which social needs influence health outcomes [42]. Social needs, such as food security, adequate housing, a safe environment, and access to health care, influence health outcomes and glycemic control [19]. When social needs are not met, T2D management becomes increasingly difficult [36,43].

An Integrated mHealth Solution for Medicaid-Eligible Pregnant Individuals With T2D That Is Inclusive and Personalized

mHealth can be used as part of a multicomponent solution to achieve glycemic control for Medicaid-eligible pregnant individuals with T2D and poor glycemic control. Mobile phone ownership exceeds 90% among reproductive-age Medicaid-enrolled women [44]. mHealth apps can improve timely care delivery, tailor patient education and support, and provide convenient communication between the patient and care team [45]. Pregnant individuals are interested in engaging in alternative prenatal care models [46], which can reduce racial and ethnic disparities in pregnancy outcomes [41]. In addition, a linked provider dashboard can facilitate regular contact between patients and providers and improve patient outcomes [47]. The value of mHealth apps for health-based solutions in diabetes outside of pregnancy has been demonstrated [48,49], and results in improved HbA_{1c}, more judicious health care usage, better PROs [50-53], and better postintervention patient engagement [54]. There is a lack of apps that encompass all of the functions necessary to improve pregnancy and diabetes care and management, so people in this population may have to separately manage these 2 complex conditions using multiple apps or systems. In addition, management needs for those with only T2D may differ, as diet, blood glucose, and medication recommendations will not be considering the needs of a growing pregnant woman and fetus.

CGM makes it easier for individuals to monitor their glucose values without needing to check finger stick values and may also detect periods of elevated glucose values, such as postprandial blood glucose levels and subclinical nocturnal hypoglycemic events, that are associated with adverse pregnancy outcomes [55,56]. For pregnant individuals with type 1 diabetes, research has demonstrated that the use of CGM rather than SMBG improves neonatal outcomes [57]. However, CGM has not been widely tested for pregnant individuals with T2D. Our prior work demonstrated that Medicaid-eligible pregnant individuals with T2D prefer CGM to SMBG [12]. When provided with CGM, pregnant individuals with T2D express high levels of satisfaction [58]. Patients are more likely to benefit from mobile technology if they understand CGM data, meaningfully displayed through an app, and how to actively respond to it to achieve their glycemic goals [59-62].

Integrating a mHealth app with a provider dashboard can enhance team-based coaching and patient engagement. Few existing apps provide comprehensive evidence-based educational content, tracking tools, UCD, and integration with electronic health records or CGM [15,16]. The UCD approach specifies the needs of end-users, and involves end-users in a co-design process to develop mHealth apps that meet their requirements and represents a digitally inclusive approach to using mHealth apps [63]. mHealth apps that are comprehensive, personalized, and integrated within care team workflows are more likely to be effective [15], increase patient uptake [64], and maintain patient and provider engagement over time [64,65]. Provider-facing bidirectional dashboards linked to data from the mHealth app can offer comprehensive diabetes information to care teams, including timely clinical alerts about glycemic control, psychosocial issues, and treatment plans [66]. Dashboards can facilitate team-based provider coaching and feedback [67], including working with the patient's agenda, recognizing patient beliefs, values, and readiness for change; and helping with behavioral modification [68,69]. Outside of pregnancy, such an approach has improved glycemic control among adults with T2D [48] and adherence to evidence-based diabetes care among young Latinx youths living with T2D [66].

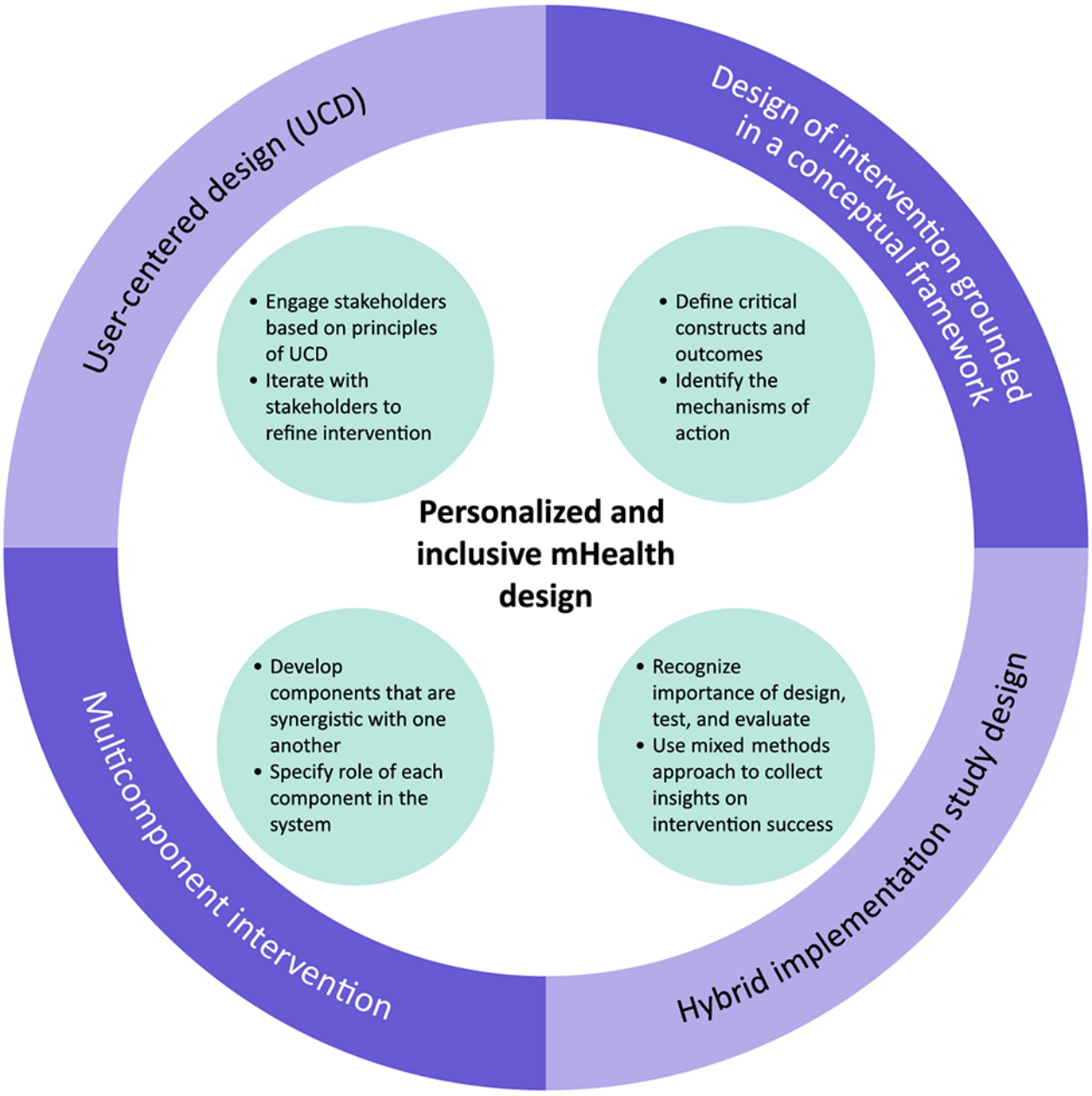
In sum, the motivation behind the development of our ACHIEVE solution was a call to action for our team to build multifaceted systems around mHealth apps that manifest as “digital ecosystems” within which patients engage with their health and their care. We present the key components of the design of this multifaceted solution below.

Evidenced-Based Framework for mHealth Personalization

Overview

We identified 4 components (Figure 1) that are vital for the design of the ACHIEVE solution and represent areas of consideration for designing mHealth apps that are both inclusive and personalized, especially for populations such as Medicaid-enrolled pregnant individuals with uncontrolled T2D. We describe each component below for our proposed evidence-based framework. Evidence collected for the development of the ACHIEVE solution and our framework is based on research activities approved by our institutional review board.

Figure 1. Evidence-based framework to design mHealth apps that are both inclusive and personalized. mHealth: mobile health.



Focus on Key Stakeholders by Being Inclusive and Using UCD

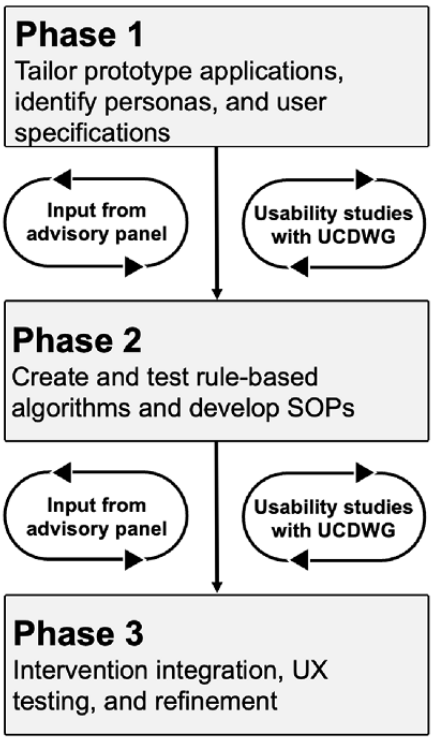
In a UCD approach, end users influence the final design. End-user involvement in the design process leads to safer, more efficient, and more effective products with greater acceptance and success [63,70]. Recent research among publicly insured populations highlights the importance of UCD as a means to extend the benefits of digital health technologies such as mHealth to clinically high-risk populations who experience a high burden of social needs [10].

We established a user-centered design work group (UCDWG) composed of 10 members from three stakeholder groups: (1) health care providers (physicians and certified diabetes care and education specialists [CDCES]) who care for pregnant individuals with T2D; (2) Medicaid-eligible individuals with T2D who have previously given birth; and (3) community-based stakeholders, including community health workers (CHWs) and licensed social workers. The purpose of the UCDWG was to guide the adaptation and refinement of the solution.

ACHIEVE UCD activities involve iterative phases that gather feedback from the UCDWG and an advisory group (Figure 2). UCDWG members review multiple versions of the prototype during focus groups and interviews to ensure that aspects of the solution align with personas, which represent examples of individuals who match the study population. The members provide feedback on the features of the app and dashboard, focusing on usability, usefulness for the population, benefits, and barriers to each feature. The key user-centered principles that we emphasize during our activities involve empathy for the user, consistency in design and goals, context of the user, and reducing the cognitive load of the tools. The feedback gathered is used to further refine the app and dashboard to meet the needs of the end users. These activities helped us identify

different aspects of personalization: functional (collectively by patient personas and providers), interface (collectively by patient and collectively for types of providers), content (individually and collectively for patient and collectively for types of providers), and distinctiveness (individually and collectively for patient and collectively for types of providers). For example, regarding content-based personalization, patients will receive different education information based on their reported PROs and clinical and social needs history.

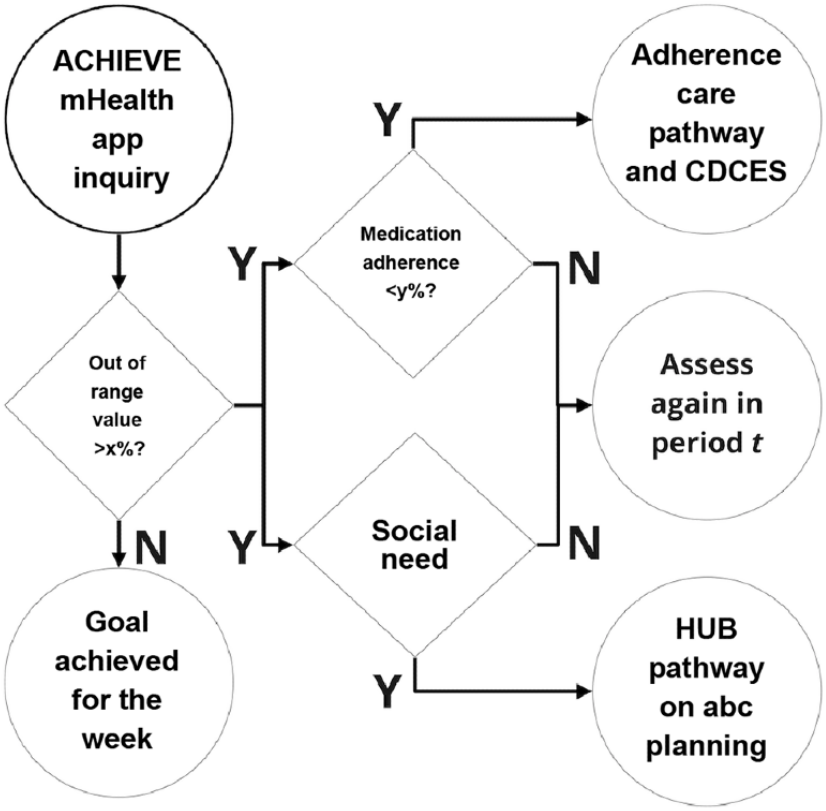
Figure 2. Depiction of the iterative phases of user-centered design activities involved in the ACHIEVE solution. SOP: standard operating procedures; UCDWG: user-centered design work group; UX: user experience.



User specifications identified during the UCD sessions are used to create and test rule-based algorithms. Inputs for our rules include identification of frequent out-of-range blood glucose values, commonly reported unmet social needs by patients, and care coordination challenges. The purpose of the algorithms is to determine the ideal clinical care (eg, adhere to specific diabetes medication treatment) or social need pathways and PROs to deploy for a specific individual and at a specific time. If a patient has financial constraints to purchase medication, which affects adherence, then a CHW will enroll them in a social needs pathway to address these financial concerns and the algorithm will subsequently assess whether medication adherence and related unmet social needs continue to persist (see Figure 3 for a general example). The algorithms' recommendations will be evaluated for consistency by CDCES who are a part of the team of providers, using proficiency and efficiency scores [71]. Clinical informatics experts on the study team will conduct a heuristics evaluation of the algorithm based on Bertini's heuristics tool [72].

Other UCD-based activities include usability testing of the integrated ACHIEVE solution and the use of a modified think-aloud approach that focuses on understanding sociotechnical aspects [73]. The think-aloud approach involves asking members of the UCDWG to respond to task scenarios and open-ended questions while working on the solution. The think-aloud sessions facilitate the identification of informational elements necessary to support effective implementation of technology systems [74,75] and those that preclude user-friendly design [76]. Findings from the think-aloud sessions informed the subsequent refinements to the ACHIEVE solution. Our feasibility study of the ACHIEVE solution prototype, using a UCD approach, indicated a favorable response to the usability of the prototype among both patients who are pregnant and living with diabetes and providers, including maternal fetal-medicine physicians and CDCES [12].

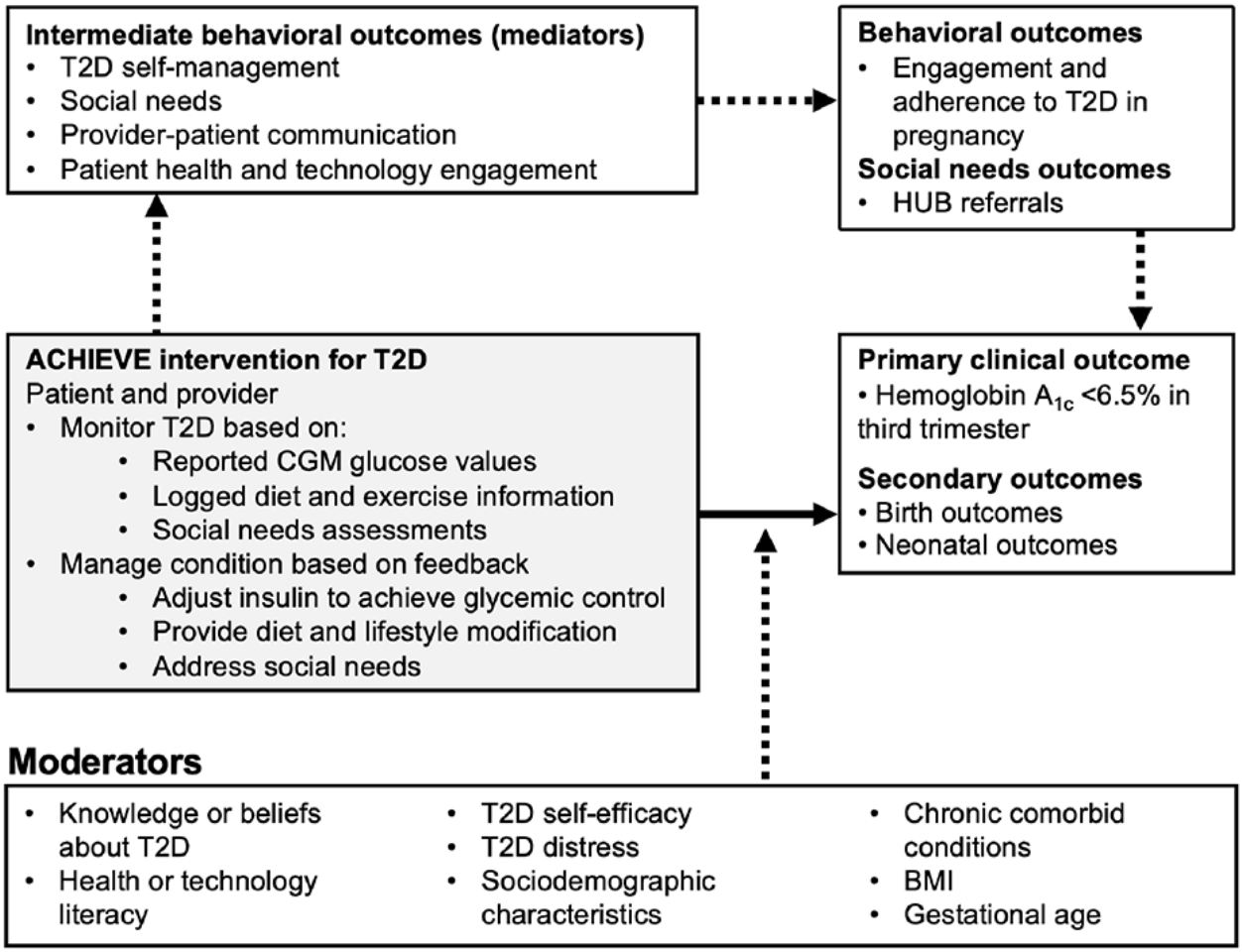
Figure 3. An example rule-based algorithm. CDCES: certified diabetes care and education; HUB: Central Ohio Pathways HUB at Health Impact Ohio; mHealth: mobile health.



Design Solution Components Grounded in a Conceptual Framework

We based our solution on a conceptual framework (Figure 4) guided by Social Cognitive Theory [13], which posits that the successful performance of a behavior depends on an individual's behavioral capability and cognitive and environmental influences on behavior via three domains: (1) skills, (2) knowledge and beliefs, and (3) self-efficacy. Our solution provides patients with educational information that clearly explains how behavior change can achieve a target HbA_{1c} of <6.5% prior to delivery (knowledge and beliefs), which is the primary clinical outcome. The solution develops patients' skills to engage with the diabetes care team by collecting and synthesizing detailed glycemic information via CGM and the provider dashboard to better communicate with the diabetes care team (skills). Team-based coaching that uses CGM data, PROs, and clinical care and social need pathways will help the patient better adhere to T2D care. Closing the loop (eg, having the CHW document the patient securing healthy food through a food pantry) will ensure that a patient's new skills yield meaningful outcomes and enhance their confidence (self-efficacy). In the context of our study, we work with the Central Ohio Pathways HUB at Health Impact Ohio (HUB) which is a generalizable, regional coordination entity that contracts with care coordination agencies that employ CHWs, who are trained and certified by the HUB, to assess the social needs of individuals and connect them to community resources.

Figure 4. Illustration of the conceptual framework of the ACHIEVE solution for T2D, guided by the Social Cognitive Theory. The model outlines the pathway from monitoring and managing T2D to improved clinical outcomes, influenced by intermediate behavioral outcomes and various moderating factors. CGM: continuous glucose monitoring; HUB: Central Ohio Pathways HUB at Health Impact Ohio; T2D: type 2 diabetes.

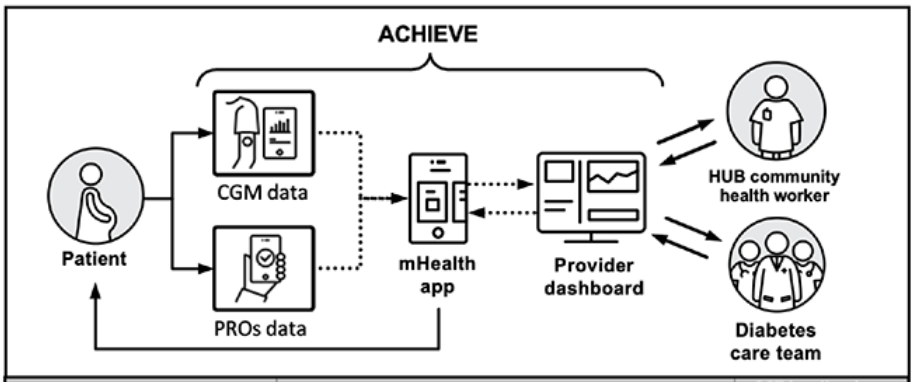


Design a Multicomponent mHealth Solution

Overview

ACHIEVE integrates new and existing technologies to develop an innovative ecosystem for Medicaid-eligible pregnant individuals with uncontrolled T2D. This solution collects real-time patient PRO and CGM data using a mHealth app. Data are transferred to a digital health platform, which displays data on a provider dashboard. Rule-based algorithms facilitate prompt recommendations on care goals and pathways for the patient and provider (Figure 5).

Figure 5. Diagram and table detailing the integrated ACHIEVE solution for managing uncontrolled T2D in Medicaid-eligible pregnant individuals. The system-based solution combines real-time patient-reported outcomes and continuous glucose monitoring data collection via a mHealth app with a provider-facing digital health platform. The system's functionalities, tailored care goals, and pathway recommendations are grounded in clinical guidelines. The table breaks down the components of the system, their subcomponents, and the implications for patients according to the Social Cognitive Theory. ADA: American Diabetes Association; CGM: continuous glucose monitoring; EHR: Electronic Health Record; HIT: Health Information Technology; HUB: Central Ohio Pathways HUB at Health Impact Ohio; mHealth: mobile health; PRO: patient reported outcome; SCT: Social cognitive theory; T2D: type 2 diabetes.



Component		Proposed subcomponent	SCT implications for patient
HIT system	mHealth app	Report and monitor PROs (eg, social needs, diet/exercise activity, and self-care) and CGM blood glucose data	Skills
		Manage T2D and pregnancy with data sharing	Skills
		Track care goals with educational information about care pathways on how to achieve goals	Knowledge and beliefs
		Reminder function with calendar	Skills
		Videoconferencing and messaging with provider	Skills
	DEXCOM G6 PRO	Monitoring of blood glucose level using a continuous glucose monitor and digital data transfer of measurements to provider via mHealth app	Skills
	Rule-based algorithms / Digital Health Platform	Integrate patient and provider data between mHealth app, portal, and EHR	Self-efficacy
		Use rule-based algorithms to prioritize care goals, care pathways, and identify "out of range" values	Self-efficacy
		Automate PRO collection schedule	Skills
	Provider dashboard	Monitor patient PROs, CGM data, goals, and care/HUB pathways	Skills
		Prioritize goals and pathways based on recommendations	Knowledge and beliefs
		Dashboard drill-downs about patient CGM and PRO data	Knowledge and beliefs
		Communicate with diabetes care team and patient	Skills
		Document, track, and make HUB referrals related to patient	Knowledge and beliefs
Personnel	Team-based coaching	Manage patient focusing on active problem solving and motivational language (concordant with ADA and clinical guidelines for T2D in pregnancy): **Diabetes care team (physician, diabetes educator)** a. Glycemic control b. Diet and lifestyle modification c. Insulin pharmacotherapy **Community health worker** a. Social needs assessment and referrals	Self-efficacy
		Prioritize care goals and care/HUB pathways (over-ride system recommendations if required)	Self-efficacy
		Increase awareness of patient challenges and motivate adherence to care pathways	Knowledge and beliefs
		Engage patient	Self-efficacy

mHealth App

The mHealth app provides diverse functions, including education, reminders, clinical care goals, clinical care or social need pathway recommendations, CGM data and PROs reporting and monitoring, messaging and videoconferencing, and a calendar function. Content is based on clinical guidelines for T2D in pregnancy as per the American Diabetes Association

and the American College of Obstetricians and Gynecologists [22,77]. Patients will be directed to appropriate resources and web-based learning to help them navigate the app and its resources. PROs in the mHealth app will be embedded to address health and social needs, and rule-based algorithms will provide tailored care goals, show care pathways, and establish the frequency of elicited PROs. PROs, including social needs screening, will be performed through the app (Section 508 compliant). Follow-up questions will use a rule-based algorithm and a pre-established frequency.

Continuous Glucose Monitoring Device

Patients will be provided with DEXCOM G6 PRO CGM sensors and transmitters. The Dexcom G6 CGM system is accurate and safe in pregnant individuals with diabetes [78]. Patients will be taught how to place and remove CGM sensors by a nurse and will be given sensors to change themselves at home every 10 days. Of note, the DEXCOM G6 PRO can be applied as a patch on the abdomen, arm, or upper buttocks, is well-tolerated in pregnancy, and does not require calibration [78]. Our mHealth app will allow for wireless synchronization with the CGM sensor so that data are seamlessly reported back to the health care team [79,80].

Digital Platform

A robust digital platform will be developed that integrates with Research Electronic Data Capture (REDCap) and algorithms that can adjust the PRO collection protocol based on defined parameters. For instance, if a social need is identified, the platform will automatically increase the frequency of outreach until it is addressed or there is a manual override by a care team member or the patient. This platform allows for the integration of our ACHIEVE mHealth app and dashboard (using a SMART-Fast Health care Interoperability Resources [FHIR] interface). The platform will integrate electronic health record (EHR) data into the provider dashboard and update it over time. It can use rule-based algorithms to synthesize data reported by pregnant individuals and their care team, tailoring care in real time based on changing clinical and social needs. The CHW will integrate their coordination system with the digital platform via a 2-way application programming interface (API) that will allow for the bidirectional communication of structured and unstructured data about a patient's health status (eg, trends in HbA_{1c} or CGM data such as time in range and comorbid conditions), social needs, and demographics.

Provider Dashboard

The ACHIEVE solution will include a bidirectional dashboard that displays information about individuals, including priority care goals and pathways, and recommendations generated via the digital platform. Health care team members can access the dashboard embedded within a portal to modify or update information and close the loop on patient tasks. The dashboard will present recommendations for patient goals and pathways provided by the digital platform algorithms. Providers can use these recommendations or manually select ones for the patient. Providers can sequence goals and pathways by level of complexity. Both the CHW and the health care team can perform ongoing assessments of social need pathway selections and assess recurring needs through the provider dashboard. Documentation of unstructured data will involve information about social need pathways that have not been completed and the reason why, as well as any resources that were used to help support the patients' needs. Unique dashboard views and access to functions will be developed based on the care team role.

Community Health Worker and Social Need Pathways

Patients will be screened at enrollment and throughout the solution for social needs using a survey adapted from validated instruments, such as the Accountable Health Communities Health-Related Social Needs Screening Tool. The questionnaire includes 26 questions addressing living situations, food security, transportation, uses, safety, financial strain, employment, family and community support, education, physical activity, substance abuse, mental health, and disabilities [50]. The care team will refer patients with affirmative responses to the HUB through the provider dashboard to address unmet social needs (eg, food insecurity, housing, and employment). HUB CHWs will perform comprehensive social needs assessments and connect patients to community resources through social need pathways, a defined action plan addressing patient needs which is recorded and tracked. For example, this approach will be used to connect a patient who identifies as living in a food desert to a food pantry, which will provide multiple food options and access to fresh produce (trackable by both the CHW and diabetes care team). Linking the digital platform to the CHW is a novel digital health approach using mHealth that can be replicated across health systems. The CHWs can interact with the direct lived experiences of patients as individuals embedded within the community.

Team-Based Coaching

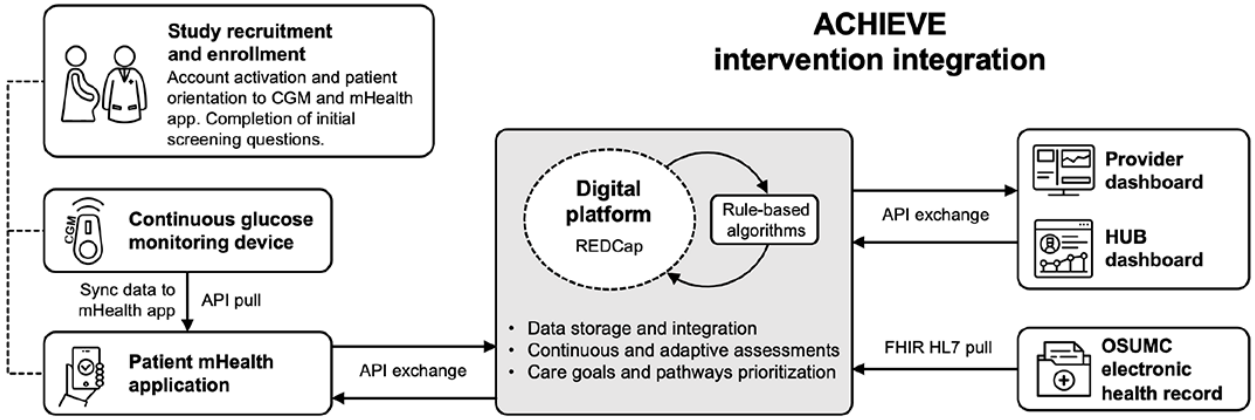
Our solution design will involve prespecified roles for health care team members addressing clinical care (physician, CDCES, and nurse) and social needs (CHW) for T2D care in pregnancy. Patients will receive core training by the CDCES to carry out tasks with the tools with the aid of web-based resources and videos. The primary goals of the care team and CHW will be to support the patient with active problem-solving, to motivate engagement with the ACHIEVE solution, and to accomplish care pathway objectives related to glycemic control. The CDCES will be available to patients via videoconferencing and messaging and can message the CHW. Both the CHW and CDCES will monitor the dashboard for social needs. If there is a need identified, a referral will be made to initiate a social need pathway and the patient's progress will be documented.

System Integration

The mHealth app will be updated for the iOS (Apple) and Android (Google; CGM and PROs) operating systems and the EHR will be integrated with the digital platform and the provider dashboard. Health Language Seven and Clinical Quality Language will be used to facilitate integration with the EHR system. Data collection will commence once a patient has concurrently activated their mHealth app and CGM device, as demonstrated in Figure 6. The data are sent in JavaScript Object Notation format to the digital platform using a Representational State Transfer API. The platform has an integrated REDCap

web server. The transferred data will be converted to a pre-established schema and stored in a MySQL (Oracle Corporation) database. The required data fields from the EHR will be integrated within the platform using the FHIR protocol for EHR data integration or exchange. Continuous data processing and execution of adaptable rule-based algorithms will be performed using standard R software (R Core Team) packages. The data exchange between the digital platform, mHealth app, and dashboard will occur with the aid of Representational State Transfer APIs at multiple time resolutions (real time, hourly, daily, and weekly). All endpoints and APIs will be secured via transport layer security, and access tokens under the APIs will be used to ensure the secure exchange of data. All users (patients and providers) will access the system for the ACHIEVE solution using an OAuth (version 2.0; Internet Engineering Task Force) compliant identity and access management system.

Figure 6. Schematic representation of the data flow within the ACHIEVE solution. The diagram highlights the integration of the CGM device, mHealth app, and EHR system with the digital platform (REDCap) and provider dashboards. API: application programming interface; CGM: continuous glucose monitoring; FHIR: SMART-Fast Health care Interoperability Resources; HL7: Health Language Seven; HUB: Central Ohio Pathways HUB at Health Impact Ohio; mHealth: mobile health; OSUMC: Ohio State University Medical Center; REDCap: Research Electronic Data Capture.



Solution Evaluation Using a Hybrid Implementation Study Design

ACHIEVE involves a hybrid trial type 1 study [81], and consists of 3 aims: aim 1, use UCD practices to adapt our mHealth app solution and provider dashboard to our target population; aim 2, conduct a randomized controlled trial of the solution versus the current standard of care. This trial will assess whether the multicomponent solution (mHealth app with CGM, provider dashboard, and care team coaching) can achieve glycemic control (HbA_{1c}<6.5%) by the end of the pregnancy prior to delivery versus current standard care; and aim 3, conduct a multistakeholder evaluation using mixed methods to identify barriers and facilitators to the implementation and uptake of the solution and its subcomponents, including patient and care team engagement, experience, and satisfaction. An effectiveness-implementation hybrid study design, such as ACHIEVE, supports the identification of problems with the delivery of the solution during the clinical trial, which can translate to vital considerations (eg, barriers or facilitators and modifications to maximize uptake and use) for subsequent real-world implementation.

Limitations to Consider

Technological, end user acceptance, and scalability are examples of challenges that will need to be mitigated through the design, implementation, and evaluation of digital health tools. The use of user-centered design principles and a focus on the context of implementation are 2 examples of approaches that help to systematically address such challenges and these approaches need to be instilled from the beginning of the design process and maintained throughout the study, as suggested by our framework. Some challenges, however, may need to be addressed over the long-term at the policy level (eg, making the internet accessible to everyone in a community, including individuals who face financial barriers). Our framework and the evidence that can be generated from it provide information to raise awareness of these priority issues both at the community and policy levels. Lessons learned from our experience with integration will also form the foundation for additional work that will need to be done to integrate our solution across EHR systems among hospital systems and community-wide.

Conclusions

We present an evidenced-based framework for mHealth design that is inclusive and personalized for individuals who live with high-risk clinical conditions and experience a high burden of social needs. Our framework is informed by our experiences with designing the multicomponent ACHIEVE solution, including mHealth, a provider dashboard, and team-based coaching, for Medicaid-eligible pregnant individuals with uncontrolled T2D, many of whom experience a high burden of social needs. ACHIEVE addresses prior challenges in using mHealth solutions that include a lack of comprehensive and adaptive evidence-based educational content, closed-loop integration with external sensors, and personalization for individuals who experience obstacles to using a mHealth solution. Our solution moves beyond simple tailoring of mHealth apps based on design specifications typically collected from homogeneous patient populations, including those who do not

experience a high burden of adverse SDoH (both clinical and nonclinical) [9]. The ACHIEVE solution will be capable of personalizing care based on shifting clinical and social need contexts for an individual and provide them with dynamic goals to influence their engagement. Our approach presents an opportunity for apps among other populations that experience a high burden of adverse SDoH.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
HbA1c: hemoglobin A1c
CDCES: certified diabetes care and education specialists
CGM: continuous glucose monitoring
CHW: community health worker
EHR: electronic health record
FHIR: SMART-Fast Health care Interoperability Resources
HUB: Central Ohio Pathways HUB at Health Impact Ohio
mHealth: mobile health
PRO: patient-reported outcome
REDCap: Research Electronic Data Capture

SDoH: social determinants of health
SMBG: self-monitoring of blood glucose
T2D: type 2 diabetes
UCD: user-centered design
UCDWG: user-centered design work group

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Original Paper

Perspectives and Needs of Malaysian Patients With Diabetes for a Mobile Health App Support on Self-Management of Diabetes: Qualitative Study

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Abstract

Background: Effective self-management of diabetes is crucial for improving clinical outcomes by maintaining glucose levels and preventing the exacerbation of the condition. Mobile health (mHealth) has demonstrated its significance in enhancing self-management practices. However, only 20% of Malaysians are familiar with mHealth technologies and use them for health management.

Objective: This study aims to explore the perceived benefits and challenges, needs and preferences, and willingness of patients with diabetes to use mHealth apps for self-management of diabetes.

Methods: The study involved one-on-one semistructured online interviews with a total of 15 participants, all of whom were aged 18 years or older and had been diagnosed with diabetes for more than 6 months. An interview guide was developed based on the constructs of the Technology Acceptance Model (TAM), the Health Information Technology Acceptance Model (HITAM), and the aesthetics factor derived from the Mobile Application Rating Scale. All interviews were recorded in audio format and transcribed verbatim. The interview content was then organized and coded using ATLAS.ti version 8. Thematic analysis was conducted in accordance with the recommended guidelines for analyzing the data.

Results: From the interviews with participants, 3 key themes emerged regarding the perceived benefits of using mHealth app support in diabetes self-management. These themes were the ability to track and monitor diabetes control, assistance in making lifestyle modifications, and the facilitation of more informed treatment decision-making for health care professionals. The interviews with participants revealed 4 prominent themes regarding the perceived barriers to using mHealth app support for diabetes self-management. These themes were a lack of awareness about the availability of mHealth support, insufficient support in using mHealth apps, the perception that current mHealth apps do not align with users' specific needs, and limited digital literacy among users. The interviews with participants unveiled 4 key themes related to their needs and preferences concerning mHealth app support for diabetes self-management. These themes were the desire for educational information, user-friendly design features, carbohydrate-counting functionality, and the ability to engage socially with both peers and health care professionals. The majority of participants expressed their willingness to use mHealth apps if they received recommendations and guidance from health care professionals.

Conclusions: Patients generally perceive mHealth app support as beneficial for diabetes self-management and are willing to use these apps, particularly if recommended by health care professionals. However, several barriers may hinder the utilization of mHealth apps, including a lack of awareness and recommendations regarding these apps from health care professionals. To ensure the effective development of mHealth app support systems for diabetes self-management, it is crucial to implement user-centered design processes that consider the specific needs and preferences of patients. This approach will help create apps that are tailored to the requirements of individuals managing diabetes.

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KEYWORDS

mHealth; self-management; diabetes; remote monitoring; telehealth; telemedicine

Introduction

Background

Diabetes is rapidly becoming one of the most prevalent diseases worldwide in the 21st century. Approximately 537 million people across the globe are affected by diabetes, with an estimated 6.7 million deaths directly linked to the condition in 2021 [1]. In Malaysia, the National Diabetes Registry recorded the enrollment of nearly 1.7 million patients, with 902,991 actively managed diabetes cases reported at the close of 2020. The majority of these patients were diagnosed with type 2 diabetes mellitus (T2DM) at 99.33%, followed by type 1 diabetes mellitus at 0.59%, and other types at 0.06%. Among the ethnic groups, the Malay community had the highest prevalence of diabetes, followed by the Chinese, Indians, and other ethnic groups [2]. T2DM is recognized as the most prevalent form of diabetes and has emerged as a significant public health issue in Malaysia. The rising prevalence of T2DM can be attributed to various factors, including unhealthy dietary habits, excessive carbohydrate intake, and a lack of physical activity [3]. Patients with inadequate diabetes management face an elevated risk of both mortality and morbidity. The chronic complications linked to diabetes, including neuropathy, retinopathy, cardiovascular disease, stroke, and the necessity for foot amputations, can substantially diminish patients' quality of life [4].

To prevent the worsening of the disease, diabetes self-management is crucial for individuals with diabetes. Patients are encouraged to make lifestyle changes and adopt healthier habits to maintain better control over their blood glucose levels [5]. In recent years, there has been rapid development in products and services aimed at self-care for diabetes [6]. Digital health tools have evolved to facilitate disease management, offering personalized functions for self-management and enabling communication between patients and health care professionals [7,8]. Wearable devices and mobile apps have demonstrated their ability to enhance patients' blood glucose levels, encourage self-management behaviors, improve medication adherence, and increase clinical satisfaction [9,10].

Self-Management Among Patients With Diabetes

Diabetes self-management is strongly encouraged among patients with diabetes as it has the potential to lower hemoglobin A_{1c} (HbA_{1c}) levels, consequently reducing the risk of exacerbations and long-term complications [11-13]. It has the potential to alleviate the burden on health care providers by promoting self-monitoring at home among patients [14,15]. Self-management behaviors encompass glucose monitoring, maintaining a healthy diet, engaging in regular physical exercise, adhering to medication regimens, risk reduction, developing coping skills, and problem-solving [16]. However, the practice of self-care among patients with diabetes in Malaysia remains relatively low. It has been reported that many patients are noncompliant with medication adherence, physically inactive, and have unhealthy eating habits, all of which contribute to the deterioration of their blood glucose levels [17]. Potential barriers to self-care practices are a lack of knowledge and skills in diabetes self-management, insufficient counseling, a low perception of the severity of the disease, a lack of motivation and support, and financial constraints [18-20].

Mobile Health Support in Self-Management

Mobile health (mHealth) is defined as "the use of mobile and wireless technologies to support the achievement of health objectives" [21]. mHealth technologies are typically patient-facing and are available on patients' mobile devices. Some of the mHealth devices are smartphones, wearable activity trackers, wireless-connected scales, blood pressure cuffs, pulse oximeters, and glucometers. Patients have been able to gain a deeper understanding of their health condition and make adjustments to their lifestyle habits through the use of mHealth [22]. mHealth aids in various aspects of self-management by collecting user health data and offering personalized information, instructions, graphical representations, guidance, and reminders [23]. However, it has been reported that only 20% of Malaysians are familiar with mHealth and actively use it [24]. The limited adoption of mHealth can be attributed to various factors, including usability concerns, perceived complexity in usage, and the absence of integration with electronic health records [25,26]. Additional factors contributing to this situation are cost-related concerns, internet connectivity issues, a lack of knowledge and skills, the perception of the limited usefulness of digital devices, and concerns about data security. These factors can potentially influence patients' attitudes and behaviors regarding digital health interventions [27].

Patients' Perspectives on Using mHealth Support for Disease Management

Numerous studies have explored patients' perspectives on using mHealth support for disease management. Some of these studies have indicated that most patients, particularly the younger generation and frequent computer users, express a strong interest in using mHealth for disease management [28-30]. Patients have described the ease of communication with clinicians, enhanced comprehension of their disease conditions, fewer frequent hospital visits, and an overall improvement in wellness and quality of life as benefits resulting from the use of mHealth [31-33]. However, older individuals have expressed their lack of familiarity with technology operations and a preference for traditional methods involving manual recording of results [28]. Additionally, they, like others, have raised concerns regarding data privacy, challenges in accessing data, the absence of personalized features, and financial constraints, all of which have been highlighted in previous studies [28,34].

Justification for Research

Previous research has examined the views and perceptions of Malaysian patients regarding general mHealth support for various health conditions [24,35], but there has been limited focus on its specific usage among patients with diabetes. Moreover, there is a dearth of knowledge concerning patients' needs and preferences for mHealth interventions, as previous studies in Malaysia have primarily concentrated on patients' perceptions and experiences with mHealth [24,28,36]. Recent research has revealed that as many as 80% of participants in mHealth interventions engage at only a minimal level [37], and approximately one-quarter of downloaded health apps are used just once [38]. Hence, researchers must delve into how the intervention can align with users' needs and preferences by gaining a profound qualitative understanding of the target population. A comprehensive understanding of patients' needs and preferences will enable developers to design mHealth features that are not only usable but also engaging [39]. This step aligns with the "empathize with the target users" phase in the design thinking process and frequently serves as the initial stage in the development of mHealth interventions [40].

Study Objectives

This study aims to investigate the perceived benefits and barriers of using mHealth apps among Malaysian patients with diabetes. The study also aims to uncover their specific needs and preferences for mHealth apps in the context of self-managing diabetes. Furthermore, we sought to determine their willingness to embrace mHealth apps as a tool for diabetes self-management.

Methods

Study Design and Recruitment of Participants

This research utilized an exploratory, qualitative design using a phenomenological approach. In-depth, one-on-one, semistructured qualitative interviews were conducted between September 2021 and November 2021. The study adhered to the guidelines outlined in the COREQ (Consolidated Criteria for Reporting Qualitative Research; Multimedia Appendix 1) checklist in both its design and reporting. Participants were recruited via advertisements posted on social media platforms. We used purposive sampling, specifically utilizing the maximum variation sampling method, to ensure a diverse representation of patients across various demographics, including age, gender, ethnicity, income level, and educational background, to capture a wide range of perspectives. Because of challenges in recruiting patients of Indian ethnicity, we applied a snowball sampling method to reach this population. This involved leveraging the social networks of existing participants, who recommended potential participants for the study. Inclusion criteria for participation were as follows: individuals diagnosed with diabetes for more than 6 months, aged 18 years or older, proficient in English, and capable of accessing the internet and using the Zoom web conferencing tool (Zoom Video Communications, Inc.). Participants were provided with a comprehensive briefing to address any concerns or queries they may have had regarding the study. An information sheet was provided to participants, and their formal consent to participate in the study was obtained. Additionally, participants were offered a 10 Malaysian Ringgit (US $2.12) e-wallet gift token as compensation for their time.

Positionality of the Research Team

WTS, a pharmacist with extensive experience in delivering medication education and counseling to patients with diabetes from various Malaysian ethnic backgrounds, brought valuable insights into the study. Her wealth of experience enabled her to empathize with the experiences and challenges encountered by patients with diabetes, which in turn influenced her perspectives during the data analysis phase. It is important to note that WTS did not conduct the interviews during the data collection process but played a significant role in the interpretive analysis of the interview transcripts.

SGK's positionality as a trainee pharmacist, coupled with her direct experiences of engaging with patients with diabetes from diverse cultural backgrounds, enabled her to establish a connection with the patients' perspectives and requirements in diabetes self-management. In her role as an interviewer, SGK established a personal rapport with the participants and effectively empathized with their lived experiences. This connection was instrumental in shaping her engagement with the data during the analysis process.

Interview Guide

We developed a semistructured interview guide (Multimedia Appendix 2), drawing inspiration from Anderson et al [11]. The interview questions were rooted in the constructs of "Perceived ease of Use" and "Perceived Usefulness" from the Technology Acceptance Model (TAM) [41], personal and social factors as outlined in the Health Information Technology Acceptance Model (HITAM) [42], and the aesthetics factor derived from the Mobile Application Rating Scale (MARS) [43]. TAM evaluates a user's attitude toward adopting a technology, comprising Perceived Usefulness and Perceived Ease of Use. HITAM, by contrast, extends the TAM concepts by incorporating the Health Belief Model [42]. HITAM is designed to describe the attitude and behavioral intentions of health consumers when they encounter health information technology. HITAM is particularly well-suited for our research, given its comprehensive consideration of various facets of health behaviors. It encompasses behavioral, personal, social, and information technology factors, including health status, health beliefs and concerns, subjective norms (social pressure within the diabetes community), health information technology reliability (the demonstrability of results through direct experience with the technology or information gathered from other consumers), and health information technology self-efficacy (confidence in using mHealth). Conversely, MARS evaluates app quality based on 4 constructs: engagement, aesthetics, functionality, and the quality of information [43]. As the quality of apps significantly impacts the user experience, we incorporated these MARS constructs into our interview guide.

We also incorporated additional questions into the interview guide to delve into participants' acceptance factors regarding the use of digital health tools (eg, "What form of information would you find most useful?") [11]. This question yielded

comprehensive insights into participants' needs and preferences regarding mHealth support. We conducted a pilot test to assess the suitability of the interview questions and to help the study researcher become proficient in guiding the conversation effectively.

Data Collection

One-on-one semistructured interviews were conducted by author SGK using Zoom. No prior relationship existed between the interviewer and participants before the interviews. Demographic information, including age, gender, ethnicity, type of diabetes, duration of diabetes, employment status, and educational level, was collected. Before the interviews, participants were shown a 5-minute video presentation explaining the use of mHealth apps in diabetes. This presentation aimed to ensure that participants had a clear understanding of the concepts and ideas related to the use of mHealth apps for self-managing diabetes. During the interviews, information regarding patients' perceived benefits and barriers, as well as their needs and preferences for using mHealth app support in diabetes self-management, was explored in accordance with the interview guide. The interviews involved asking open-ended questions, with the interviewer also posing follow-up and probing questions to encourage participants to provide comprehensive responses. On average, the interviews lasted approximately 45 minutes. All interviews were recorded in audio format and subsequently transcribed verbatim by the researcher immediately after each interview. The interviewer also took field notes during and immediately after the interviews. We did not discover any new, pertinent codes or themes emerging from the interview transcript of participant 13. Consequently, we decided to conclude the recruitment process after collecting data from a total of 15 interviews [44,45].

Data Analysis

The interview content was systematically organized and coded using ATLAS.ti (ATLAS.ti Scientific Software Development GmbH), version 8. The data were then subjected to thematic analysis, following the guidelines outlined by Braun and Clarke [46]. Both WTS and SGK independently coded all the transcripts using NVivo software (QSR International). Initially, they read the transcripts multiple times to become thoroughly acquainted with the data. Subsequently, they independently coded the transcripts, creating initial codes based on meaningful paragraphs and grouping them under potential themes if they shared similar contexts. The coders engaged in coding meetings to discuss the codes and resolve any discrepancies that arose during the coding process. The codebook underwent refinements through iterative reviews of new codes and themes derived from additional interviews. Ultimately, the final set of themes was determined through consensus among all the researchers. Transcripts were not returned to the participants for comments or corrections, nor were participants asked to provide feedback on the findings.

Ethical Considerations

This study received approval from the SEGi University Research Ethics Committee (approval number SEGIEC/SR/FOP/29/2021-2022). Participant confidentiality was upheld through the use of study codes. Participation in the study was entirely voluntary, and participants were informed that they had the option to withdraw at any point. Data access was strictly limited to the study researchers. The ethics procedures of this study adhere to the principles outlined in the Declaration of Helsinki.

Results

Demographics of Participants

A total of 15 participants were recruited for the study. Detailed demographic characteristics of the participants are presented in Table 1. Notably, less than half of the participants (6/15, 40%) were using digital health support for diabetes self-management.

Table 1. Participant characteristics.

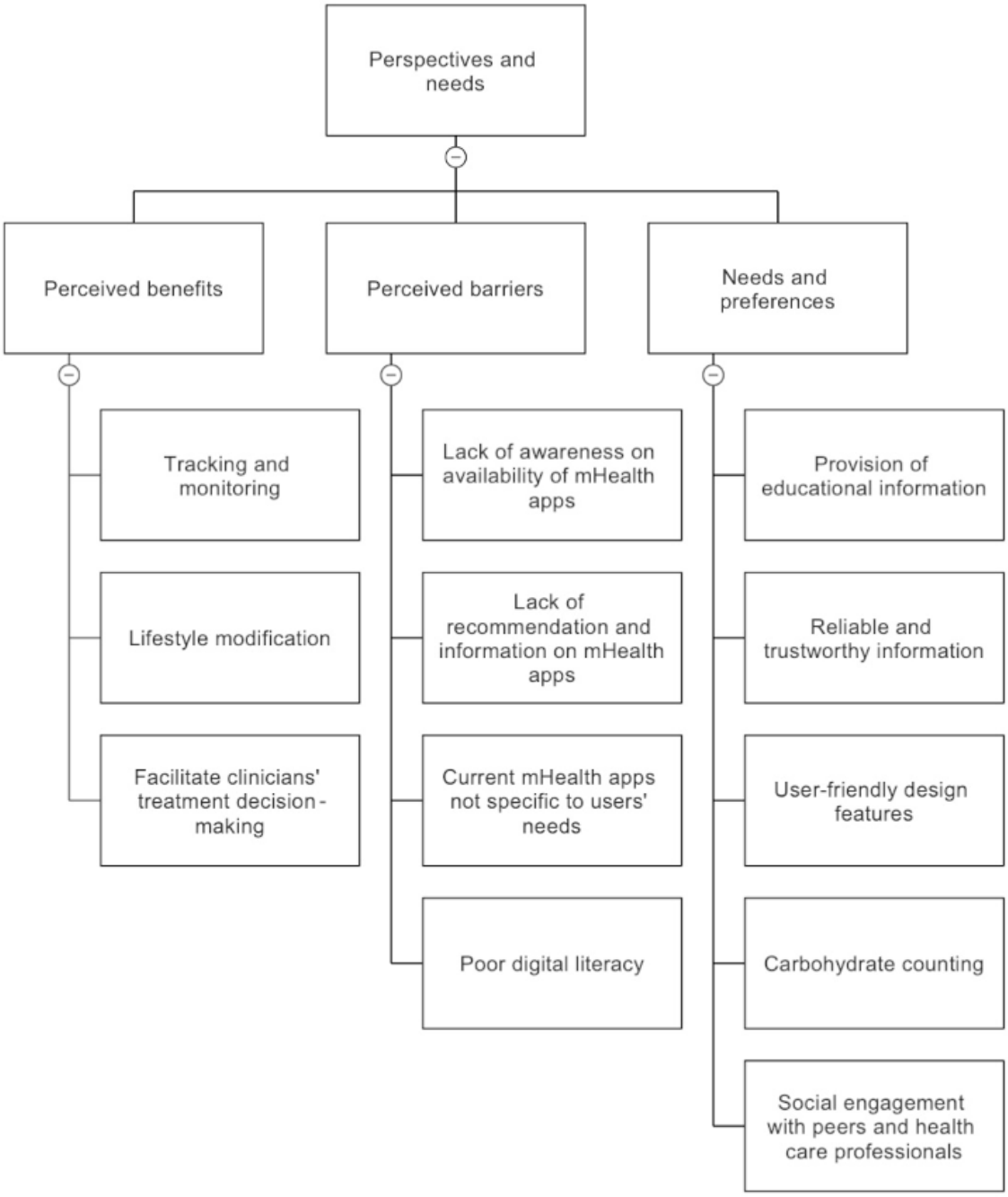
Participant characteristics	Values (N=15), n (%)
Use of a mobile health app for self-management	
Yes	6 (40)
No	9 (60)
Age (years)	
18-30	4 (27)
31-40	2 (13)
41-50	1 (7)
51-60	3 (20)
61-65	0 (0)
>65	5 (33)
Gender	
Female	8 (53)
Male	7 (47)
Race	
Chinese	6 (40)
Indian	4 (27)
Malay	5 (33)
Diabetes type	
Type 1	3 (20)
Type 2	12 (80)
Duration of diabetes	
6 months-2 years	1 (7)
2-5 years	4 (27)
>5 years	10 (67)
Working status	
Employed	9 (60)
Unemployed	6 (40)
Education level	
Primary education	0 (0)
Secondary education	7 (47)
Tertiary education	8 (53)
Diabetes management	
Lifestyle modification only	3 (20)
Oral medication only	8 (53)
Oral medication and insulin	1 (7)
Insulin only	3 (20)

Perceived Benefits of Using mHealth App Support

Overview

The interview with participants revealed 3 key themes regarding the perceived benefits of using mHealth app support in diabetes self-management: tracking and monitoring diabetes control, aiding in lifestyle modification, and facilitating improved treatment decision-making for health care providers (Figure 1).

Figure 1. Generated themes on the perspectives and needs of Malaysian patients with diabetes on mobile health (mHealth) apps for diabetes self-management.



Theme 1: Tracking and Monitoring Diabetes Control

The majority of participants believed that using an mHealth app could assist them in tracking and monitoring their diabetes control effectively. They were confident that they could effortlessly record and monitor their health data, allowing them to revisit previous records and observe their health trends at their convenience.

> *I like it when there's a wealth of data there, you can kind of look back and see what's your average? What is your trend? What are your habits?* [Participant 1, Female, age 18-30 years, mHealth app user]

Theme 2: Assist in Lifestyle Modification

The support provided by mHealth apps can play a significant role in facilitating lifestyle modifications for individuals with diabetes. A majority of participants expressed the belief that they could establish dietary goals and targets by monitoring their blood glucose trends using these apps. Additionally, participants felt that they could practice diabetes self-management independently, without the need for external reminders or assistance.

> *When I view the data on the app, I want them to reach a certain level or goal.* [Participant 1, Female, age 18-30 years, mHealth app user]

> *I cannot depend on other people to control my diabetes or to remind me of what to do every day. The app can help me build a habit, like a new lifestyle.* [Participant 9, Male, age 51-60 years, mHealth app nonuser]
>
> *When my blood sugar level is high from the app, I will start to do something...Next day I will cut down a lot of carbs and then do more exercises.* [Participant 11, Female, age 65 years and above, mHealth app nonuser]

Theme 3: Facilitate Better Treatment Decision-Making for Clinicians

Participants were confident that mHealth apps could assist health care professionals in making more informed decisions about their treatment plans. They could readily share and discuss their health records with health care providers, thanks to the data stored in these apps.

> *By checking the data with our doctor, we can discuss with our doctor on the trend.* [Participant 4, male, age 18-30 years, mHealth app nonuser]
>
> *With more data, I think doctors can make better treatment decisions.* [Participant 7, Female, age 18-30 years, mHealth app user]

Barriers and Challenges to the Adoption of mHealth Support

Overview

During the interviews with participants, 4 distinct themes surfaced concerning the perceived barriers to using mHealth support for diabetes self-management. These included a lack of awareness regarding the availability of mHealth support, insufficient support in the usage of mHealth technology, the inadequacy of current mHealth apps to cater to users' specific needs, and limited digital literacy.

Theme 1: Lack of Awareness on the Availability of mHealth Apps

Our findings indicated that a significant portion of non–mHealth users were unaware of the availability of mHealth app support for diabetes management. Participants expressed that they had no prior knowledge about the existence of mHealth apps designed for diabetes self-management, and as a result, had not considered using such apps for managing their diabetes.

> *I don't know that diabetes apps exist.* [Participant 5, Male, age above 65 years, mHealth app nonuser]
>
> *Well, in the first place nobody has recommended me. This is the first time I hear of it, I have very little knowledge of this actually.* [Participant 14, Female, age 18-30 years, mHealth app nonuser]

Theme 2: Lack of Recommendation and Information on Using mHealth Apps

Conversely, participants also conveyed that there was a noticeable absence of recommendations and information regarding the use of mHealth apps. They reported that health care professionals, primarily doctors, provided guidance on medications and lifestyle modifications but did not suggest or endorse any mHealth apps or other digital health resources for managing diabetes.

> *No the doctor didn't mention it, so far no.* [Participant 5, Male, age above 65 years, mHealth app nonuser]
>
> *Nobody has informed me, not even the clinic that I go to. They have not informed me anything.* [Participant 11, Female, age 65 years and above, mHealth app nonuser]

Theme 3: Current mHealth Apps Not Specific to Users' Needs

Several participants had negative experiences with mHealth apps, primarily due to the perception that these apps did not cater specifically to their individual needs. They described the current apps as having limited options and functionalities for personalized diabetes self-management. These limitations encompassed the absence of certain critical information, the requirement for users to manually input data, and diet recommendations in the apps that were not tailored to the local context.

> *I remembered that some apps have carbohydrates counting, but they are not very specific yet, for example, for rice, only brown rice and white are listed on the app.* [Participant 15, Female, age 51-60 years, mHealth app user]
>
> *We can set the sugar intake limit or a range that we want...But the application did not specify the limit for pregnant or normal patients. We need to set the limit ourselves.* [Participant 12, Female, age 31-40 years, mHealth app user]

Theme 4: Poor Digital Literacy

Furthermore, limited digital literacy emerged as a significant barrier to the adoption of mHealth apps, particularly among the older generation. Older participants expressed that they were not accustomed to using digital technology, leading to difficulties in operating newer technologies such as mHealth apps. They mentioned that they lacked the knowledge and skills required to use mHealth apps and often preferred using basic mobile phones instead.

> *I am not computer user, so I prefer the simpler method.* [Participant 8, Male, age above 65 years, mHealth app nonuser]
>
> *I'm an old school I'm not used to tech stuffs.* [Participant 9, Male, age 51-60 years, mHealth app nonuser]
>
> *I use the normal phone, I didn't use smartphone.* [Participant 2, Female, age 51-60 years, mHealth app nonuser]

Needs and Preferences Toward mHealth App Support

Overview

During the interviews with participants, 4 distinct themes emerged concerning their needs and preferences regarding mHealth app support for diabetes self-management. These

included the desire for educational information, user-friendly design features, features related to carbohydrate counting, and the opportunity for social engagement with peers and health care professionals.

Theme 1: Provision of Educational Information

Participants offered several suggestions to enhance the design of digital health solutions aimed at facilitating diabetes self-management. Primarily, they expressed a preference for mHealth apps to include educational content, particularly information related to diet, glucose control, and hypoglycemia management. Furthermore, participants emphasized that it would be beneficial if these apps offered dietary advice, specifying which foods to include and avoid while allowing users to set targets for achieving desired glucose levels. Additionally, they suggested the inclusion of Asian recipes within the apps alongside Western recipes, ensuring a more culturally relevant and diverse selection.

> *I prefer the apps to offer education, such as what type of food is better and what type of food I should avoid...* [Participant 6, Male, age 65 years and above, mHealth app nonuser]
>
> *I prefer to know the range of healthy blood glucose level, and then maybe some info on the hypoglycaemia management.* [Participant 12, Female, age 31-40 years, mHealth app user]
>
> *A lot of the apps for diabetes have recipes, but they are mostly Western recipes. If they have Malaysian or Asian types of recipes, that would be good.* [Participant 13, Female, age 31-40 years, mHealth app user]

Nevertheless, participants also reported that repetitive educational messages are less desirable.

> *Sometimes the apps keep on sending the same thing (the educational text messages). I mean these things are all very similar. It's just like maybe I read them (the educational text message) before, so they are no more interesting to me.* [Participant 3, Male, age 41-50 years, mHealth apps user]

Theme 2: User-Friendly Design Features

Some participants expressed the desire for different digital health devices and apps to be able to interoperate and communicate with each other seamlessly. They also emphasized the importance of personalized functions within the apps, including options to access information through videos, articles, or by sharing information and engaging with peers in a forum-style environment.

> *If these devices can communicate with each other, then it's perfect...* [Participant 7, Female, age 18-30 years, mHealth app user]
>
> *I prefer reading the article and see the video, because I don't like to see pictures...* [Participant 10, Male, age 65 years and above, mHealth app nonuser]

Participants also expressed a desire for reminder and notification features within mHealth apps. They were interested in using apps that could assist them in monitoring their health and provide alerts or notifications when their health was not well-controlled. Additionally, they highlighted the need for medication reminders, particularly for those who were managing multiple medications and had busy schedules.

> *It will be good when I have low blood sugar, a message pop up to inform me something, like whether I have certain symptoms...Like a notification reminder...* [Participant 1, Female, 18-30 years, mHealth app user]
>
> *...for patients who take a lot of medication, reminders for them will be really good.* [Participant 4, male, age 18-30 years, mHealth app nonuser]

Theme 3: Carbohydrate Counting

Furthermore, participants recommended the inclusion of a carbohydrate-counting feature in mHealth apps. Many participants emphasized the importance of being able to monitor their food intake and track their diet as a crucial aspect of diabetes self-management.

> *If we can put a picture of our meal in the app...which can scan how much carbohydrate is there through the picture...that would be a very big bonus point for all of us.* [Participant 4, male, age 65 years and above, mHealth app nonuser]
>
> *I would like to know what kind of food (and they) contains how much carbs.* [Participant 9, Male, age 51-60 years, mHealth app nonuser]

Theme 4: Social Engagement With Peers and Health Care Professionals

Finally, participants expressed a preference for mHealth apps to include engaging features that facilitate effective communication between health care professionals and other patients. In their daily lives, participants often sought advice and shared experiences with their friends with diabetes when facing challenges in diabetes management. Additionally, some participants found it challenging to consult with doctors in between appointments. Therefore, participants suggested incorporating more opportunities for interaction with fellow patients with diabetes and health care professionals through the mHealth apps to address these needs and enhance their diabetes self-management experience.

> *...with friends that also have diabetes, we also discuss among ourselves how to go about improving diabetes.* [Participant 5, Male, age 65 years and above, mHealth app nonuser]
>
> *...the limitation for me is that we only see the doctor every three months. So in between if whatever happened, it is hard to ask my doctor.* [Participant 7, Female, age 18-30 years, mHealth app user]

Willingness to Use mHealth Support for Diabetes Self-Management

Currently, less than half of the participants are using mHealth apps to support their diabetes management. However, most participants expressed a strong willingness to embrace mHealth app support in the future. The majority of participants indicated

their readiness to use mHealth app support provided they received appropriate guidance and recommendations. Furthermore, participants exhibited a positive attitude toward using mHealth apps, especially when these apps proved to be beneficial in managing their diabetes conditions.

> *I wouldn't mind to use the app if it can help to manage my diabetes level.* [Participant 6, Male, age above 65 years, mHealth app nonuser]
>
> *I think it will be a very good support.* [Participant 8, Male, age above 65 years, mHealth app nonuser]
>
> *Yeah, I don't mind doing that, if there is somebody to recommend or introduce to me.* [Participant 11, Female, age above 65 years, mHealth app nonuser]

Discussion

Perceived Benefits of Using Digital Health Support

In general, participants held a positive perception of mHealth app interventions, considering them as beneficial for enhancing their diabetes management. This viewpoint aligns with existing evidence that suggests an association between the utilization of digital health support and the potential improvement in diabetes self-management among individuals with diabetes [47]. Patients can acquire a more comprehensive understanding of how various factors impact their blood glucose levels by tracking their data and visualizing trends through mHealth apps [48]. Additionally, these apps facilitate easy recording of blood glucose readings compared with traditional paper-based methods [49]. It is worth noting that frequent monitoring of blood glucose trends is recognized as beneficial for achieving better glycemic control [25].

In this study, we observed that patients expressed enthusiasm for using mHealth apps due to their potential to support lifestyle modification. This aligns with findings from a study conducted by Fleming et al [50], who reported that patients were more motivated to engage in glucose monitoring and make lifestyle modifications when using digital health support. From the patients' standpoint, mHealth apps enabled them to share their health data with health care professionals. The utilization of mHealth apps can support health care professionals in making more informed clinical decisions by providing access to patient data. Studies have shown that the use of mobile apps for clinical decision support can lead to improvements in the appropriateness of diagnoses and clinical outcomes [51].

Barriers and Challenges to the Adoption of mHealth

Patients' perceived barriers and challenges related to the adoption of mHealth apps primarily center on the limited options and functionalities offered by the apps, as well as issues with app usability. This includes the inconvenience of having to manually input health data into the app. An assessment of free Android health care apps unveiled that the majority of mHealth apps only supported manual data entry, highlighting the prevalent need for users to input their health information manually [52]. Fu et al [53] proposed the enhancement of user satisfaction by integrating Health Behavior Theory into the design and development of digital health technology. Additionally, the concern about poor digital literacy was particularly notable among older participants. The older generations frequently voiced challenges related to navigating mHealth apps and generally reported experiencing fewer benefits from mobile app usage compared with younger generations [14,54]. Developers should exercise special care when designing mHealth apps for older individuals. Considerations should include factors such as font size, color contrast, button visibility, and the inclusion of helpful tips and explanations to ensure that these apps are accessible and user-friendly for older users [55].

There was a clear lack of awareness among patients regarding the availability of mHealth support. Most patients had never received guidance from health care professionals on the use of mHealth apps for diabetes self-management. Research has shown that the absence of patient-health professional interactions is a significant barrier to the adoption of mHealth technology. A study by Biruk and Abetu [56] reported limited knowledge about digital health support for disease management among health care professionals in North West Ethiopia. Therefore, it is essential to educate health care professionals about the advantages of incorporating mHealth interventions into the management of chronic diseases as a first step.

Patients' Needs and Preferences Toward Digital Health Support

Our study also highlights opportunities for improvement in the design and functionality of mHealth apps for diabetes management. One of the key recommendations that emerged from the findings was the need for the provision of educational information within these apps. Studies have demonstrated that numerous mHealth apps do not offer sufficient educational information to users [25]. It is worth noting that education provided within mHealth apps can enhance self-care practices [57]. Additionally, patients frequently encountered difficulties in calculating the carbohydrate content of their meals and expressed a preference for apps to include a feature that allows them to scan images for calorie information. This is particularly significant because carbohydrate-counting features, enhanced by image recognition and artificial intelligence technology, can significantly improve the accuracy of measuring carbohydrate intake [58].

The majority of participants responded positively to the suggestion of incorporating reminders and notifications into mHealth apps. Reminders and notifications have proven effective in assisting patients in adhering to their medication regimens [59]. A recent study revealed that reminders for diabetes-related appointments, medication adherence, screening, and routine laboratory tests had a substantial impact on the clinical outcomes of the patients [60]. The IDF (International Diabetes Federation) Europe has also recommended the inclusion of SMS text messages or notification features within mHealth apps, recognizing their importance in preventing long-term complications among patients with diabetes [61].

Patient-provider interactions facilitated by digital technology can significantly enhance the quality of care for patients. This includes assistance in coordinating care, providing information about medical conditions and treatment decisions, aiding in disease management, and supporting the learning of health behavior changes [62]. Additionally, wireless communication

and integration between various apps and devices are crucial for health data collection, storage, and sharing with health care professionals.

Limitations of the Study

The recruitment method for participants in this study primarily involved advertising through social media. It is important to note that this recruitment approach may have attracted participants with a higher level of technology literacy. However, it is worth mentioning that even with this bias, 60% (9/15) of the study participants had never used mHealth apps for self-management of diabetes, indicating that a significant portion of the sample had limited prior experience with such technology. While this study used maximum variation sampling to recruit a diverse group of participants, it is noteworthy that a majority of the participants were from urban regions in the Klang Valley. These areas typically have stable internet connectivity and higher levels of technology literacy. As a result, the study findings may not fully represent the experiences and perspectives of the Malaysian population with diabetes residing in rural regions. Additionally, due to constraints in time and resources, snowball sampling was applied to recruit patients with diabetes of Indian ethnicity. This may have introduced some limitations in the diversity of the participant pool. It is worth acknowledging that the snowball sampling method may have introduced certain biases into the study. While it is recognized that this method does not guarantee sample diversity [63], the research team made efforts to promote sample heterogeneity through the primary sampling method, which was purposive sampling during recruitment.

Another limitation of this study was the recruitment of English-speaking patients. Malaysia has a multilingual population, with Malay, Chinese, English, and Tamil being the main spoken languages. Because of resource constraints, the study was limited to recruiting patients who could understand and converse in English. As a result, the study might not have captured the important perceptions of Malaysian individuals who do not primarily speak English, particularly regarding their perceived benefits, needs, and preferences related to using mHealth support. This limitation should be considered when interpreting the study's findings.

Implications for Practice and Future Research

The findings of this study indicate that the majority of participants held a positive perception regarding the use of mHealth for self-management of diabetes. Nonetheless, it is crucial to emphasize the importance of education and training to ensure that patients, particularly older individuals, can effectively use mHealth technology for their diabetes management needs. To address the needs of individuals with low technology literacy, it is essential to develop mHealth app designs that are simple and easy to navigate. This user-friendly approach can significantly facilitate the usage of mHealth apps among this population. Furthermore, the study has highlighted various barriers to using mHealth support and has suggested the incorporation of user-centered design features to address these challenges effectively. This emphasis on user-centered design is crucial for meeting the needs of individuals in their daily tasks, ultimately contributing to improved patient health outcomes [64]. Additionally, the study underscores the vital role of health care providers in promoting the use of mHealth among their patients. When health care providers actively encourage patients to engage in self-management at home through mHealth, it is likely that more patients will adopt and benefit from these digital tools.

Future research could extend its focus to include patients from rural areas to provide a more comprehensive understanding of mHealth usage in diverse settings. Additionally, exploring the impact of factors such as behavioral characteristics, health literacy, cultural differences, and socioeconomic disparities on patients' engagement with mHealth support would offer valuable insights. Furthermore, investigating clinicians' perceptions regarding the use of mHealth support in patient care could provide a well-rounded perspective on the integration of these technologies into health care practices.

Conclusions

In summary, this study offers valuable insights into the perspectives of Malaysian patients with diabetes regarding the use of mHealth support for diabetes self-management. The participants' willingness to embrace mHealth app support was motivated by their recognition of the perceived benefits and recommendations from health care providers. These perceived benefits encompassed the ability to track and monitor diabetes control, aid in lifestyle modifications, and facilitate more informed treatment decision-making for health care professionals. Significant barriers to the adoption of mHealth app support are a lack of awareness about the availability of mHealth apps, insufficient recommendations and information on using these apps from health care providers, limited digital literacy among users, and apps that may not align with the specific needs of individual users. The study has also shed light on the patients' requirements for future mHealth apps, emphasizing the importance of incorporating engagement features, user-friendly designs, educational information, and carbohydrate-counting functionality in these apps.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 523 KB - diabetes_v8i1e40968_app1.pdf]

Multimedia Appendix 2
Interview guide.
[DOCX File , 15 KB - diabetes_v8i1e40968_app2.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
HbA_{1c}: hemoglobin A_{1c}
HITAM: Health Information Technology Acceptance Model
IDF: International Diabetes Federation
MARS: Mobile Application Rating Scale
mHealth: mobile health
TAM: Technology Acceptance Model

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Original Paper

Supporting the Management of Gestational Diabetes Mellitus With Comprehensive Self-Tracking: Mixed Methods Study of Wearable Sensors

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Abstract

Background: Gestational diabetes mellitus (GDM) is an increasing health risk for pregnant women as well as their children. Telehealth interventions targeted at the management of GDM have been shown to be effective, but they still require health care professionals for providing guidance and feedback. Feedback from wearable sensors has been suggested to support the self-management of GDM, but it is unknown how self-tracking should be designed in clinical care.

Objective: This study aimed to investigate how to support the self-management of GDM with self-tracking of continuous blood glucose and lifestyle factors without help from health care personnel. We examined comprehensive self-tracking from self-discovery (ie, learning associations between glucose levels and lifestyle) and user experience perspectives.

Methods: We conducted a mixed methods study where women with GDM (N=10) used a continuous glucose monitor (CGM; Medtronic Guardian) and 3 physical activity sensors: activity bracelet (Garmin Vivosmart 3), hip-worn sensor (UKK Exsed), and electrocardiography sensor (Firstbeat 2) for a week. We collected data from the sensors, and after use, participants took part in semistructured interviews about the wearable sensors. Acceptability of the wearable sensors was evaluated with the Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire. Moreover, maternal nutrition data were collected with a 3-day food diary, and self-reported physical activity data were collected with a logbook.

Results: We found that the CGM was the most useful sensor for the self-discovery process, especially when learning associations between glucose and nutrition intake. We identified new challenges for using data from the CGM and physical activity sensors in supporting self-discovery in GDM. These challenges included (1) dispersion of glucose and physical activity data in separate applications, (2) absence of important trackable features like amount of light physical activity and physical activities other than walking, (3) discrepancy in the data between different wearable physical activity sensors and between CGMs and capillary glucose meters, and (4) discrepancy in perceived and measured quantification of physical activity. We found the body placement of sensors to be a key factor in measurement quality and preference, and ultimately a challenge for collecting data. For example, a wrist-worn sensor was used for longer compared with a hip-worn sensor. In general, there was a high acceptance for wearable sensors.

Conclusions: A mobile app that combines glucose, nutrition, and physical activity data in a single view is needed to support self-discovery. The design should support tracking features that are important for women with GDM (such as light physical activity), and data for each feature should originate from a single sensor to avoid discrepancy and redundancy. Future work with a larger sample should involve evaluation of the effects of such a mobile app on clinical outcomes.

Trial Registration: Clinicaltrials.gov NCT03941652; https://clinicaltrials.gov/study/NCT03941652

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KEYWORDS

gestational diabetes; self-management; self-tracking; wearable sensor; mobile application; self-discovery; behavior change; user experience

Introduction

Background

Gestational diabetes mellitus (GDM), defined as hyperglycemia first recognized during pregnancy, is an increasing global challenge currently affecting approximately 8%-23% of pregnancies depending on the continent [1]. GDM has considerable health effects as it increases the risk for short- and long-term health disadvantages among both the mother and child [2]. Although GDM is a temporary condition that lasts until the birth of the child, it increases the later risk of type 2 diabetes for mothers by over 7 times [3]. Healthy lifestyle choices help in GDM management, with nutrition being the primary factor affecting glucose levels [4], and physical activity [5-9], stress [10], and sleep [11] also have impacts on glucose homeostasis. However, women with recently diagnosed GDM do not adequately know how their own lifestyle choices influence glucose levels [12,13], although they need to adapt to the new situation quickly [14]. Given that pregnancy usually lasts approximately 40 weeks and GDM is diagnosed after 12 to 28 weeks of pregnancy, any health intervention designed for managing GDM can be used for a limited time (for approximately 12-28 weeks). On the other hand, women with GDM show extra motivation for managing diabetes owing to the child [13,15], and pregnancy represents an exceptional opportunity for lifestyle changes [16].

A recent meta-analysis of eHealth interventions targeted to women with GDM showed that interventions providing weekly or more frequent feedback from health care professionals to women with GDM have the potential to improve glycemic control [17]. Typically, in these interventions, women with GDM can communicate with the study interventionists remotely [18,19]. For example, a recent study by Miremberg et al [18] revealed a statistically significant improvement in glycemic control among women with GDM when systematic feedback was provided by study personnel (every evening the participants received individualized feedback via email from the clinical team regarding their daily glycemic control). However, mobile health (mHealth) interventions without such substantial input from health care professionals are limited and have not been shown to be effective [20,21]. We expect that the effectiveness of mHealth interventions can be increased with comprehensive self-tracking through wearable sensors by providing more insights for women with GDM into learning associations between lifestyle and glucose levels [22,23], a process known as self-discovery (eg, [24]).

To establish knowledge on how self-tracking with wearable sensors (including glucose levels and lifestyle) should be designed to support self-management in GDM, we explored the usage of continuous glucose monitors (CGMs) and 3 types of wearable sensors for measuring physical activity. The overall aim was to examine how wearable sensors can support self-discovery and behavior change, and how women with GDM experience them.

Wearable Sensors for Supporting Self-Discovery for Women With GDM

Wearable sensors (eg, fitness trackers) have been included in investigations on the management of noncommunicable diseases, such as diabetes, migraine, and multiple sclerosis [25-32]. Moreover, in pregnancy, a recent review showed that wearable sensors have the potential to support physical activity among pregnant women, decrease gestational weight gain, predict neonatal outcomes, and support monitoring of fetal heart rate and movements [33]. However, there are no studies where the focus is on investigating how different wearable sensors (eg, in terms of body placement) and their data can support self-discovery. Traditionally, studies on personal discovery in diabetes management have been based on the data that users enter into an app [34] or write in a paper-based journal [24].

The personal discovery of understanding medical conditions with self-tracking data has gained a lot of attention [24,25,27,29,35-37]. Personal discovery is an iterative and complex process consisting of multiple stages [24,26,35]. These stages include finding potential features that may affect the desired outcomes, forming hypotheses, and evaluating their impacts on outcomes [24,38]. In diabetes, successful self-management requires knowledge of how one's activities and lifestyle (eg, nutrition, physical activity, sleep, and stress) affect glucose levels. To help people with diabetes in self-discovery, self-tracking with wearable sensors together with glucose monitoring may provide a useful tool. However, the role of self-tracking of activities and lifestyle together with glucose levels using wearable sensors in the self-discovery process is largely unknown. For example, while physical activity and sleep have been found to influence glucose levels [6,8,11] and a handful of wearable sensors for measuring physical activity and sleep are available for self-tracking, the applicability of wearable sensors in supporting the understanding of people with diabetes about how their own lifestyle choices affect glucose levels is largely unknown.

Women with GDM represent an interesting user group to study self-discovery, as they have not been managing their condition for long. The design of supporting the discovery phase becomes an especially important part of the management of GDM, as "coming to terms with GDM" and learning new strategies for self-regulation are important phases in GDM self-management [13,15]. Qualitative studies have reported feelings of failure, anxiety, loss of control, and powerlessness after receiving a GDM diagnosis [13,14]. However, women with GDM experience "a steep learning curve," and they move from the initial shock of the diagnosis to acceptance and active management of their condition [39].

For women with GDM, it is typical to find associations between nutrition and blood glucose by trying out different foods and measuring glucose afterward [13,39,40]. The behavior where patients try to establish hypotheses between daily activities and changes in disease-specific outcomes has been identified as a stage-based discovery process [24,35,38].

The framework from Mamykina et al [24] has been formulated to explain the discovery process between daily activities and changes in blood glucose levels. According to the framework [24], self-discovery consists of the following 4 stages: (1) feature selection (individuals identify activities that they believe have an impact on outcomes, eg, blood glucose in the context of diabetes); (2) hypothesis formulation (individuals formulate suspected associations with activities and outcomes); (3) hypothesis evaluation (individuals observe new information about their condition and evaluate how it fits to already collected data); and (4) goal specification (individuals formulate future goals based on identified relationships between features and outcomes).

Multiple studies have emphasized the importance of automatic data collection in diabetes apps [22,41], although this is rarely found in apps used in diabetes research [22,41]. Current standards emphasize the necessity of self-tracking glucose levels in diabetes management [5], and measurement of blood glucose levels has been found to be the most important feature of a GDM app [42]. However, the requirement of manually entering blood glucose values has decreased significantly for collecting glucose data [42,43]. Glucose measurements can be performed automatically and more frequently with CGMs. CGMs have been found to be acceptable among women with GDM [44-47]. However, recent research suggests that a CGM alone does not improve glycemic control [45,48] or decrease macrosomia [47]. One reason is that the cause and effect between lifestyle choices and glucose levels are not clear for women with GDM after receiving a diagnosis [13-15,39,40].

While self-discovery frameworks have been critiqued for expecting too rational and coherent behavior from people using self-tracking [25] (users are not scientists [49]), the trial and error aspect (hypothesis formulation and evaluation) has been identified as typical behavior among women with GDM [13,39,40]. Moreover, the framework by Mamykina [24] also considers the iterative nature of self-discovery, which is important in the context of GDM, as the development of pregnancy has an impact on glucose control [50]. Objectively and automatically measured and constantly available data obtained through wearable sensors can be expected to support self-discovery [26,27].

User Experience With Wearable Sensors for Women With GDM

Self-tracking is often mentioned as an effective behavior change technique [51], for example, shown as increased physical activity among people with type 2 diabetes [52]. Thus, we investigated the possibilities and challenges of self-tracking with wearable sensors beyond self-discovery. Wearable sensors have the potential to facilitate the management of GDM, as there is proof that lifestyle interventions using wearable sensors can be effective among pregnant women. For example, Chan and Chen [53] reported in their review that interventions with wearable devices for increasing physical activity were more effective than those without wearable devices among pregnant women.

Physical activity is one of the cornerstones in the management of GDM [5,7], but the automatic collection of physical activity data has gained minimal attention in GDM apps [22]. This was emphasized in a study by Skar et al [42] who asked women with GDM to manually enter their physical activity data into an app, but no participant entered the data, preventing the collection of any physical activity data. This is understandable as pregnant women often have limited energy for monitoring their own behavior, since they already have a lot to do and deal with [40,54]. Rigla et al [55] enabled tracking of physical activity for women with GDM by recording the activity with an accelerometer in a mobile phone. However, recording required manual start and stop by pressing buttons in a mobile app, and participants recorded their physical activity only approximately once a week on average. Even engagement with automatic self-tracking has been shown to decrease among people with type 2 diabetes and type 1 diabetes [56]. For example, Böhm et al [56] reported that the number of active users of CGMs dropped by over 20% after 20 weeks, and similarly, active users of automatic physical activity tracking dropped by over 30% after 20 weeks.

The other issue to consider in addition to the automaticity of tracking is what types of physical activities are possible to track. Carolan et al [15] noted that although walking is commonly advised for women with GDM by diabetes educators and midwives, it can be painful for many. However, automatic self-tracking beyond steps is more challenging. Årsand et al [30] found that the largest problem for people with type 2 diabetes to track their physical activity was that wearable sensors did not support the measurement of other activities, such as cycling and swimming, which are common physical activities among pregnant women [57]. More recent studies implied that wearable sensors have still rather low validity in tracking physical activities beyond walking and running, such as bicycling and resistance training [58].

Studies investigating the practical challenges of wearable sensors for self-tracking among women with GDM are largely lacking. As described above, only few studies have enabled self-tracking of physical activity among women with GDM [42,55], and in the case of self-tracking of other lifestyle factors (eg, sleep and stress) with wearable sensors, no studies have investigated

self-discovery among women with GDM. In the context of pregnancy, automatic self-tracking of lifestyle (eg, nutrition, physical activity, and symptoms) has been argued to help in countering pregnancy-related health risks [59,60]. However, some women perceive pregnancy medicalization and state that they lack control over their own bodies even without multiple wearable sensors [13,54]. The use of sensors can further increase the feeling of losing a normal pregnancy [13]. Moreover, it is unclear how the sensors fit pregnant women whose physical and mental conditions are different from those of the general population. Pregnancy causes several lifestyle changes (eg, diet limitations), physical changes (eg, difficulty moving, contractions of the uterus, and increased waist size and heart rate), sleeping disorders, and tiredness. The effect of differences in these conditions on self-tracking with wearable sensors should be investigated.

Methods

Research Design

We conducted a mixed methods study where women with GDM (N=10) used a variety of wearable sensors and their mobile apps for a week. Our primary aim was to examine how wearable sensors can support the self-management of GDM. We studied this with 2 research questions (RQs) as shown in Textbox 1. We investigated how self-tracking with wearable sensors can support or inhibit self-discovery (RQ1) and how women with GDM experience wearable sensors (RQ2). The study was performed in Finland.

Textbox 1. Research questions.

- Research Question 1: How self-tracking with wearable sensors (not only continuous glucose monitors) can support or inhibit the self-discovery of women with gestational diabetes mellitus (GDM)? We investigated the role of wearable sensors at each stage of the self-discovery process (feature selection, hypothesis formulation, hypothesis evaluation, and goal setting), as described in the section Wearable Sensors for Supporting Self-discovery for Women With GDM.
- Research Question 2: How do women with GDM experience wearable sensors? Although wearable sensors have been investigated with pregnant women and people with type 1 or type 2 diabetes, the knowledge of how women with GDM perceive wearable sensors is less known, as described in the section User Experience With Wearable Sensors for Women With GDM.

Ethical Considerations

The study was performed in compliance with the Declaration of Helsinki and was approved by the Ethics Committees of Helsinki Central Hospital (September 14, 2006; Dnro 300/E9/06). The study was registered at Clinicaltrials.gov (NCT03941652).

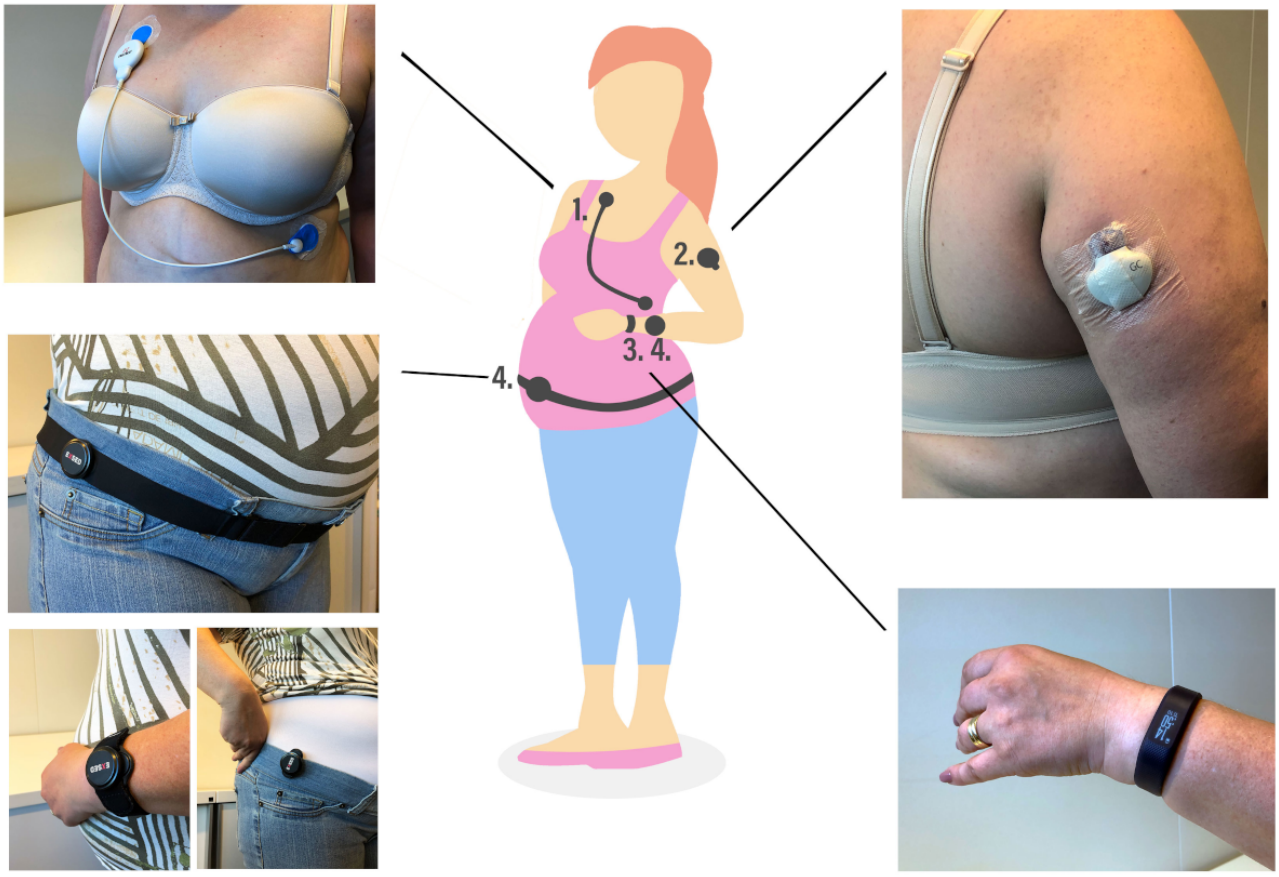
Sensors

Continuous Glucose

Medtronic Guardian Connect CGM with an Enlite sensor (Medtronic; Figure 1) can continuously measure tissue glucose. A flexible filament is inserted just under the skin to measure glucose levels in interstitial fluid every 5 minutes. Values are sent to the Medtronic Guardian app via Bluetooth. If a Bluetooth connection is not possible, the CGM system transmitter collects the data for several days. Medtronic requires calibration of the sensor through fingertip blood glucose measurements 2 times a day. The overall mean absolute relative difference has been reported to be 13.6% [61].

The Medtronic CGM was attached to the skin by a study nurse. This was because participants wished to wear the CGM on the arm and they could not attach the CGM to the skin using only one hand. Currently, CGMs do not allow tracking of lifestyle data, and additional sensors are needed to support tracking beyond glucose.

Figure 1. The wearable sensors used in the study: (1) Firstbeat, (2) Medtronic Guardian Connect, (3) Vivosmart 3, and (4) Exsed.



Physical Activity

We chose to use multiple physical activity sensors to study which sensor or combination of sensors should be used in terms of wearing comfort and provided data. Details are provided in Figure 1 and Table 1. Exsed (UKK-Institute) was worn on the hip and provided data about standing and sitting. The data analysis was based on validated MAD-APE algorithms [62,63]. These analyses have been employed in population-based studies of Finnish adults [64,65]. Vivosmart 3 (Garmin) was worn on the wrist and provided data about intensity minutes. Vivosmart 3 has been shown to measure steps well at slow walking speeds (mean absolute percentage error was 1.0%) [66], which is important as walking speed is affected by pregnancy [67].

Physical activity sensors also varied in terms of how visible they were to others nearby. Exsed could be worn in a discreet manner so that others would not see it, whereas Vivosmart 3 was worn on the wrist and was more conspicuous. This *physicality* has been shown to be a prominent issue for wearable sensors [49].

The heart rate variability (HRV) sensor Firstbeat Bodyguard 2 (Firstbeat Technologies) was added to explore the validity of physical activity and sleep data recorded with physical activity sensors. The device is able to continuously measure beat-to-beat HRV with an error of <3 ms and a detection rate of >99.9% as compared with clinical-grade electrocardiography [68].

Due to incompatibility issues between different operating systems and sensors, the participants were given an iPod touch with the sensor apps preinstalled. The participants were able to use their own mobile phones with Vivosmart 3, as we found no incompatibility issues in the Garmin Connect app prior to the study.

Table 1. Wearable sensors worn by the participants (participants wore all sensors simultaneously).

Sensor name	Type	Data provided	Wearability	Components	User interface	Waterproof	Worn by each participant
Medtronic Guardian Connect CGM[a] with an Enlite sensor	CGM	Interstitial fluid glucose value every 5 minutes	Typically worn on the area of the abdomen, which is at least 5 cm from the navel, but participants wished for attachment to the upper arm.	Enlite sensor: flexible filament measures glucose levels in interstitial fluid; Guardian Connect transmitter: Bluetooth	None. Data access through a mobile app (Medtronic Guardian Connect). The app enables viewing the time series of glucose values, and the viewing range can be changed from 1 hour to 1 day. Users insert the calibration values twice a day, and it is possible to add carbohydrates and physical activities to the timeline.	Yes, up to 2.5 meters for up to 30 minutes	Mean=94% of the time (23 h and 3 min/day)
Garmin Vivosmart 3	Activity tracker	Steps, intensity minutes, stairs climbed, heart rate, sleep duration, sleep quality, stress, and calorie consumption	Worn on the wrist with an adjustable plastic strap.	Bluetooth Smart, ANT+, 3D accelerometer, optical heart rate sensor (green LED), barometric altimeter, and ambient light sensor	Touch screen, and data access through a mobile app (Garmin Connect). The app enables viewing of many kinds of information about the recorded data, and the time span of the graphs can be varied between 1 day and 1 year.	Yes, up to 50 minutes	Mean=93% of the time (22 h and 30 min/day)
Exsed	Activity tracker	Duration of physical activity, sedentary behavior, sleep sensor, sitting, standing, breaks in sitting, steps, sleep duration, and sleep quality	Worn on a belt around the hip or on a clip attached to trousers, and worn on the wrist during nighttime.	Bluetooth, 3D accelerometer, and gyroscope	None. Data access through a mobile app (Exsed2). The app visualizes the recorded data on a daily graph and a weekly graph.	Yes, up to 30 meters	Mean=83% of the time (19 h and 55 min/day)
Firstbeat Bodyguard 2	HRV[b] sensor	Stress, recovery, duration of physical activity with intensities, HRV, heart rate, excess postexercise oxygen consumption, respiration rate, and others	The device is attached to the chest with 2 disposable clinical-grade electrocardiography electrodes.	3D accelerometer and beat-to-beat heart rate	None. Data are provided in a PDF after the measurement period.	No	Mean=93% of the time (22 h and 30 min/day)

[a]CGM: continuous glucose monitor.

[b]HRV: heart rate variability.

Recruitment and Data Collection

Our goal was to recruit 10 women with GDM from maternity and antenatal clinics in the Helsinki Metropolitan Area (Finland). The goal for the number of participants is similar to that in multiple qualitative studies on women with GDM [12]. The clinic nurse asked women with GDM at least at 24 gestational weeks about their interest in participation. If interested, the study nurse contacted the mother with more information about the study and confirmed eligibility. The exclusion criteria were type 1 or type 2 diabetes, use of medication that can influence glucose metabolism (eg, oral corticosteroids, metformin, and insulin), diagnosis of GDM in previous pregnancies, current substance abuse, presence of a severe psychiatric disorder, significant difficulty in cooperating (eg, inadequate Finnish language skills), and significant physical disabilities that would prevent the use of a smartphone or moving without aid. Data were collected using the following procedure. After obtaining informed consent, we collected background information (eg, age, pregnancy weeks, and familiarity with mobile apps) through a questionnaire.

Participants were asked to wear wearable sensors (see the section Sensors) for 6 days and nights, after which they were interviewed in their native language (Finnish). The length of

the usage period was decided based on the battery life of the transmitter of the CGM, which was 6 days. To compare data from wearable sensors with their perception of physical activity and sleep, participants filled out a logbook for physical activity and sleep (duration in hours) for 6 days. For physical activity, participants were asked to write down the type of activity, duration, and intensity (light, moderate, or vigorous). The perceived intensity levels were defined according to descriptions by Norton et al [69]. Moreover, Firstbeat used the same intensity categorization as provided in [69]: 20%-40% of maximal oxygen consumption (VO_2 max) is considered light physical activity, 40%-60% of VO_2 max is considered moderate physical activity, and over 60% of VO_2 max is considered vigorous physical activity. Vivosmart 3 shows the intensity of physical activity as intensity minutes, which is gathered when physical activity at a moderate level is performed for at least 10 consecutive minutes. Physical activity at a vigorous level doubles the gathered intensity minutes. Explicit thresholds for moderate and vigorous activities are not provided in the documentation. Exsed did not provide data regarding the intensity of physical activity.

One of the most prominent features is tracking and managing diet, as this is the primary factor that affects glucose levels. However, wearable eating detection systems are not able to detect the macros of food [70,71]. As such, wearable sensors were not used to measure diet, and participants kept a diet logbook for 3 days during the study period. We chose to gather diet data for 3 days, because keeping a food diary is laborious and it has been shown that diet data for 3 days provide valid results [72].

Before starting the measurement period, participants were met by an experimenter and a study nurse. In the meeting, participants provided written consent, filled in a background questionnaire, and were instructed on how to use the sensors. They were given contact information in case they faced problems in using the sensors. Finally, at the end of the meeting, participants filled in a technology acceptance questionnaire based on the Unified Theory of Acceptance and Use of Technology (UTAUT) [73], which has been widely used for evaluating the acceptance of technology in diabetes management [74]. After the usage period, participants filled out the same UTAUT questionnaire and took part in a semistructured interview, which was audio-recorded. At first, we asked questions concerning all the sensors, such as how they impacted the users' daily lives. After this, we asked questions concerning each sensor, such as what the users were able to discover from the data, how the data impacted their daily behavior, what data they valued, and what challenges they had with each sensor. See Textbox 2 for the main interview questions. Interviews were conducted in quiet places that were easiest for the participants to arrive at and were conducted in their mother tongue. Interviews lasted approximately 1 hour on average. After a 15-minute break, participants continued with an interview about a prototype GDM application (results are reported elsewhere [23]).

Textbox 2. Main interview questions regarding the wearable sensors.

Main questions about self-discovery

- Have you made deductions based on the data from the sensors and their apps? If yes, what kind of?
- Has the usage of the sensors influenced your behavior? If yes, how?
- Do you think that the <sensor name> would help you to manage blood glucose? Please justify.
- Has the information from the sensors or their apps been confusing or unclear? If yes, what?
- Did you feel that the information from the sensors described your behavior truthfully?

Main questions about the user experience

- What factors influenced wearing the sensors?
- Have the sensors or their apps caused you any discomfort or inconvenience? If yes, which sensors or apps and how?
- Think about your experience with the sensors and their apps. How would you improve them?

Analysis

Interviews were transcribed, and 2 researchers familiarized themselves with the interviews by reading the transcripts. The analysis was performed according to the framework method, which is a recommended approach for multidisciplinary health research [75]. We used self-tracking of blood glucose, diet, physical activity, sleep, and stress as initial codes. Coding was implemented with Atlas.ti by employing emergent theme analysis of the data collected [76], resulting in 66 codes altogether. These codes were combined into larger categories, which are presented and discussed in relation to the main themes of the study (ie, self-discovery and experiences with wearable sensors).

Quotes provided in the results were translated into English intelligent verbatim, a process whereby filler words such as "er" are removed during translation. Log files from the sensors were used to determine how much the participants wore them, how data from the sensors correlated with self-reported data, and whether there were differences in data between the sensors. The statistical significance of differences in data between sensors was computed with the Friedman test, and correlations between automatically measured and self-reported data were calculated with Spearman or Pearson correlations, depending on the test for normality (Shapiro-Wilk). Finally, we triangulated among

these data sources (interviews, data from the sensors, and logbooks) to understand how self-tracking with wearable sensors should be designed to support self-discovery.

Results

Participants

Ten women with GDM (Table 2) were recruited. We had a variety of participants in terms of age (minimum 24 years, maximum 40 years). Participants were familiar with mobile apps and measuring glucose, but they had less experience with using wearable physical activity sensors, as depicted in Table 2. The same participants participated in another study after this study [23]. The mean age of the participants was 33.6 years, which is similar to that of women with GDM in Finland (mean 32.5, SD 5.3 years) and in the Helsinki area (mean 33.1, SD 5.1 years) [77]. The mean BMI of the participants was 25.7 kg/m^2, which is in the range of the mean BMI of women with GDM in the Helsinki area (mean 27.1, SD 6.0 kg/m^2) and in Finland (mean 28.5, SD 6.3 kg/m^2) [77].

Table 2. Participant demographics and their experience with mobile apps and sensors.

ID	Age (years)	Weeks of gestation	BMI before pregnancy (kg/m^2)	How many minutes per day do you exercise at a moderate level?	I am used to using various mobile apps[a]	I am used to using physical activity sensors (such as Fitbit, Vivosmar, and Polar)[a]	I am familiar with measuring blood glucose[a]
1	36	35.0	22.2	150	4	3	5
2	32	33.3	30.1	4	4	2	4
3	40	31.2	23.1	120	4	2	4
4	24	33.7	29.8	240	5	2	5
5	31	35.6	26.0	3	4	2	4
6	31	30.3	21.0	210	5	1	4
7	32	36.6	20.2	3	2	1	5
8	36	37.0	25.4	120	5	5	5
9	35	34.8	22.9	120	5	1	4
10	39	28.1	36.6	150	5	5	5
Mean	33.6	33.6	25.7	25.7	4.3	2.4	4.5

[a]For the statements, the Likert scale ranged from 1 (strongly disagree) to 5 (strongly agree).

Factors Supporting Self-Discovery (RQ1)

Continuous Glucose Monitoring

While participants were familiar with measuring their glucose levels (Table 2), they learned new things owing to continuous monitoring.

> *I wish I had this [CGM] when I got the GDM diagnosis, so I would have got some knowledge of the glucose curve.* [Participant #9]

They learned new causalities between food and glucose levels.

> *I think it is better to have the data from 24 hours. Then you can see what happens in between. Nowadays, I eat nuts because I know that when I started eating nuts, my blood glucose started to be at a good level.* [Participant #1]

Improved glucose control was noted in Participant 2, who started monitoring glucose levels continuously and learned to adjust eating accordingly.

> *I had a couple of hypers [hyperglycemia], but I think with normal measurements those would not be noticed because they were irregular...especially the hypers in the morning...At first, I was like I don't have any problem with them [glucose levels] but when you had that continuous measurement I figured out that it is not actually the case.* [Participant #2]

The CGM facilitated monitoring the variability of glucose, and among 7 of the 10 participants, the variability of glucose values decreased, which was calculated as a trend in the variability of glucose using LAGE (large amplitude of glucose excursions) [78]. The CGM not only supported self-discovery but also improved motivation to change the diet.

> *...you are able to see it [glucose] for the whole day...it motivates for changing the diet.* [Participant #2]

While participants had extra costs from wearing the CGM (see the section Wearing the CGM on the Arm) and calibration (see the section Needed Effort Using the Sensors), most of the participants would have liked to continue using the CGM, as they got used to it.

Numerical Affirmation for Assumed Cause and Effect

Half of the participants (5/10) discussed that they found numerical evidence for the assumptions they had before the study.

> *These sensors have confirmed my assumptions what are the most important factors to control blood glucose and GDM and weight management in the*

> *future...so the regular eating is of paramount importance for me.* [Participant #10]

Moreover, this included more specific causalities that had been assumed before using the sensors, as Participant 9 found evidence for an association between physical activity and blood glucose.

> *If you move or plan to move, then you can eat food which has more carbs...so I have been following if I do something I can eat a little bit more...this kind of normal thing that I kind of had thought before...but now it was more like you can actually see it.* [Participant #9]

Factors Inhibiting Self-Discovery (RQ1)

Most of the participants (7/10) did not discuss finding cause and effect between physical activity and glucose levels. For example, Participant 9, who was data-oriented, tried to figure out the causalities.

> *Well, maybe the information from the activity bracelet was useful, as I have never used such a device before and I am interested in numbers...and this information connected to what is happening in my blood glucose...so I tried to figure out connections.* [Participant #9]

As the self-discovery process seemed to be tedious for many of the participants, they would have liked to receive clear instructions on how to change their behaviors. Some participants wished to see important data being highlighted.

> *I wished I could have seen highlighting or other markings, what to look for from the data.* [Participant #10]

As such, the current tools did not support establishing links between glucose levels and physical activity. In the following text, we discuss issues that inhibited self-discovery.

Lack of Trackable Features

Participants had less physical activity than recommended during the measurement period, as measured with Firstbeat. According to the recommendation, pregnant women should have at least 150 minutes of moderate physical activity in a week [79], but according to Firstbeat, the participants had approximately 7 minutes per day of moderate physical activity (Figure 2). In most cases, the lack of physical activity was explained by being in the third trimester of pregnancy.

> *Unfortunately, I did not have much physical activity as I get pain from normal walking...I was tempted to do more, but my condition did not allow it.* [Participant #2]

Thus, without enough physical activity, it was difficult to interpret the effect on glucose.

As the intensity levels of physical activity were difficult to quantify and recognize, the participants had only very little understanding of what the physical activity shown as intensity minutes meant.

> *They were very confusing, I did not follow them actively, one day I just realized that I have got more of them, but I did not have any clue what they are based on. On one day I became unwell in a shop, and I noticed that I had received intensity minutes because my heart rate had increased...but it was not something nice.* [Participant #4]

The number of intensity minutes varied a lot between participants, as 1 participant did not gain intensity minutes at all during the measurement period and 1 participant gained 145 minutes (the goal being 150 minutes per week). Moreover, Vivosmart 3 required physical activity to last 10 consecutive minutes to be counted, which was not often the case for participants as their physical activities were performed for shorter periods, such as walking the stairs.

While the intensity of physical activity was difficult to recognize and the intensity minutes were not achieved much or understood well, steps were easily understood, and step goals provided by sensor applications were achieved more often. However, half of the participants (5/10) did not care about the goal, as walking was perceived to be tedious.

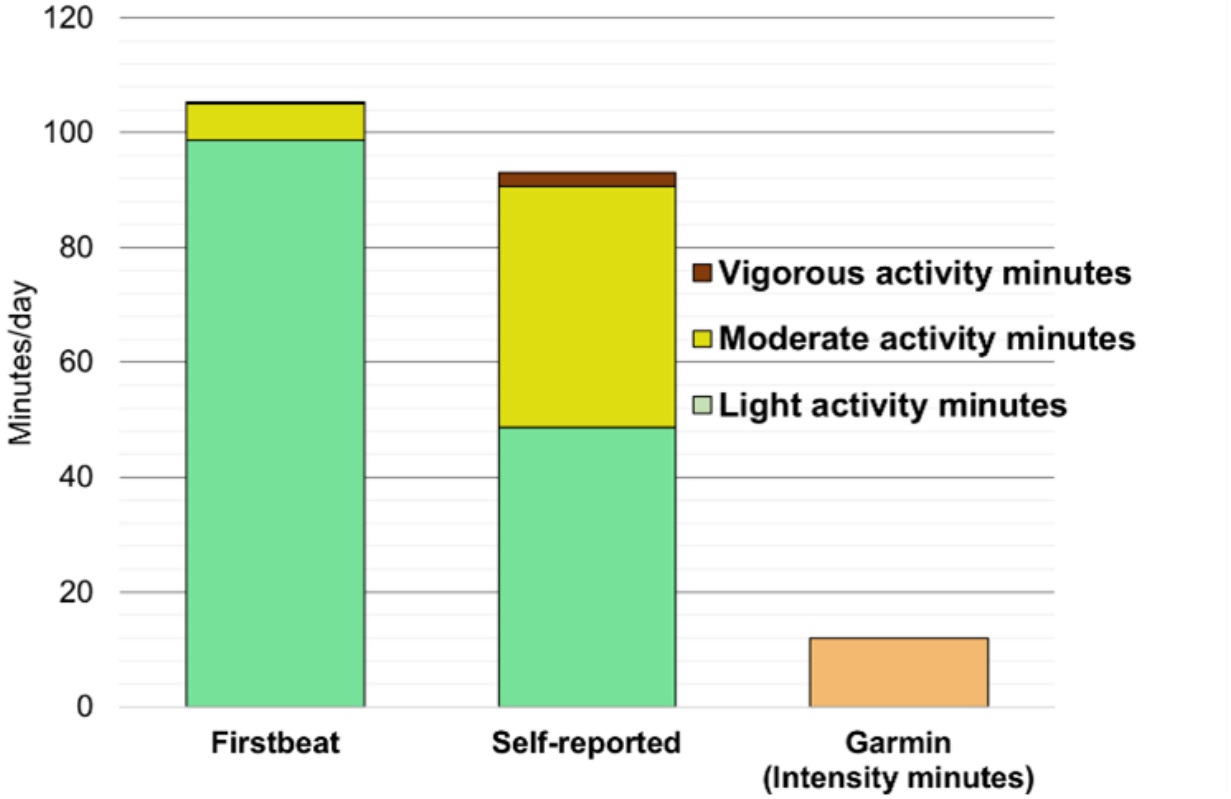
> *I did not care about the step goals, before pregnancy I could have challenged myself, but now I go for a walk which feels good and that's it.* [Participant #5]

Three of the 10 participants discussed the importance of the possibility of tracking swimming and water running, as these were the only exercises they were able to perform well.

> *For a gestational diabetes patient, swimming is almost the only sport that you can pretty normally do, so the sensor should definitely be one that encourages you to move, especially to swim.* [Participant #1]

This highlights the importance of the waterproofness of physical activity trackers and the possibility of tracking swimming for women with GDM.

Figure 2. Duration and intensity of daily physical activity as measured with Firstbeat (heart rate variability) and as self-reported. A substantial portion of physical activity that heart rate variability measured to be light was perceived as moderate.



Difficulty of the Quantification of Self-Tracking Data

We expected the quantified information through wearable sensors to help in forming hypotheses, as an abstraction to quantifiable units (eg, from a fast walk to the heartbeat) is often required at the hypothesis formulation stage [24]. However, the discrepancy between perceived and measured quantification and clearly erroneous quantification with wearable sensors imposed significant challenges for hypothesis formulation. This study showed a significant difference between measured and perceived quantification of physical activity. Participants interpreted the intensity of physical activity as higher than it was measured, that is, participants perceived light activity as moderate activity. This can be seen in Figure 2, which shows a high proportion of physical activity being light, as measured with Firstbeat. The participants self-reported their overall duration of physical activity rather similarly to Firstbeat. In fact, there was a statistically significant correlation between Firstbeat and self-reports (Spearman r_{59}=0.43; P<.001) in terms of the duration of physical activity. However, the participants categorized the intensity (intensity was instructed according to [69]) of physical activity differently than Firstbeat. There were no statistically significant correlations between self-reported values and the values from Firstbeat when looking at each intensity within the categories.

In general, the participants had difficulties in interpreting what is counted as physical activity.

> *At this point of pregnancy you move a little, and tasks like fetching the mail is already pretty tough...so it is a bit difficult to say what is counted as exercising and what is not.* [Participant #4]

As such, perceiving physical activity as more intense than measured might lead to incorrect conclusions about its effect on glucose levels.

Contradicting Self-Tracking Data

Differences in the data provided by the sensors caused significant challenges for self-discovery. Regarding physical activity, there were statistically significant differences in the number of steps between the devices, as evaluated with the Friedman test (χ^2_2=16.22; P=.008). These differences were not explained by the differences in how long the sensors were worn, as Vivosmart 3 and Firstbeat were worn for similar durations, but Vivosmart 3 (mean 7191 steps/day) provided twice as many steps as Firstbeat (mean 3519 steps/day). Exsed was in the middle with a mean of 6307 steps/day. Firstbeat required a longer continued movement to start the counter, whereas Vivosmart 3 started counting the steps immediately. It is probably a more desirable strategy to also count the steps during small transitions (eg, in the home), as there were only a few pregnant women who exercised. However, Vivosmart 3 counted movement as steps, even though the participants had not walked.

> *When I woke in the morning, I had several hundred steps, although I had not walked that much during the night.* [Participant #1]

Contradictory data between sensors were not only limited to steps, as there was no significant correlation in the duration of moderate physical activity between Firstbeat and the amount of intensity minutes in Vivosmart 3 (Spearman r_{57}=0.22; P=.12).

Regarding sleep, there was a statistically significant difference in the length of sleep between the devices, as evaluated with

the Friedman test (χ^2_2=17.27; P<.001). Exsed showed significantly less sleep (mean 7.2 h/night) compared with Vivosmart 3 (mean 7.8 h/night) and Firstbeat (mean 8.0 h/night). These differences raised a lot of questions among participants and decreased the credibility of the data. These responses on contradictory data also reflect the UTAUT responses on incompatibility (see the section General Acceptance Based on the UTAUT). Three participants found that the data provided by the sensors they normally use (activity bracelets by Fitbit, Polar, and Suunto) varied significantly in terms of physical activity and sleep.

In addition, 6 of the 10 participants discussed differences between continuous glucose measurements taken from tissue and fingerstick measurements taken from the blood. The reported differences varied a lot. Some participants reported that the differences were significant.

> *...a couple of times it [Medtronic] showed that the glucose was low, but it wasn't that low...at one time it [Medtronic] showed 2.8 [mmol/l], but it was 5.3 [mmol/l, as measured from fingertip].* [Participant #4]

On the other hand, some reported that the differences were minor.

> *I don't think they differed much...looking at the graph you were able to see an increase after eating and during night time it was low, so they seemed to be pretty accurate.* [Participant #6]

Nevertheless, the differences decreased the credibility of glucose monitoring data.

> *...the values were somewhat different than taken from fingertip...so it made me think how much I can trust this data.* [Participant #9]

However, the use of multiple sensors supported gathering a lot of data from many perspectives, with the potential to increase understanding.

Challenges in Self-Tracking of Sleep

As pregnancy decreases the quality and length of sleep [80], sleep information could be valuable for women with GDM, as they learn to understand their sleeping disorders. Five of the 10 participants mentioned information about sleeping to be particularly interesting.

> *On Thursday night I slept two hours and six minutes, so it was pretty interesting to get that kind of readings, but I think it is positive in the sense that it proves that I am not becoming crazy but instead slept too little.* [Participant #10]

Moreover, these participants discussed that they were interested in the quality of sleep.

> *It was interesting to look at the sleep graph...so in the early night I had slept deeper and lighter towards the morning, and how you have woken or not woken up.* [Participant #9]

However, 2 of the 10 participants did not want to get feedback about their sleeping as they knew they had slept too little.

> *I have not had any possibilities to influence my sleeping during the past month, so it could be a bit depressing information that you have slept lousy...Well, I know that already.* [Participant #1]

Thus, seeing sleep data was clearly a matter of personal preference.

Participants sometimes had difficulties in estimating at what time they had fallen asleep; thus, objectively measured sleep has the potential to provide unbiased information for the self-discovery process. In general, participants' self-reported duration of sleep (mean 7.8 h/night) correlated with the duration of sleep measured with the wearable sensors Firstbeat (Pearson r_{42}=0.58; P<.001), Vivosmart 3 (Pearson r_{42}=0.57; P<.001), and Exsed (Pearson r_{36}=0.55; P=.001). Moreover, sleep data gathered through sensors were more comprehensive as participants sometimes forgot to mark the waking and sleeping times in the logbook.

Nevertheless, participants were not able to link their sleep with glucose values, although they tried to increase their understanding of how to manage glucose values.

> *I am most interested in the quality of sleep and stress levels. And how and if they impact the glucose somehow...my fasting glucose values don't seem to be within the limits no matter what, so it is the same whatever I eat, so I feel that they are always high.* [Participant #8]

Challenges in Self-Tracking of Stress and Recovery

In general, all participants were curious about their stress levels and how these levels were linked to glucose levels. However, most of them (7/10) had difficulties interpreting the stress data provided by Vivosmart 3. Pregnancy increases the resting heart rate and decreases the HRV [81], which has been used as a measurement for stress [82]. The decrease in HRV due to pregnancy most likely caused Vivosmart 3 to interpret standing as stress, although participants did not feel stressed.

> *The stress data was confusing. I did not understand how it figured out that I had been very stressed that day. I stood a lot at my workstation, so I wondered if it is so silly that it thinks that I am terribly stressed if I stand.* [Participant #3]

However, 3 of the 10 participants valued the stress data from Vivosmart 3 as it helped them know whether they recovered from stress.

> *There was one day when I was using a computer and I had meetings for the whole day, it was very stressful for the body, even though I did not do anything physically...these stress sensors sort of gave me information on what is enough rest for recovery, this was new to me.* [Participant #9]

Seeing themselves being described as stressed did not seem to make them more stressed but sometimes helped to distinguish between stress and rest.

> *I was able to look at the stress level, so it concretized when I am like resting and when the stress is high.* [Participant #7]

Participant 8 discussed that the stress reading from the sensor could be used as an objective value like body temperature, which would make a partner understand the condition.

> *...at home I can show, look how stressed I am...so you should take care of the child while I'm resting.* [Participant #8]

Thus, stress data were valued by other means than supporting the self-discovery of glucose levels.

Toward Better Tools for Supporting Self-Discovery

Although the participants had received their GDM diagnosis some weeks prior to the study's measurement period, they were still in the discovery phase [38], meaning that they were figuring out the factors affecting their glucose levels. We found many instances that followed the chosen self-discovery framework [24]. Over half of the participants (7/10) found causalities between nutrition and glucose values in continuous glucose monitoring, and 3 of the 10 participants found causalities between physical activity and glucose values in continuous glucose monitoring. However, these causalities were based on gained experience (ie, the food that was just eaten or the walk that was just taken) and CGM data, but not on the data from lifestyle sensors. This indicates that establishing causalities based on self-tracking data through wearable sensors appears to be too challenging, and better tools (or more support from health care professionals) for interpreting the self-tracking data through wearable sensors are needed. In this study, 6 of the 10 participants commented that they would have liked to have added information in a single app, which would have decreased the amount of redundant data shown.

> *So that the same information would not be entered in many places, but also the same or overlapping information would not be presented to the user, so you should have one app.* [Participant #10]

This was also reflected by Participant 9.

> *So that all the information is visible in one place, and there won't be many links and sources. So, the challenging thing was what I should write on the paper, what I see on the bracelet...so there should be one place and one way to show this information.* [Participant #9]

The other issue was that participants had to enter the blood glucose values taken from their fingertips into the Medtronic app, as well as write them down with a pen and paper and report these values to a health care professional. This requires double marking of blood glucose values, which can decrease the motivation to track glucose values in the GDM application in the long term [42]. As such, participants indicated that they wished to have a single application where all the data from lifestyle sensors and the CGM are gathered. This would decrease the amount of redundant and contradictory data, as participants were confused by the differences in the data provided by multiple sensors.

Experiences of Wearing the Sensors (RQ2)

Wearing the CGM on the Arm

Most of the participants (8/10) preferred wearing the CGM on the arm instead of near the navel. One reason was that participants did not like to attach the sensor near the baby.

> *Now when you feel with your hands your baby moving, it would feel somehow weird if there was something in that place during pregnancy.* [Participant #6]

Other reasons were that the abdomen was sore and the sensor would be visible to self and others. However, wearing the CGM on the arm caused problems with glucose measurement during the night, as the participants slept on the glucose sensor, which caused the sensor readings to drop below the alarm limit, and this woke up most of the participants (8/10). The participants had to turn off the iPod to silence the alarm, which caused some of the glucose measurements to be missing from the sensor. Thus, the participants could not sleep on the side where the sensor was placed. We tried to avoid this by asking on which side the participant typically sleeps and attaching the sensor on the other side, but this did not always help as some participants slept on both sides.

> *At this stage of pregnancy...you must sleep on both sides, they are the only poses in which you can sleep, so the position has to be something else than that [the arm]...* [Participant #1]

While most participants (9/10) preferred not to wear the glucose sensor near the navel, Participant 10 preferred that option. However, this participant hit the glucose sensor at various places, such as a car seat.

> *For example, I hit it [glucose sensor] on the car seat every time I got in the car or got out of the car it hurt...so I wonder if there is a better place for it.* [Participant #10]

In fact, 3 of the 10 participants reported the issue of hitting the sensor on various objects, causing some pain in the arm. As such, there was no optimal place where this CGM could be placed. An issue with the stickers holding the CGM is that they can be loosened when swimming, which was an important hobby for 3 participants. In fact, the stickers holding the CGM were loosened in 1 participant, and the sensor got detached when swimming. Therefore, stickers as a fastening mechanism for sensors should be avoided in the long run.

> *...six days is pretty heavy, so you do not want to take them all with you, so I think, especially when there are these glues, so I would not like to wear them for very long.* [Participant #1]

Wearing the Lifestyle Sensors

Overall, the participants wore the sensors over 80% of the time (ie, over 19 h/day), as shown in Table 1. Participants wore the sensors, except when they were showering or swimming. Sometimes they forgot to wear the sensors, and this was especially the case with Exsed (hip worn), which required a change of position before and after sleeping. In fact, there was

a statistically significant difference in measurement durations, as evaluated with the Friedman test (χ^2_3=8.124; *P*=.04). A post-hoc test using Bonferroni correction [83] revealed that data from Exsed were acquired for a significantly (*P*=.03) shorter time (mean 83% of the time) than from the Vivosmart 3 activity bracelet (mean 93% of the time). No other differences were found between the sensors in terms of measurement durations. The Exsed hip sensor operated with batteries during the whole period and did not require charging; however, the Vivosmart 3 sensor was worn more. Participants had only limited wearing issues with Vivosmart 3. Two participants discussed that it caused some swelling, but no other issues were raised. This was different from Exsed worn on the hip. Information regarding the preference of Exsed was obtained from 9 participants. Of the 9 participants, 4 preferred to wear Exsed on a clip, 2 preferred to wear it with a belt, and 3 did not have a preference. The primary reason participants preferred wearing Exsed on a clip was that it was difficult to adjust the tightness of the belt. When the belt was loose, it easily moved around.

> *It rolled all the time and fell down, so it was a bit irritating.* [Participant #10]

Moreover, if it was tight, it pressed uncomfortably.

> *The belt pressed even more [than the clip], I do not know how much it could have been looser.* [Participant #8]

The belt was used if no place was available for the clip.

> *I am wearing a skirt or dress, so the belt has been more natural.* [Participant #5]

Participants also had issues with the clip, as it chafed the skin.

> *As I have this belly, it [Exsed] is irritating on the waist. ...I had to fix its [Exsed] position and move it so if I am sitting it is under pressure.* [Participant #2]

In fact, 5 of the 10 participants reported that they had some issues with wearing Exsed with either the clip or belt. As such, pregnancy decreased the feasibility of using a hip sensor for tracking physical activity. However, the hip sensor was perceived as unnoticeable by some participants as it did not have a user interface and it was worn in the trousers.

> *You did not notice it at all, so sometimes I forgot that I needed to put it on when I took my trousers off.* [Participant #4]

Needed Effort Using the Sensors

The requirement to calibrate the CGM twice a day was found to be tedious.

> *It [calibration] was needed surprisingly often...although it did not bother me during the week, but in the long term it could become an issue, all those calibrations if you are somewhere [else than home]...* [Participant #2]

This influenced the sleep of Participant 4, as this participant needed to wake up in the mornings to calibrate the sensor.

> *On some mornings, it was irritating that it notified me half an hour before calibration, I thought I could have slept half an hour more.* [Participant #4]

The other issues that needed substantial effort from participants were keeping the nutrition diary and filling the physical activity logbooks. These would not be feasible in the long term.

> *Writing the diaries took a lot of time. I could not manage that every day.* [Participant #3]

These responses support the findings from [42] that the requirement of manually entering physical activity reduces the amount of data significantly in the long run among women with GDM. Even manual start/stop for recording exercises was not used much, as it was easily forgotten.

> *...it was very difficult to remember to mark the activities, like starting the activity and stopping the activity.* [Participant #10]

General Acceptance Based on the UTAUT Questionnaire

Responses to the UTAUT questionnaire (see results in Multimedia Appendix 1) showed good acceptance of sensors before and after usage. For example, participants agreed with the statement “I would find using the sensors as a good idea” (before: mean 6.0, after: mean 6.1; out of 7, where 7 is “strongly agree”). Participants felt that wearable sensors supported behavior change, and they agreed with the statement “Using the sensors will improve my possibility to make a concrete improvement in my lifestyle” (before: mean 6.0, after: mean 5.9; out of 7, where 7 is “strongly agree”). Participants mentioned that being able to see trends could guide their behavior related to diet and physical activity.

Acceptance was not affected by the usage of the sensors, as there was no statistically significant difference in acceptance before and after usage (evaluated with the Wilcox signed-rank test). The largest difference between before and after usage was in the statement “The sensors are not compatible with the other sensors I use for self-tracking.” Before usage, the study participants disagreed with the statement (mean 2.5), but after usage, they slightly agreed (mean 4.5). Only the participants who were using other self-tracking sensors responded to this statement, so the sample size was too small to conduct a meaningful statistical test. However, the responses in the interviews reflected the change in responses on incompatibility.

> *I found differences in both activity sensors [Exsed and Vivosmart 3] compared to this my own Polar, which was on my other hand. I changed its settings to correspond with the right arm...it [Polar] gave different readings on activity and steps, although the length of a step was set to the same. It was so mysterious why they differed so much.* [Participant #10]

Despite this incompatibility with the participants’ existing self-tracking devices, the use of wearable lifestyle sensors together with the CGM was acceptable.

Discussion

Principal Findings

This is the first study that aimed to investigate how to support self-management of GDM with wearable sensors in addition to CGMs. Regarding self-discovery (RQ1), we found that the CGM supported the learning of the associations between blood glucose and nutrition, but the wearable sensors measuring physical activity, sleep, and stress did not provide significant support for the learning. The challenges included the dispersion of data among multiple apps, missing trackable features, such as type and intensity of physical activity, and a lack of GDM-specific goals for behavior. From the user experience perspective (RQ2), this study highlighted that the benefits overcame the discomfort and effort when wearing the sensors. There were differences in sensor preference, and a wrist-worn sensor was preferred over a hip-worn sensor and was worn for longer. In general, this study further emphasizes the findings [22,43] that self-tracking among women with GDM should be highly automatic. We discuss these results in the following sections with respect to each RQ.

Supporting Self-Discovery With Wearable Sensors (RQ1)

Feature Selection

Starting from *feature selection* (ie, identification of activities that have an impact on blood glucose), this study highlighted the need to tailor the available features and their presentation with respect to GDM. Women with GDM had difficulties in interpreting and accessing the physical activity features. The activity bracelet required users to perform physical activity at a moderate level for 10 consecutive minutes to be able to see the duration of physical activity, which was not often the case for the women with GDM as they performed small activities, such as short walks. In fact, 2 participants did not achieve intensity minutes at all. This might mean showing light physical activity, for example, in terms of steps. However, there are no official health recommendations for steps among pregnant women, and thus, showing the duration of moderate or vigorous physical activity with respect to health recommendations (150 min/week of physical activity at a moderate level [79]) would be a feasible feature on a weekly basis.

Although we used multiple distinct types of wearable sensors for measuring physical activity, there was a lack of automatic recognition of physical activities (ie, swimming and water running) that are important for women with GDM. This challenge will decrease in the future as the automatic recognition of diverse types of physical activities is improving. However, this challenge of automatic recognition of features related to nutrition will remain for a long time. To cover a wide variety of features, MacLeod et al [27] suggested the use of manual tracking as an aid to automatic tracking. This approach allows tracking a large number of features. However, qualitative studies emphasize that pregnant women are typically overwhelmed [54,84] and that women with GDM face considerable time pressures [84]. As such, we argue that automatic self-tracking is especially important for these user groups. In this study, most efforts were required to keep a food diary with a pen and paper, and less demanding methods were requested. Chung et al [85] proposed a lightweight photo-based food diary to support the collection of nutrition data for clinical visits of patients with irritable bowel syndrome. This photo-based diary approach appears to be promising for women with GDM as well. Peyton et al [54] suggested that self-monitoring of pregnant women can be supported and encouraged, in addition to photographic journals, by using simple designs, such as reminders, and by keeping the techniques for user data input simple. Data collection techniques that are undemanding (eg, checkboxes instead of long text) support a quantifiable format, which is needed in the *hypothesis formulation* process [24].

Hypothesis Formulation

With respect to *hypothesis formulation* (ie, formulation of suspected associations with activities and blood glucose), participants experienced difficulties in the quantification of the self-tracking data on physical activity, sleep, and stress. Still, most of the participants were interested in monitoring stress, which plays a significant role in the lives of women with GDM [13,86], and sleep, which allows following sleeping disorders due to pregnancy. Thus, this quantified information about stress and sleep provided value to the participants in terms of providing information about their condition, being part of *documentary tracking* [49]. As such, participants were interested in monitoring their sleep and stress rather than changing them. This was opposite to nutrition and physical activity, which were more related to *goal-driven tracking* [49], and their features (although not based on self-tracking data) were an integral part of the self-discovery process.

The results of this study indicate that quantification by sensors needs to match with quantification by the user so that meaningful hypotheses can be formulated. For physical activity, misperception of intensity is problematic as the rate of change of glucose levels depends on the intensity of physical activity [87], and perceiving physical activity differently may lead to wrong conclusions about its effect. This finding of a discrepancy in the perceived and measured intensity of physical activity is in line with the finding in a previous report [88], where women with GDM estimated the amount of vigorous physical activity to be higher than that measured with a hip-worn accelerometer. These results are opposite to the results of a previous study [32], where users with type 2 diabetes reported a high correlation between self-reported physical activity and the duration of vigorous activity measured with an activity bracelet. This indicates that the discrepancy between perceived and measured physical activity is more prominent among pregnant women than among people with type 2 diabetes. This would mean that the intensity levels should be more clearly defined for women with GDM, and providing feedback during the activity (eg, “Now you are swimming at the moderate level.”) would be a good approach. Moreover, the quantification of features with wearable sensors was unreliable, for example, participants could not rely on stress data, which were affected by decreased HRV due to pregnancy. Thus, we agree that more advanced techniques are required to differentiate between the decreased HRV caused by pregnancy and decreased HRV due to stress [59].

Hypothesis Evaluation

For *hypothesis evaluation* (ie, evaluation of how the latest information about associations fits with existing knowledge), we observed the challenges of scattered and conflicting data. At this stage, we expected that having the wearable sensors would have facilitated hypothesis evaluation, as there is more data available and its quantified form enables quantitative comparison against existing data. However, we found 2 major reasons why this stage was difficult for the participants. First, the data were scattered across different apps, making comparisons between lifestyle and glucose tedious. The dispersion of data has been identified as a challenge in personal informatics [26,89,90], and this study further emphasized that there should be integrative tools to support self-discovery. Second, the data were contradictory between sensors in multiple ways. For example, there was a statistically significant difference in the number of steps and the duration of sleep between sensors. Moreover, the discrepancies between CGM and fingerstick measurements caused confusion regarding how much participants could rely on CGM data. The discrepancies in data were not limited to the given sensors but extended to participants' existing sensors (see the section General Acceptance Based on the UTAUT). These discrepancies directed the attention of women with GDM from self-discovery to evaluation of these differences. While the use of multiple sensors potentially increases the reliability of the data, the use of a single sensor for each lifestyle variable would be more appropriate to support reflection. Then, the attention of the user would not be on looking at differences in the data between sensors, but rather on evaluating the impact of activities on glucose levels between instances, such as small variations in meals and physical activities. Moreover, the relative differences in data within a single wearable sensor would provide useful information. However, we acknowledge that trackable features may be unknown for people with chronic illnesses, especially in *poorly understood conditions* [27]. Thus, figuring out the relevant features may require the use of multiple wearable sensors to gather various aspects of chronic illnesses. However, in that case, the data from multiple sensors should not be conflicting but rather supportive for increasing the understanding of the chronic condition.

Goal Setting

The goal for women with GDM is simple. The fasting glucose value in the morning should be less than 5.5 mmol/L, and the glucose value 1 hour after a meal should be under 7.8 mmol/L. However, this is a very high-level goal, which participants try to transform into concrete behavioral goals. For the *goal specification* (ie, identification of future goals based on activities and outcomes) phase in self-discovery, we found that participants primarily created goals based on continuous glucose monitoring and experience. Of all the target behaviors, changing the diet was the one that the participants seemed to be the most optimistic about, and they could name several ways of changing it. For example, Participant 1 defined a goal of eating nuts in a meal as the participant figured out that this helps to keep the glucose level below the maximum limit. To help in goal setting, this participant with GDM should know how many nuts or how many grams of nuts to include in the meals and should have a tool to track this goal, which should be developed following a goal-directed self-tracking approach [91]. Transformation of goals defined by the participants (eg, eating more nuts by Participant 1) into features, which are possible to track with wearable sensors, is still a major challenge.

Goals provided by wearable sensors (eg, 150 min/week of physical activity at a moderate or vigorous level) are related to general guidelines and are not specific to the management of GDM. This decreases their value for women with GDM. Some limitations are part of every chronic illness, and individuals with a chronic illness should not be pushed too hard to achieve the goals, as there is a risk of causing *goal frustration* [92], if it is impossible to achieve the goals due to implications from their illness. The goals should be concrete (eg, "walking for 30 min at a moderate level would decrease your glucose levels") and trackable with wearable sensors. Another type of goal specification we observed was that participants defined goals to collect further evidence for their hypothesis. For example, for Participant 3, the goal was to climb stairs to see whether this had a real impact on glucose levels. Again, this goal should be trackable. Half of the participants (5/10) discussed that they would be willing to change behaviors for physical activity. One reason was that physical activity was measured in a straightforward way (ie, steps) and was experienced as more tangible by the participants than the target behaviors related to sleep and recovery (see the section Challenges in Self-Tracking of Sleep and the section Challenges in Self-Tracking of Stress and Recovery).

One way to approach this would be to provide options for concrete goals, where women with GDM could choose the most preferred goals. Having such a set of options for goals would ease the tracking with wearable sensors, as the number of trackable features and goals could be narrowed down to certain options. Harrison et al [93] suggested having practical options for goals for encouraging physical activity among women with GDM, as the authors found that women with GDM wish to have clear goals for physical activity while still retaining autonomy. We made similar observations for nutrition goals. The requested goals did not only include what to eat considering the diet limitations (eg, due to pregnancy) but also when to eat. This reflects the wish of people with type 2 diabetes, who have experience with continuous glucose monitoring, to have more knowledge on the effect of meals on temporal glucose patterns [94]. While we made the same observation, the women with GDM wished to have concrete suggestions on how to influence these glucose patterns by the content and timing of the meals.

Experiences of Self-Tracking With Wearable Sensors (RQ2)

We learned that the body placement of sensors is a key factor in acceptability, quality of measurements, and preference, and ultimately a challenge for collecting data. Wearing the physical activity sensor on the wrist, instead of on the hip, has several benefits for pregnant women. Half of the participants (5/10) had issues with wearing the sensor on the hip, as it moved around or chafed the skin when sitting. The drawback of a wrist-worn sensor is that it is not possible to recognize whether the user is sitting or standing. A sensor worn on the hip can

recognize this [63]. However, the regulation of sitting and standing relates more to long-term health and health risks [95] rather than to the management of GDM. The sensor on the wrist was worn significantly more than the sensor on the hip, providing more data to the user. Although the hip-worn sensor was used less than the activity bracelet, it was still worn for more than 10 hours a day, which is the minimal duration to obtain credible data [96].

Wrist-worn sensors are particularly feasible for pregnant women, as bracelets can be adjusted with respect to swelling. This is not the case with activity rings, such as Oura, which are not easily worn during pregnancy owing to swelling of the fingers [97]. While there are wearability issues with wrist-worn devices among pregnant women, such as smartwatches if they are heavy [97], the activity bracelet used in the study did not raise issues beyond slight irritation of the skin. This finding has evidence from a long-term study conducted with a similar activity bracelet among pregnant women [98].

The lifestyle sensors were highly accepted among women with GDM. This result extends the finding by Scott et al [46] that CGMs are highly accepted in self-tracking during pregnancy. Women with GDM seem to be less concerned about using wearable sensors compared with people having chronic illnesses, such as chronic heart patients who have had feelings of uncertainty, fear, and anxiety [99]. In our study involving women with GDM, the clear purpose of the wearable sensors (supporting self-discovery and healthy behavior) could have increased the acceptability of the sensors. This was the opposite in the case of heart patients, where the purpose of the sensors was to gather "self-tracking of activity data in relation to their embodied condition and daily practices of dealing with a chronic heart condition" [99]. Thus, clear framing of the purpose of wearable sensors and supporting the goals of the user (in this case, management of glucose levels) with wearable sensors seem to increase the acceptability of self-tracking.

Although the data provided by the CGM was highly valued among participants, most of the participants (8/10) had issues wearing the CGM. Most of the participants (9/10) preferred wearing the CGM on the arm, instead of having it near the navel, which is the primary placement location for the sensor. Wearing the sensor on the arm caused false alarms of glucose levels dropping too low because women with GDM slept on top of the sensor. As such, if the CGM is worn on the arm, a more robust sensor that can overcome pressure issues is needed as pregnant women tend to sleep on their side, at least when over 30 weeks into gestation [100]. Moreover, due to placement on the arm, the participants could not attach the sensor themselves. This decreases the feasibility of using this CGM in the long term, as the CGM needs to be recharged once a week and the sensor can detach, for example, due to swimming (see the section Wearing the CGM on the Arm).

To support self-management, having a single "output" (ie, a GDM application where all the collected data would be shown in a single view; see the section Toward Better Tools for Supporting Self-discovery) also induces the question of having a single "input" (ie, a wearable sensor that collects all the data). A feasible approach would be adding lifestyle tracking capabilities to continuous glucose monitoring. This kind of sensor does not exist yet. An integrated sensor would decrease the problems of wearing and managing multiple sensors, and the data would be recorded in synchrony and without discrepancies, thus helping in establishing the causalities between lifestyle and glucose levels. Moreover, having a single sensor would remove the technical work required to integrate data from multiple cloud services [101]. Ultimately, this integrated sensor would be worn on the wrist. Having a wrist-worn sensor would overcome the difficulties associated with wearing the CGM behind the arm (which can cause false alarms during the night) and wearing the physical activity sensor on the hip. However, noninvasive glucose tracking from the wrist shows poor accuracy resulting from movement, exercise, and sweating [102]. Thus, an optimal solution for a single wearable sensor is yet to be developed.

While we focused on self-discovery without the help of health care professionals, they were very often mentioned. The continuous data collected by the wearable sensors provide an opportunity for remote monitoring and feedback by health care professionals [60]. The participants discussed the importance of having contact with a diabetes nurse, so that they can share the data with them and discuss the data provided by the glucose sensor. This is in line with previous findings that people with a chronic illness need help from experts in the self-discovery process [24,27] and in behavior change. This is further supported by reviews on technological support for diabetes management, which emphasize the importance of 2-way communication between people with diabetes and health professionals [103,104]. Further, self-tracking with wearable sensors can increase the completeness of the self-tracking data presented to health care professionals [105] and can increase the perceived usefulness of the sensors [103,104]. Thus, at this stage, having a 2-way channel between women with GDM and diabetes nurses (eg, through a text chat as suggested by 1 participant) would be a crucial factor in supporting the management of GDM.

Although no wearable sensor other than the CGM supported self-discovery, the sensors increased self-awareness of one's own lifestyle, and women with GDM believed that this would help them to improve their habits. Thus, wearable sensors have the potential to support behavior change for women with GDM, as self-tracking itself has been found to be an effective behavior technique among people with type 2 diabetes [52]. However, participants discussed that behavior change should be facilitated with recommendations, which would be formulated either automatically based on self-tracking data or manually by health care professionals, and further, the use of artificial intelligence approaches can increase the understanding of cause-and-effect relationships [55,106]. This understanding can be used for setting personal goals for lifestyle changes among women with GDM [107], which were highly requested by the participants of this study.

Study Limitations and Future Research

We acknowledge that the number of participants could have been higher. However, the main approach of this study was qualitative, and we believe that the number of participants was enough as no new codes emerged after 8 interviews, indicating

the saturation of data. Moreover, the same number of participants has been used in qualitative studies on experiences of GDM (eg, [14]). Quantitative investigations on the acceptance of self-tracking among women with GDM would require a longer usage period with more participants.

Women with GDM wore multiple wearable sensors at the same time in this study, which might have affected their acceptance. Despite this, responses to the UTAUT questionnaire in this study reflected high acceptance of wearable sensors. The high acceptance could have been influenced by the fact that the participants volunteered for the study, and thus, they showed at least some interest in self-tracking and were not afraid of pricking their skin. In fact, 1 participant did not want to participate as this participant heard that the study involves skin pricking. Therefore, the acceptability could be biased, and this is similar to studies investigating the acceptability of CGMs among women with GDM [44-47].

The self-discovery process of GDM is challenging and demanding, which currently takes a considerable amount of time. Carolan-Olah et al [84] investigated how the teaching of GDM could be improved, particularly among women with multiethnic and low socioeconomic backgrounds. Cultural differences may pose a need for different trackable features for GDM, for example, water activities among women (eg, swimming and water running) are less feasible in some cultures [108].

This study focused on CGMs and wearable physical activity sensors. As nutrition is an important factor in the management of GDM, future work should investigate the use of wearable sensors for nutrition tracking. At the current stage, they are not able to detect the intake of macronutrients (eg, carbohydrates) [70,71,109], and thus, their support for self-discovery is expected to be limited. However, research on wearable and nutrition collection methods is very active and should be considered in the future.

We have designed a mobile app according to the results of this study, and we will conduct a long-term clinical evaluation in a randomized controlled trial to explore the effect of comprehensive self-tracking with a mobile app on glucose levels [110].

Conclusions

We have provided the results of a user-centered design process of a mobile health intervention for supporting the self-management of GDM. Our holistic approach for supporting the self-management of GDM with mobile technology included investigations of wearable sensors and a mobile app from self-discovery (learning) and user experience perspectives. We showed multiple issues that inhibit self-management, such as inadequate support for self-tracking physical activity, data discrepancy, and challenges wearing the CGM. One major challenge was the scatteredness of self-tracking data. To support learning further, visualization with guidance through tips and recommendations should be designed to increase the ability of women with GDM to manage diabetes in their pregnancy. The design should consider pregnancy-specific wearability challenges and requirements for data gathering and representation proposed in this paper.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Responses to the Unified Theory of Acceptance and Use of Technology (UTAUT) questionnaire.
[DOCX File , 17 KB - diabetes_v8i1e43979_app1.docx]

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Abbreviations

CGM: continuous glucose monitor
GDM: gestational diabetes mellitus
HRV: heart rate variability
UTAUT: Unified Theory of Acceptance and Use of Technology
VO2 max: maximal oxygen consumption

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Original Paper

Glycemic Control, Renal Progression, and Use of Telemedicine Phone Consultations Among Japanese Patients With Type 2 Diabetes Mellitus During the COVID-19 Pandemic: Retrospective Cohort Study

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Abstract

Background: Reduced or delayed medical follow-ups have been reported during the COVID-19 pandemic, which may lead to worsening clinical outcomes for patients with diabetes. The Japanese government granted special permission for medical institutions to use telephone consultations and other remote communication modes during the COVID-19 pandemic.

Objective: We aimed to evaluate changes in the frequency of outpatient consultations, glycemic control, and renal function among patients with type 2 diabetes before and during the COVID-19 pandemic.

Methods: This is a retrospective single-cohort study conducted in Tokyo, Japan, analyzing results for 3035 patients who visited the hospital regularly. We compared the frequency of outpatient consultations attended (both in person and via telemedicine phone consultation), glycated hemoglobin A_{1c} (HbA_{1c}), and estimated glomerular filtration rate (eGFR) among patients with type 2 diabetes mellitus during the 6 months from April 2020 to September 2020 (ie, during the COVID-19 pandemic) with those during the same period of the previous year, 2019, using Wilcoxon signed rank tests. We conducted a multivariate logistic regression analysis to identify factors related to the changes in glycemic control and eGFR. We also compared the changes in HbA_{1c} and eGFR from 2019 to 2020 among telemedicine users and telemedicine nonusers using difference-in-differences design.

Results: The overall median number of outpatient consultations attended decreased significantly from 3 (IQR 2-3) in 2019 to 2 (IQR 2-3) in 2020 (P<.001). Median HbA_{1c} levels deteriorated, though not to a clinically significant degree (6.90%, IQR 6.47%-7.39% vs 6.95%, IQR 6.47%-7.40%; P<.001). The decline in median eGFR was greater during the year 2019-2020 compared to the year 2018-2019 (–0.9 vs –0.5 mL/min/1.73 m2; P=.01). Changes in HbA_{1c} and eGFR did not differ between patients who used telemedicine phone consultations and those who did not. Age and HbA_{1c} level before the pandemic were positive predictors of worsening glycemic control during the COVID-19 pandemic, whereas the number of outpatient consultations attended was identified as a negative predictor of worsening glycemic control during the pandemic.

Conclusions: The COVID-19 pandemic resulted in reduced attendance of outpatient consultations among patients with type 2 diabetes, and these patients also experienced deterioration in kidney function. Difference in consultation modality (in person or by phone) did not affect glycemic control and renal progression of the patients.

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KEYWORDS

glycemic control; renal progression; telemedicine; phone consultations; COVID-19; diabetes mellitus; type 2 diabetes

Introduction

In April 2020, the Japanese government declared a state of emergency in response to COVID-19, affecting the nation's habits and lifestyle. This declaration resulted in various impacts, including social distancing and restrictions on daily movement, such as going out [1]. Diabetes mellitus (DM) is a known risk factor of severe COVID-19, and patients with DM have been encouraged to take precautions [2,3]. It was reported that drastic lifestyle changes during COVID-19 worsened glycemic control [4], and the overwhelming of health care systems caused a deterioration of chronic medical conditions [5]. Reports showed reduced or delayed hospital visits, with fear of catching the infection preventing patients from continuing in-person hospital visits [6-9]. Management of DM during the pandemic was critically important because patients with diabetes were reported to have higher probabilities of hospital admissions and deaths due to COVID-19 infection, compared to those without diabetes [10]. Evidence also showed that patients with DM were observed to experience progression of chronic kidney disease over a short period of time, warranting close monitoring of kidney function among these patients [11].

Telemedicine has expanded in many countries during the pandemic [12-14] to maintain access to health care services. The University of Tokyo Hospital started telemedicine consultation for the first time, using voice-only phone consultations, after Japan's Ministry of Health, Labour, and Welfare granted special permission for medical care via telephone calls and other remote communication modes during the COVID-19 pandemic. With telemedicine consultations, physicians reviewed patients' health conditions through phone interviews, provided lifestyle advice, and prescribed patients' usual medicines for refill when health status was stable. When the physicians determined a need for further examinations, the patients were asked to visit the hospital for blood tests and physical examinations.

Before the pandemic, Japan's government adopted a conservative strategy toward telemedicine, and the use of telemedicine for medical consultation has been limited [15]. Miyawaki et al [16] performed a telemedicine use survey among Japanese working-age population during COVID-19 and discovered a lower use rate of telemedicine, which was 4.7%. It was unknown if this newly introduced telemedicine model was well implemented among patients with diabetes, who were predominantly older patients. As continuity of care is imperative among patients with diabetes, there is a need to examine the utility of telemedicine among these patients as well as its impact toward disease control, such as glycemic control and renal function [17].

The primary objective of this study was to evaluate changes in the frequency of outpatient consultations, glycemic control, and renal function among a study cohort of patients with type 2 DM before and during the early phase of the COVID-19 pandemic (ie, April to September 2020). We also aimed to investigate the utilization rate of telemedicine via phone consultation. Next, we compared the glycemic control and renal function among telemedicine users and telemedicine nonusers during COVID-19.

Methods

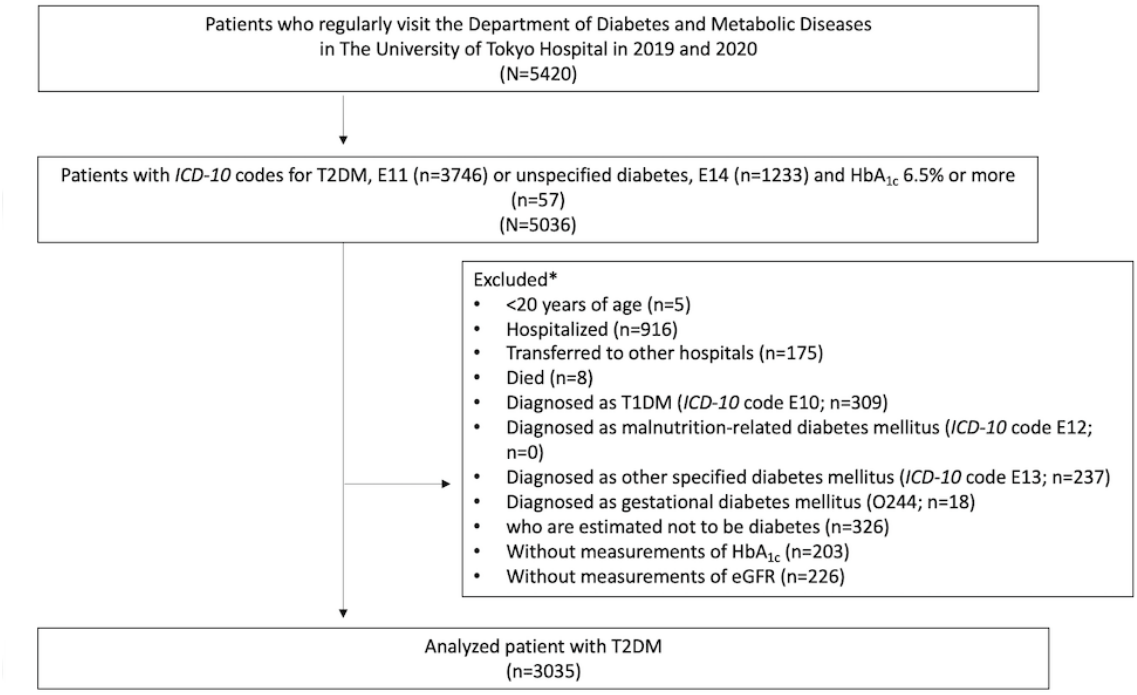
Study Design

This is a single-center retrospective cohort study conducted at The University of Tokyo Hospital in Tokyo, Japan. The evaluation periods were from April to September 2019 and from April to September 2020.

Study Population

Before the pandemic, patients usually visited the hospital every 1 to 3 months to check their hemoglobin A_{1c} (HbA_{1c}), blood glucose, and similar metrics. During the pandemic, most patients continued with in-person hospital visits, though some chose telemedicine phone consultation in addition to in-person hospital visits. As the focus of our study was the impact of telemedicine use on disease management in adults, we excluded patients who were aged <20 years, transferred to other hospitals, had incomplete records, or experienced outcomes beyond routine disease management (eg, hospitalization, death, and change in diagnosis; Figure 1). We defined telemedicine users as patients who attended a telemedicine phone (voice) consultation with physicians at least once during the pandemic and telemedicine nonusers as patients who did not attend a telemedicine phone (voice) consultation with physicians at all.

Figure 1. Recruitment of study population. eGFR: estimated glomerular filtration rate; HbA_{1c}: hemoglobin A_{1c}; *ICD-10: International Classification of Diseases, Tenth Revision*; T1DM: type 1 diabetes mellitus; T2DM: type 2 diabetes mellitus. *The excluded categories may have overlaps, as one patient could potentially fall into multiple categories.



Data Collection Procedures

Demographic, clinical, and laboratory data were extracted from electronic health records. We extracted complications using the *International Classification of Diseases, Tenth Revision* (*ICD-10*) codes registered in the electronic health records, including dyslipidemia, hypertension, cardiovascular disease, chronic kidney disease, cognitive impairment, and malignancy (Table S1 in Multimedia Appendix 1). We collected age, sex, and medical comorbidities as the participants' baseline characteristics.

Statistical Analysis

We analyzed the frequency of outpatient consultations (including in-person and telemedicine phone consultations), HbA_{1c}, estimated glomerular filtration rate (eGFR), and urine albumin-creatinine ratio (UACR), comparing data from April to September 2020 with data from April to September 2019 using Wilcoxon signed rank tests, while changes in dipstick proteinuria were compared using the McNemar test. We used a definition of clinically significant deterioration of HbA_{1c} as an elevation of HbA_{1c} by more than 2% of the median value of HbA_{1c} in 2019 [18]. To evaluate the change in the rate of decline of eGFR, we compared the change of eGFR from 2019 to 2020 (ΔeGFR 2019-2020) with that of the previous year's change (ΔeGFR 2018-2019) using the Wilcoxon signed rank test. In addition, we conducted a multivariate logistic regression analysis to identify factors related to the changes in glycemic control and eGFR. We also compared the changes in HbA_{1c} and eGFR from 2019 to 2020 among telemedicine users and telemedicine nonusers using difference-in-differences design. Data are presented as mean (SD) or median (IQR). Values of $P<.05$ were defined as statistically significant. Statistical analyses were performed using JMP Pro 16 (SAS Institute Inc).

Ethical Approval

The study protocol was approved by the Research Ethics Committee of The University of Tokyo (2020267NI). Informed consent by participants were obtained by opt-out approach.

Results

Characteristics of Study Participants

We identified 5036 patients who visited the Department of Diabetes and Metabolic Diseases at 1 to 3 months intervals in 2019 and 2020, consisting of 3746 patients with *ICD-10* code E11 (type 2 DM), 1233 with *ICD-10* code E14 (unspecified DM), and 57 with HbA_{1c} levels of 6.5% or higher. After excluding patients who did not fulfil the inclusion criteria, the remaining 3035 patients were included as the study cohort (Figure 1).

The characteristics of the study patients are shown in Table 1. The median age of patients was 70 (IQR 61-77) years, with 37.3% (1131/3035) being female. Dyslipidemia (2406/3035, 79.3%) and hypertension (2079/3035, 68.5%) were the 2 main comorbidities. Telemedicine users were more likely to be female compared with telemedicine nonusers (141/297, 47.5% vs 990/2738, 36.2%; $P<.001$).

Table 1. Characteristics of study participants.

Variables	Overall (N=3035)	Telemedicine users (n=297, 9.8)	Telemedicine nonusers (n=2738, 90.2)	*P* value[a]
Age, median (IQR)	70 (61-77)	71 (61-78)	70 (61-77)	.17
Female gender, n (%)	1131 (37.3)	141 (47.5)	990 (36.2)	<.001
Comorbidities, n (%)				
Dyslipidemia	2406 (79.3)	235 (79.1)	2171 (79.3)	.95
Hypertension	2079 (68.5)	196 (66)	1883 (68.8)	.33
Cardiovascular disease	1734 (57.1)	160 (53.9)	1574 (57.5)	.23
Malignancy	1714 (56.5)	171 (57.6)	1543 (56.4)	.69
Chronic kidney disease	1235 (40.7)	112 (37.7)	1123 (41)	.27
Cognitive Impairment	149 (4.9)	10 (3.4)	139 (5.1)	.17

[a]Analysis was performed using Wilcoxon rank sum test.

Phone-Based Telemedicine Consultation Among Outpatients With Diabetes

The total median number of outpatient consultations (both in-person and telemedicine phone consultations) was 4 (IQR 3-4) among telemedicine users, of which the median number of telephone-based telemedicine consultations was 1 (IQR 1-1). The total median number of outpatient consultations was 2 (IQR 2-3) among telemedicine nonusers in 2020, significantly lower than that of telemedicine users (*P*<.001).

Evaluation of Changes in the Number of Outpatient Consultations, Glycemic Control, and Renal Function Among Outpatients With Diabetes Between the Time Before the Pandemic and the Early Stages of the Pandemic

Table 2 and Table 3 present the changes in frequency of outpatient consultations, HbA_{1c}, eGFR, UACR, and dipstick proteinuria among the study patients before and during the COVID-19 pandemic. The overall median number of outpatient consultations decreased significantly from 3 (IQR 2-3) in 2019 to 2 (IQR 2-3) in 2020 (*P*<.001). The frequency of outpatient consultations was between 3-4 for 63.9% (n=1938) of the patients before the pandemic, which is significantly higher than that during the pandemic (n=1354, 45.6%; *P*<.001). The median HbA_{1c} level of 6.95% (IQR 6.47%-7.40%, 95% CI 6.90-6.97) in 2020 (during the pandemic) increased (*P*<.001) compared with the median HbA_{1c} level of 6.90% (IQR 6.47%-7.39%, 95% CI 6.88-6.94) in 2019 (before the pandemic) among the same cohort of patients, but the increase was not clinically significant.

The median eGFR levels declined slightly in 2020 compared to 2019. The decline in median eGFR was significantly greater in the period of 2019-2020 (–0.9, IQR –4.0 to 2.1, 95% CI –1.2 to –0.8 mL/min/1.73 m^2) compared to 2018-2019 (–0.5, IQR –3.4 to 2.3, 95% CI –0.7 to –0.3 mL/min/1.73 m^2; *P*=.01). To examine whether the decline in eGFR was transient or sustained in nature, we also analyzed the eGFR of the study cohort for the year 2021. We found that the median eGFR declined further in 2021. The decline in the median eGFR was significantly greater in the period of 2020-2021 (–1.4, IQR –7.4 to –1.4, 95% CI –1.5 to –1.1 mL/min/1.73 m^2) compared to the period of 2018-2019 (Table S2 and S3 in Multimedia Appendix 1).

The median UACR levels increased significantly (19.0, IQR 11.0-60.5, 95% CI 17.0-21.0 g/gCr; *P*<.001) during the pandemic in 2020. In dipstick proteinuria tests, the number of patients with negative proteinuria decreased from 2076/2737 (75.8 %) patients in 2019 to 1842/2798 (65.8 %) patients in 2020. The number of patients with overt proteinuria increased from 564/2737 (20.6 %) patients in 2019 to 625/2798 (22.3 %) patients in 2020 (*P*<.001).

The adjusted logistic regression analysis indicated that age and HbA_{1c} level during 2019 were positive predictors of worsening glycemic control during COVID-19 in 2020, whereas the number of outpatient consultations attended was identified as a negative predictor of worsening glycemic control (odds ratio 0.89, 95% CI 0.82-0.96; *P*=.004). The logistic regression model also indicated the decline of eGFR (ΔeGFR) and urinary proteinuria during 2019 as positive predictors of worsening glycemic control during the COVID-19 pandemic in 2020 (Table 4).

Table 2. Comparison of frequency of outpatient consultations attended (both in person and telephone-based), glycated hemoglobin A_{1c} (HbA_{1c}), estimated glomerular filtration rate (eGFR), and urinary albumin creatinine ratio (UACR) among patients with diabetic kidney disease before and during the COVID-19 pandemic.

Variables	Before pandemic (2019)		During pandemic (2020)		Difference (2020-2019), median (95% CI)	*P* value
	Median (IQR)	95% CI	Median (IQR)	95% CI		
Number of outpatient consultations attended (N=3035)	3 (2 to 3)	3.0 to 3.1	2 (2 to 3)	2.6 to 2.7	0 (0 to 0)	<.001[a]
HbA_{1c} (%; N=3035)	6.90 (6.47 to 7.39)	6.88 to 6.94	6.95 (6.47 to 7.40)	6.90 to 6.97	0.033 (0.017 to 0.050)	<.001[a]
eGFR (mL/min/1.73 m^2; N=3035)	66.1 (54.5 to 77.3)	65.1 to 66.9	64.7 (53.7 to 76.0)	64.0 to 65.4	–0.92 (–1.17 to –0.75)	<.001[a]
ΔeGFR[b] (mL/min/1.73 m^2; n=2946)	–0.5 (–3.4 to 2.3)	–0.7 to –0.3	–0.9 (–4.0 to 2.1)	–1.2 to –0.8	–0.33 (–0.67 to 0.00)	.01[a]
UACR (g/gCr; n=858)	19.0 (9.0 to 51.8)	17.0 to 20.7	19.0 (11.0 to 60.5)	17.0 to 21.0	1.0 (0.5 to 2.0)	<.001[a]

[a]Analysis performed using Wilcoxon signed rank tests.

[b]The change of eGFR from 2019 to 2020.

Table 3. Percentages of outpatient consultations attendance (both in person and telephone-based) and percentages of patients with negative, trace, and positive proteinuria for dipstick proteinuria tests among patients with diabetic kidney disease before and during the COVID-19 pandemic (N=3035).

Variables	Before pandemic (2019)	During pandemic (2020)	*P* value
Frequency of outpatient consultations attended, n (%)			__[a]
1	72 (2.4)	197 (6.5)	
2	1025 (33.8)	1484 (48.9)	
3	1204 (39.7)	879 (29.9)	
≥4	734 (24.2)	475 (15.7)	
Dipstick proteinuria tests, n (%)			<.001[b]
Negative	2076 (75.8)	1842 (65.8)	
Trace	97 (3.5)	331 (11.8)	
Positive (1 to 4)	564 (20.6)	625 (22.3)	

[a]Not applicable.

[b]Analysis performed using the McNemar test.

Table 4. Odds ratios (ORs) for deterioration of glycemic control and estimated glomerular filtration rate (eGFR) during the COVID-19 pandemic.

Variables	Glycemic control[a]				eGFR[b]			
	Model 1		Model 2[c]		Model 1		Model 2[c]	
	Crude ORs (95% CI)	*P* value[d]	Adjusted ORs (95% CI)	*P* value[d]	Crude ORs (95% CI)	*P* value[d]	Adjusted ORs (95% CI)	*P* value[d]
Age	1.01 (1.00-1.02)	<.001	1.01 (1.00-1.02)	.002	1.00 (0.99-1.00)	.84	1.00 (0.99-1.01)	.65
HbA_{1c} in 2019	1.11 (1.01-1.22)	.02	1.19 (1.07-1.32)	.001	0.95 (0.87-1.04)	.25	1.01 (0.88-1.15)	.94
ΔeGFR in 2019	0.99 (0.98-1.01)	.47	1.00 (0.98-1.01)	.56	0.64 (0.62-0.66)	<.001	0.64 (0.62-0.67)	<.001
Urinary proteinuria in 2019	1.00 (0.82-1.21)	.97	1.03 (0.84-1.26)	.61	1.06 (0.88-1.28)	.03	1.47 (1.13-1.90)	.007
Number of outpatient consultations attended in 2020	0.90 (0.85-0.97)	.004	0.89 (0.82-0.96)	.003	0.96 (0.90-1.02)	.22	0.96 (0.87-1.06)	.41

[a]Deterioration of glycemic control is defined by elevated hemoglobin A_{1c} (HbA_{1c}) level more than 2% from the baseline.

[b]Deterioration of eGFR is defined as larger eGFR decline in 2019-2020 compared to 2018-2019.

[c]Multivariable regression analysis adjusted for the following: age; sex; HbA_{1c} in 2019; ΔeGFR in 2019; urinary proteinuria in 2019; the number of visits in 2020; use of telemedicine; and *International Classification of Diseases, Tenth Revision* codes for chronic kidney disease, cardiovascular disease, cognitive impairment, dyslipidemia, hypertension, and malignancy.

[d]Analysis was performed using multivariable logistic regression.

Comparison of Glycemic Control and Renal Function During the Early Stages of the Pandemic Between Telemedicine Users and Telemedicine Nonusers

Difference-in-differences analyses showed no significant differences in the change of median HbA_{1c} (0.01%, 95%CI –0.14 to –0.16; *P*=.90) and eGFR (0.6, 95% CI –0.1 to 1.4 mL/min/1.73m^2; *P*=.10) between telemedicine users (n=297) and telemedicine nonusers (n=2738; Table 5).

Table 5. Difference-in-differences analysis to compare glycated hemoglobin A_{1c} (HbA_{1c}) and estimated glomerular filtration rate (eGFR) between telemedicine and telemedicine nonusers during the COVID-19 pandemic.

	Telemedicine users (n=297), median (IQR)		Telemedicine nonusers (n=2738), median (IQR)		Difference-in-differences analysis	
	2019	2020	2019	2020	Estimates (95%CI)	*P* value[a]
HbA_{1c} (%)	6.90 (6.30-7.38)	6.90 (6.40-7.42)	6.90 (6.50-7.39)	6.95 (6.50-7.40)	0.01 (–0.14 to 0.16)	.90
eGFR (mL/min/1.73 m^2)	66.8 (55.7-78.6)	65.7 (54.9-77.4)	66.0 (54.4-77.1)	64.5 (53.6-75.8)	0.6 (–0.1 to 1.4)	<.10

[a]Analysis is done using difference-in-differences technique.

Discussion

Principal Findings

In this study, we evaluated changes in the frequency of outpatient consultations, glycemic control, and renal function among a study cohort with type 2 DM before and during the early phase of the COVID-19 pandemic (ie, April to September 2020). We also investigated the utilization rate of telemedicine via phone consultations and compared the glycemic control and renal function among telemedicine users and nonusers during the COVID-19 pandemic. Our study revealed that the frequency of outpatient consultations showed a statistically significant reduction during the COVID-19 pandemic. There was a decline in glycemic control during the first 6 months of the pandemic, although the difference was not clinically significant. Our cohort of patients also experienced acceleration in the sustained decline of renal function during the pandemic over a period of 2 years (2020 and 2021). Next, our study shows that the proportion of the cohort of patients who used telemedicine consultations was only 9.8% (297/3035). Glycemic control and renal function of telemedicine users did not differ much from those who did not attend phone telemedicine consultations during the COVID-19 pandemic.

Comparison to Prior Work

The decrease in frequency of outpatient consultations from 3 (IQR 2-3) visits before the pandemic to 2 (IQR 2-3) visits during the early phase of the pandemic is considered clinically significant in the context of diabetes care. As patients with well-controlled diabetes typically attend outpatient follow-up visits every 3 months, missing 1 appointment could result in a disruption of continuity of care. Furthermore, it has been reported that missing the last scheduled primary care appointment is associated with an increased risk of hospital

admission among patients with diabetes who were recently hospitalized [19,20].

Although there was a decline in glycemic control during the first 6 months of the pandemic, the difference was not clinically significant, as reported previously [21]. Nevertheless, older patients and patients with poor glycemic control should be given extra attention, as we found that advancing age and HbA_{1c} level are associated with worsening glycemic control during COVID-19. Treatment intensification may not have been properly implemented in patients with poor glycemic control due to reduction in outpatient visits. From our study, we also discovered that a reduction in attendance of outpatient consultations was significantly associated with declining glycemic control during COVID-19. Our findings aligned with the evidence that showed the importance of continuity of care in improving glycemic control among patients with diabetes [22].

Our cohort of patients also experienced an acceleration in the sustained decline of renal function during the pandemic over the period of 2 years (2020 and 2021). Our findings also align with those of another study that reported a significant decline in the frequency of physician appointments and a significant increase in the mean creatinine levels among patients with diabetes during the COVID-19 pandemic [23]. Furthermore, since deterioration of renal function during COVID-19 is associated with urinary proteinuria before the pandemic, this group of patients should be closely monitored. Continuity of care from physicians has been shown to reduce renal progression among patients with diabetes [24]; therefore, consistent and regular outpatient care is important for them.

Telemedicine can be implemented by various modalities [25]. In Japan, 72.9% of the telemedical first visits in September 2020 were reported to be via phone calls, and the prevalence of telemedicine use is still quite low, as is the case with this study [26,27]. Our study shows that the proportion of the cohort of patients who used telemedicine consultations was only 9.8% (297/3035), and the number of telephone consultations used was only 1 over the 6-month study period. Due to consistent report of low utilization rate of telemedicine shown in our study as well as other studies, there is a need to increase patients' awareness of the availability of telemedicine consultation services and educate patients on how to use and benefit from telemedicine consultations. Understanding patients' barriers to using telemedicine is important, as it has been reported that some older patients were unready for telephone visits because of difficulties in hearing and communication or dementia [28]. Moreover, as telemedicine was not yet widespread in Japan before the COVID-19 pandemic [15], it was possible that health care providers were unfamiliar with the safety and efficacy of implementing telemedicine consultations, and thus, hesitant to provide them.

Our results show that the glycemic control and renal function of patients who attended phone telemedicine consultations did not differ much from those who did not attend phone telemedicine consultations during the COVID-19 pandemic. Our results correspond with those of a study that revealed that the difference in consultation modality (in person or by phone) did not affect glycemic control [29]. Although phone consultation during the pandemic allowed the telemedicine users to have more frequent contact with physicians compared with the telemedicine nonusers, the benefits on the improvement of glycemic control and renal function progression were limited, as shown in our study. This could be due to the infrequent use of phone consultations among the telemedicine users in our study cohort. Another study that implemented weekly phone consultations showed significantly improved overall glycemic control and lipid profile of patients with diabetes [30]. Moreover, an average frequency of once in 6 months for telemedicine consultations via phone alone may not be sufficient for physicians to assess patients' clinical progression. Compared with phone consultations, video consultations provide some aspects of physical examination and a more personal connection between clinicians and patients [31]. Telemedicine consultation could be coupled with remote monitoring using home self-test kits and self-care assistance via smart phone–based mobile health (mHealth) interventions. In addition to real-time feedback to patients, mHealth facilitates information exchange and interactions between patients and health care providers [32]. Furthermore, the use of smart phone–based mHealth apps is associated with increased patient satisfaction with telemedicine appointments [33]. The combination of different telemedicine modalities may improve quality of care.

Limitations

There are some limitations in our study. Medical consultations are covered by health insurance for every resident in Japan; our results may not generalize to countries using different health insurance systems. As data were only collected from a single tertiary medical institution located in an urban region in the capital city, generalizability to other Japanese settings should be interpreted with caution due to differences in telemedicine facility and patient management style during COVID-19. The study was limited to the first half year of the pandemic. BMI, blood pressure, and lipid control, critical for the progression of diabetic complications, were not assessed. Decline of renal function is affected by aging, gender, medication therapy, and genetic background [34], and eGFR and HbA_{1c} could be affected by changes in medications. These factors were not considered in our analyses. There is a possibility that COVID-19 infection may cause proteinuria and acute kidney injury [35]; however, we do not have access to information of COVID-19 diagnosis among the study cohort during the study period.

In this study, we only compared the frequency of outpatient consultations before and during the early phase of the pandemic; we did not examine the frequency of other diabetes-related preventive services. We did not examine patient-reported outcomes of diabetes. The small sample size of telemedicine users and the limited number of telemedicine consultations among telemedicine users may affect the results of our findings; therefore, the findings should be interpreted with caution.

Additionally, this study refers to data during the early phase of the COVID-19 pandemic and may not be applicable to the current phase of the pandemic. As the pandemic enters its third year with several countries announcing plans to transition from pandemic control to endemic management of COVID-19 [36],

the Japanese government has also loosened COVID-19 restrictions. As of March 2023, the Japanese government has issued an official statement to discontinue the previous deregulations on the use of telemedicine for medical consultations, which will take effect in August 2023 [37]. Nevertheless, this study offers valuable insights on the utility of telemedicine outpatient consultations for patients with diabetes.

Conclusions

The COVID-19 pandemic led to declines in outpatient consultations among patients with type 2 DM in Japan. Glycemic control of patients was well maintained, but patients experienced rapid declines in renal function during the pandemic. These clinical outcomes did not differ between patients who used telemedicine phone consultations and those who did not. Further studies are needed to explore the effectiveness of different modalities and frequencies of telemedicine consultations for patients with diabetes.

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Conflicts of Interest

KW is an advisor at NIHON CHOUZAI Co, Ltd. The company had no role in this study.

Multimedia Appendix 1
Supplementary material.
[DOCX File , 18 KB - diabetes_v8i1e42607_app1.docx]

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Abbreviations

DM: diabetes mellitus
eGFR: estimated glomerular filtration rate
HBA_{1c}: hemoglobin A_{1c}
ICD-10: International Classification of Diseases, Tenth Revision
mHealth: mobile health
UACR: urine albumin creatinine ratio

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Original Paper

A Machine Learning Web App to Predict Diabetic Blood Glucose Based on a Basic Noninvasive Health Checkup, Sociodemographic Characteristics, and Dietary Information: Case Study

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Abstract

Background: Over the past few decades, diabetes has become a serious public health concern worldwide, particularly in Bangladesh. The advancement of artificial intelligence can be reaped in the prediction of blood glucose levels for better health management. However, the practical validity of machine learning (ML) techniques for predicting health parameters using data from low- and middle-income countries, such as Bangladesh, is very low. Specifically, Bangladesh lacks research using ML techniques to predict blood glucose levels based on basic noninvasive clinical measurements and dietary and sociodemographic information.

Objective: To formulate strategies for public health planning and the control of diabetes, this study aimed to develop a personalized ML model that predicts the blood glucose level of urban corporate workers in Bangladesh.

Methods: Based on the basic noninvasive health checkup test results, dietary information, and sociodemographic characteristics of 271 employees of the Bangladeshi Grameen Bank complex, 5 well-known ML models, namely, linear regression, boosted decision tree regression, neural network, decision forest regression, and Bayesian linear regression, were used to predict blood glucose levels. Continuous blood glucose data were used in this study to train the model, which then used the trained data to predict new blood glucose values.

Results: Boosted decision tree regression demonstrated the greatest predictive performance of all evaluated models (root mean squared error=2.30). This means that, on average, our model's predicted blood glucose level deviated from the actual blood glucose level by around 2.30 mg/dL. The mean blood glucose value of the population studied was 128.02 mg/dL (SD 56.92), indicating a borderline result for the majority of the samples (normal value: 140 mg/dL). This suggests that the individuals should be monitoring their blood glucose levels regularly.

Conclusions: This ML-enabled web application for blood glucose prediction helps individuals to self-monitor their health condition. The application was developed with communities in remote areas of low- and middle-income countries, such as Bangladesh, in mind. These areas typically lack health facilities and have an insufficient number of qualified doctors and nurses. The web-based application is a simple, practical, and effective solution that can be adopted by the community. Use of the web application can save money on medical expenses, time, and health management expenses. The created system also aids in achieving the Sustainable Development Goals, particularly in ensuring that everyone in the community enjoys good health and well-being and lowering total morbidity and mortality.

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KEYWORDS

blood glucose prediction; boosted decision tree regression model; machine learning; noncommunicable diseases; noninvasive

Introduction

Diabetes mellitus (DM), which is characterized by elevated blood glucose levels (BGLs), is a disease that is proliferating swiftly worldwide [1]. The International Diabetes Federation predicted that by the end of 2045, 800 million people would have this disease [2]. Diabetes is a noncommunicable disease (NCD) that is often regarded as the primary cause of numerous illnesses [3]. Uncontrolled diabetes harms almost all body organs. Over time, the excessive glucose in the blood stream causes serious and even mortality-related complications, such as heart conditions, kidney issues, eye issues, diabetic neuropathy, and diabetic retinopathy [4]. Diseases such as asthma, edema, and oral diseases are substantially correlated with diabetes incidence [5].

High blood glucose affects a person's health and is a risk factor for developing NCDs [6,7]. It is important to detect and monitor diabetes and prevent or control the major complications of the disease. Thus, early prediction of BGLs can reduce the amount of money spent on public health annually and help people become more aware of how to protect themselves from diabetes. Such prediction is crucial to the efficient management of diabetes. The goal of managing type 1 diabetes is to achieve optimal and long-lasting BGL control. This goal can be supported by the automated prediction of BGL using machine learning (ML) techniques, which are thought to be a promising approach. ML is a technique for improving performance by automatically learning from experience and making more accurate predictions [8,9]. Numerous factors influence BGLs. Future BGLs are influenced by prior glucose observations as well as insulin dosage, carbohydrate intake, and other lifestyle factors. Obesity and biomarkers (eg, body fluids including urine, blood, and saliva) are a few of the many factors that have a significant role in the onset and course of DM [9].

In Bangladesh, urban residents exhibit a greater tendency to develop NCDs, including diabetes, than rural residents. This is due to several factors, including their occupational lifestyle (eg, heavy workloads and prolonged sitting to complete their tasks). Thus, people working in the private corporate sector are more likely to develop NCDs [10].

One of the main goals of health policy is to lower the costs associated with controlling NCDs [11]. Hence, studies on how to regularly assess BGLs in a cost-effective way are needed [12]. ML-based prediction models can help to achieve this goal. However, studies supporting the practical validity of ML techniques for predicting health parameters using data from low- and middle-income countries, such as Bangladesh, are very few [13]. Specifically, Bangladesh lacks research using ML techniques to predict BGLs based on basic noninvasive clinical measurements and dietary and sociodemographic information. To formulate strategies for public health planning and the control of diabetes, this study aimed to develop a personalized ML model that predicts the BGLs of urban corporate workers in Bangladesh. We used 5 regression prediction models, including boosted decision tree regression, decision forest regression, Bayesian linear regression, neural network, and linear regression. The models were trained and tested using a data set collected by the team using basic noninvasive clinical measurement devices together with dietary and sociodemographic information. Among the models, boosted decision tree regression exhibited the best performance in predicting the BGLs of the collected data, achieving the lowest root mean square error (RMSE) of 2.3 and mean absolute error (MAE) of 1.3. The model was then incorporated into a web app called the BloodGlucosePrediction Calculator [14], that allows individuals with basic noninvasive health measurements, dietary information, and sociodemographic information to predict their BGL value. Visual Studio was used to develop the web app. The app was developed based on the ML predictive model application programming interface and POST URL. The automated web-based BGL prediction system in this study is capable of aiding communities, especially those in highly remote areas, to diagnose BGLs quickly and easily.

Many studies on the prediction of BGLs have been conducted, each using a different set of data, patients, and features [15]. For example, a study used recurrent artificial neural networks (ANNs) and Elman recurrent ANNs to predict BGLs based on previous blood glucose values. They used a virtual data set called "Case 002" compiled from the free AIDA simulator. The study used RMSE to measure performance and obtained average RMSE values of 6.43 mg/dL, 7.45 mg/dL, 8.13 mg/dL, and 9.03 mg/dL for prediction horizons of 15 minutes, 30 minutes, 45 minutes, and 60 minutes, respectively. The researchers suggested additional case studies [16].

In another study [17], prediction models using nonlinear autoregressive neural networks and long short-term memory (LSTM) networks were introduced for predicting future glucose levels. These models were trained on a large set of continuous glucose monitoring data. The LSTM model, in particular, demonstrated superior predictive performance, achieving a lower RMSE value of 19.47 compared to other models. In a study using the OhioT1DM data set, which contains data from 6 patients with type 1 diabetes who participated in an institutional review board–approved study for 8 weeks between March 2016 and April 2017, the researchers applied LSTM and neural attention models for blood glucose prediction [18]. Their study found that the LSTM algorithm showed the best performance among the tested models.

The ML model mentioned in the research by Orabi et al [5] was trained on a data set of information from patients with type 2 diabetes. The data set, containing 23 characteristics, was collected by the Egyptian National Research Center specifically from patients with diabetes. The developed system showed 84% prediction accuracy. Meanwhile, Wu et al [19] predicted type 2 DM using the Pima Indian Diabetes data set. They achieved

an accuracy of 95.42% using the improved K-means algorithm and the logistic regression algorithm. They suggested further work to develop an application based on the proposed model. Kaur and Kumari [8] also used the Pima Indian Diabetes data set to develop ML models that classify the patients into diabetic and nondiabetic categories [8]. They applied and compared 5 different predictive models. The highest accuracy was reported for the linear kernel support vector machine, which achieved an accuracy of 0.89. The other 4 algorithms, including radial basis kernel support vector machine, k-nearest neighbor, ANN, and multifactor dimensionality reduction, achieved accuracies of 0.84, 0.88, 0.86, and 0.83, respectively.

According to a review of diabetes prediction papers [9], various data set characteristics, such as dimensionality, the number of instances relative to the number of features, or the data set type (genetic or clinical), can significantly impact the algorithm's performance. As a result, an algorithm that performs best on one data set may have lower prediction accuracy than other algorithms on different data sets.

Numerous studies have focused on predicting BGLs by using various feature sets and applying mathematical and ML models. However, no model has achieved 100% accuracy. Moreover, most of the previous ML-based studies in health care were conducted using data from high-income countries [20]. The application of supervised ML approaches to medical data to predict diseases, the survivability of diseases, and different types of health checkup test results by using sample data from Bangladesh is lacking. A search through several academic databases, including PubMed, IEEE Xplore, and Google Scholar, found that no existing studies specifically focused on ML blood glucose prediction in Bangladesh using dietary and sociodemographic data. Therefore, more research is needed in this area. Consequently, this paper focuses on predicting continuous BGLs based on data from noninvasive basic health checkup tests, dietary information, and sociodemographic characteristics collected from patients from Bangladesh.

Methods

Data Collection

The data were collected from the employees at the Grameen Bank complex in Dhaka, Bangladesh, which includes 18 distinct organizations with more than 500 employees, including Grameen Bank, Grameen Communications, other nongovernmental organizations, and private companies. The study collected data from 271 workers to predict their BGLs. Typically, a larger sample size is expected for ML approaches. However, previous studies included relatively few participants (eg, 118 [21] and 300 [22]). It must be mentioned that a small sample size is sometimes associated with higher classification accuracy [23]. A simple random sampling procedure drew the sample. In this study, we informed people first about our portable health clinic (PHC) system. After the initial introduction of the PHC system, the survey was conducted among those who came to the service point and received the PHC service at least once.

We calculated the required sample size using the following sample size formula, $S = Z^2 \times P \times (1-P)M2$, where S is the sample size for infinite population, Z is the *z* score, P is the population proportion (assumed as 50% or 0.5), and M is the margin of error.

Using the above formula for Z=1.960, P=0.5, and M=0.05, we calculated the required sample size to be 384. However, due to missing values, we included 275 observations in our study.

This study collected the test items used as input factors using the human-assisted PHC system. However, measurements such as arrhythmia, blood cholesterol, blood hemoglobin, blood grouping, urinary sugar, and urinary protein were excluded due to many missing cases. The blood glucose measurement was considered as an output factor. The PHC system has been previously described in detail [24].

Clinical measurements were obtained through direct diagnosis using PHC devices operated during data collection by a well-trained nurse or health care professional. The clinical measurements assessed by a PHC were as follows: blood pressure; pulse rate; body temperature; oxygenation of blood; arrhythmia; body mass index (BMI); waist, hip, and waist to hip ratio; blood glucose; blood cholesterol; blood hemoglobin; blood uric acid; blood grouping; urinary sugar; and urinary protein. Data on dietary information and sociodemographic characteristics were collected during face-to-face interviews using a standard questionnaire.

Regression Predictive Modeling

Machine Learning Models

Since the study's targeted output variable was a continuous variable, a person's BGL value was predicted using a regression prediction model. A regression predictive model's performance is reported as an error in those predictions because it predicts a quantity. The most popular ML models, including boosted decision tree regression, decision forest regression, Bayesian linear regression, linear regression, and neural network, were evaluated. This study chose these models for comparison because they are widely used to predict medical data.

Linear Regression

The linear regression model is a very simple ML method in which each data point consists of a pair of vectors, namely, the input vector and the output vector. Even on larger data sets, it is the most straightforward, traditional, and widely-applied correlational method [13]. The form of the linear regression model is $U_{pred} = \beta x_{in}$, where β represents the vector of coefficients, which are calculated by applying the least-squares method; U_{pred} is the predicted value; and x_{in} is the value of the independent variable [4].

Boosted Decision Tree Regression

Boosting is a popular ML ensemble method [25], where boosting in a decision tree ensemble tends to improve accuracy with some small risk of less coverage. It is an ML method for regression issues. It builds each regression tree in a stepwise fashion using a predefined loss function to measure the error in each step and correct for it in the next. Thus, the prediction

model is an ensemble of weaker prediction models. In regression problems, boosting builds a series of trees in a stepwise fashion, and then selects the optimal tree using an arbitrary differentiable loss function [26]. Like random forest, it combines many smaller, weaker models into a final summed prediction. However, the idea of boosting is to add new models to the ensemble in a sequence for a number of sequences. In each iteration, a new weak model is trained for the whole ensemble learned up to that new model. These iteratively produced new models are built to be maximally correlated with the negative gradient of the loss function that is also associated with the ensemble as a whole. In this approach, a performance function is placed on the gradient boosting machine to find the point at which adding more iterations becomes negligible in benefit (ie, adding more simple models, in this case decision trees, no longer reduces the error by a significant margin). At this point, the ensemble sums all of the predictions into a final overall prediction [27]. The boosted trees model is an additive model that makes predictions by combining decisions from a sequence of base models. More formally, the class of models can be written as $G(x) = f_0(x) + f_1(x) + f_2(x) + \ldots + f_n(x)$, where the final classifier, G, is the sum of simple base classifiers f_i. For the boosted tree model, each base classifier is a simple decision tree. This broad technique of using multiple models to obtain better predictive performance is called model ensembling.

Neural Network

The neural network is a network of connected neurons. The neurons cannot operate without other neurons with whom they are connected. Usually, they are grouped in layers, process data in each layer, and pass it forward to the next layer. The last layer of neurons makes the decisions [28].

Decision Forest Regression

This regression model consists of an ensemble of decision trees. A collection of trees constitutes a forest. Each tree in a regression decision forest outputs a Gaussian distribution as a prediction. Aggregation is performed over the ensemble of trees to find a Gaussian distribution closest to the combined distribution for all trees in the model [29]. This technique generates several decision trees during training, which can split randomly from a seed point. This results in a "forest" of randomly generated decision trees whose outcomes are ensembled by the random forest algorithm to predict more accurately than a single tree does alone. One problem with a single decision tree is overfitting, which makes the prediction seem very good on the training data but unreliable in future predictions [27]. By using decision forest regression, a model can be trained with a relatively small number of samples and produce good results.

Bayesian Linear Regression

Recently, Bayesian learning has been widely adopted and proven more powerful than other ML techniques. Bayesian linear regression allows a fairly natural mechanism to survive insufficient or poorly distributed data. It allows putting a prior on the coefficients and noise so that the priors can take over in the absence of data. The result of Bayesian linear regression is a distribution of possible model parameters based on the data and the prior. This allows the uncertainty about the model to be quantified with fewer data points, and the posterior distribution will be more spread out.

Experimental Setup

Azure Machine Learning Studio (Microsoft Corp) was used for the implementation of trained models. Azure Machine Learning Studio provides a user-friendly, visual approach to building ML pipelines. Azure Machine Learning Studio offers a graphical interface that allows users to design and build ML pipelines using a drag-and-drop approach. It also provides a wide range of prebuilt modules for data preprocessing, feature engineering, model training, and evaluation. These modules can be combined to create complex pipelines without writing code. We trained 5 relevant ML models using our data. The detailed technical aspects of the modeling process are shown in Figure 1.

Figure 1 shows the ML algorithms used in this study. First, the data file was uploaded into the experiment. Then, the data were edited, and variables for use in the predictive algorithms were selected. Next, the data set was split, and the ML algorithms were trained with the given data set to develop the model. After training, the score model was obtained and the trained model was evaluated to measure its accuracy (ie, performance).

To evaluate the performance of the models, RMSE values from each model were used. The RMSE of a model is the average difference between the model's prediction and the actual outcome [27]. It indicates how close the predicted value is to the actual value. There is no cutoff or benchmark for RMSE values. The smaller the value, the better the prediction. The MAE was also used. It is the sum of the absolute differences between predictions and actual values. Additionally, the coefficient of determination (R^2) was measured. R^2 represents how close the predicted value is to the actual value, and a higher value of R^2 is desirable.

Each model was trained on a 70% training sample to ensure uniform training. We split data according using a 0.7:0.3 training set to test set ratio. We did not use the cross-validation method because K-fold cross-validation produces strongly biased performance estimates with small sample sizes [23].

The input-process-output model for predicting blood glucose based on sociodemographic characteristics, dietary information, and some basic health checkup test results is shown in Figure 2. The 3 types of inputs were fed into the process using the 5 ML regression algorithms. The output was the predicted BGL.

Figure 1. Flowchart of Azure machine learning algorithms.

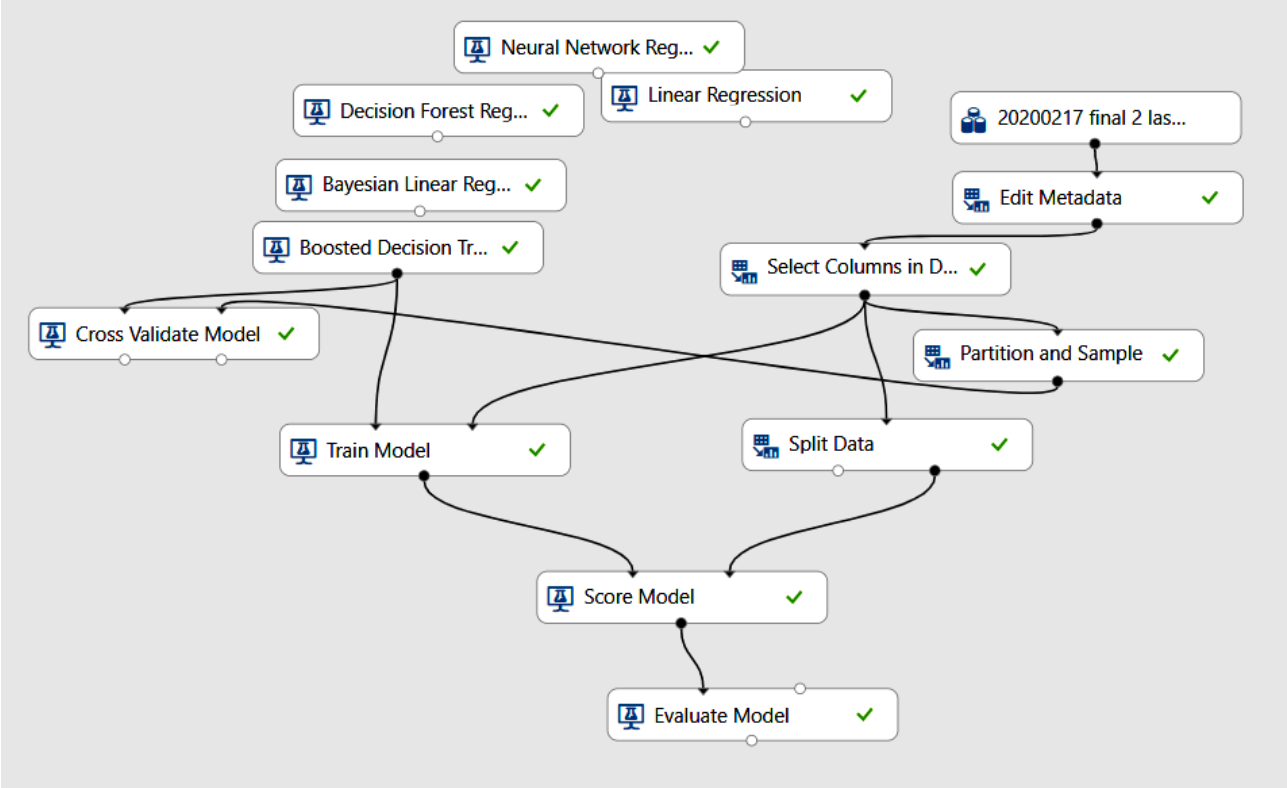
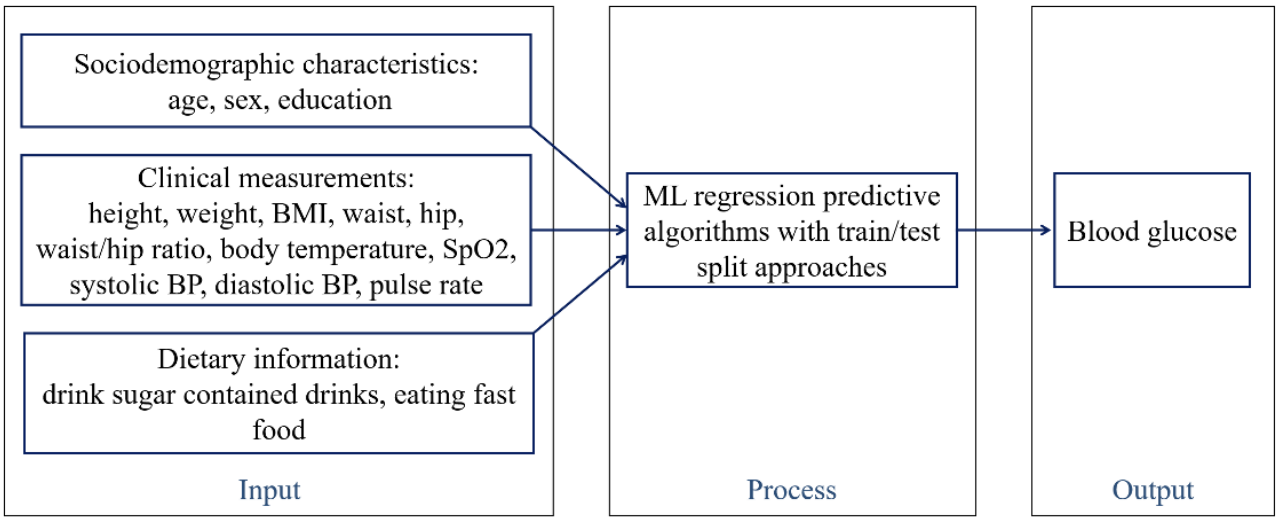


Figure 2. The input-process-output model used to predict blood glucose levels after processing 17 input variables using ML algorithms. BMI: body mass index; BP: blood pressure; ML: machine learning.



Ethical Considerations

The authors obtained ethics approval from the National Research Ethics Committee of the Bangladesh Medical Research Council (18325022019).

Results

Description of the Study Population

The descriptive statistics of the study participants and the summary statistics of the selected categorical predictors used in ML are shown in Table 1 and Table 2, respectively.

The mean age of the respondents was 49.61 (SD 7.39) years, and most participants were aged 50 years. On average, the respondents had a BMI of 25.37 (SD 3.20). The World Health Organization defines BMIs ranging from 25 to 29.9 as overweight; therefore, most of the respondents were overweight. The respondents' average BGL was on the borderline at 128.02 (SD 56.92) mg/dL (whereas the normal value is 140 mg/dL). This shows that it is important for the respondents to check their blood glucose regularly.

The majority (n=225, 83%) of the respondents were men and most had completed at least a college or university degree. Among the 271 respondents, 9.6% (n=26) reported that they drink sugar-containing drinks (eg, Coke, Fanta, soda, or fruit

juice) 3 or more times a week, and 18.1% (n=49) reported that they eat fast foods (eg, pizza, hamburgers, and deep-fried foods) 3 or more time a week.

Table 1. Summary statistics of the selected continuous predictors used in machine learning (n=271).

Variables	Range	Mean (SD)
Age (years)	34-77	49.61 (7.39)
Height (cm)	140.00-184.00	163.05 (7.45)
Weight (kg)	44.20-114.40	67.52 (10.06)
BMI[a] (kg/m^2)	18.39-40.53	25.37 (3.20)
Waist (cm)	63.60-118.00	90.24 (7.80)
Hip (cm)	80.00-127.00	94.54 (6.29)
Waist:hip ratio	0.64-1.11	0.96 (0.06)
Body temperature (°F)	92.12-99.64	96.07 (1.15)
SpO2[b]	93-99	97.67 (1.17)
Systolic BP[c] (mmHg)	92-180	126.68 (14.88)
Diastolic BP (mmHg)	59-108	81.71 (8.43)
Pulse rate (bpm)	51-123	80.27 (11.66)
Blood uric acid	3.10-11.00	6.63 (1.54)
Blood glucose (mg/dL)	66.60-392.40	128.02 (56.92)

[a]BMI: body mass index.

[b]Blood oxygenation.

[c]BP: blood pressure.

Table 2. Summary statistics of the selected categorical predictors used in machine learning.

Category	Participants (n=271), n (%)
Gender	
Men	225 (83)
Women	46 (17)
Education	
No education (no school entered)	10 (3.7)
Primary school completed	30 (11.1)
Secondary school completed	11 (4.1)
High school completed	23 (8.5)
Vocation school completed	1 (0.4)
College or university completed	63 (23.2)
Higher education (master or doctor) completed	133 (49.1)
Drinks sugar-containing drinks[a]	
Yes	26 (9.6)
No	245 (90.4)
Eats fast foods[b]	
Yes	49 (18.1)
No	222 (81.9)

[a]Drinks sugar-containing drinks (eg, Coke, Fanta, soda, fruit juice, orsother Sweet or sugar-containing drinks) 3 or more times a week.

[b]Eats fast foods, such as pizza, hamburgers, or deep-fried foods (eg, singara, samosa, moglai parata) 3 or more times a week.

Prediction Performance Assessment

To examine the prediction performance of the regression predictive technique using ML, the main evaluation criterion used was the RMSE. The RMSE measures the average magnitude of the error by taking the square root of the average of the squared differences between the prediction and actual observations. The RMSE value gives us an idea of how much, on average, the predicted values deviate from the actual values; it is a measure of the fit of the model to the data points. Table 3 presents the performance of the regression models. The boosted decision tree regression model performed the best among the tested models. Its RMSE was the lowest at a value of 2.30, indicating that, on average, the boosted decision tree regression model's predicted blood glucose deviated from the actual blood glucose by around 2.30 mg/dL. Its RMSE and MAE were significantly lower than those of the other models, while it's R^2 was the largest (0.99).

The score model of the best predictive model—the boosted decision tree regression—is shown in Figure 3. The "Scored Labels" column (last column) in Figure 3 indicates the predicted value of BGLs. It can be seen that the deviation between the scored labels and the actual BGL reported in the "Bglucose" column was small.

Table 3. Comparison of modeling techniques.

Model name	Root mean squared error	Mean absolute error	R^2
Neural network	45.54	36.24	0.18
Decision forest regression	22.99	17.46	0.79
Linear regression	44.66	35.59	0.21
Boosted decision tree regression	2.30	1.30	0.99
Bayesian linear regression	44.49	34.50	0.22

Figure 3. Partial view of the score model (prediction of blood glucose level) obtained by the boosted decision tree regression model. BloodPressuresys: systolic blood pressure; BloodPressuredia: diastolic blood pressure; Bglucose: blood glucose level; Ffood: fast food; Sdrinks: sugary drinks.

Blood Glucose Prediction through ML › Score Model › Scored dataset

rows 82 columns 18

Waist	Hip	WaistHipRatio	BodyTemperature	SpO2	BloodPressuresys	BloodPressuredia	PulseRate	Bglucose	Sdrinks	Ffood	Scored Labels
109	120	0.91	96.62	97	131	88	81	169.2	No	Yes	181.47113
87	93	0.94	96.26	98	126	88	91	90	No	No	91.594948
92	98	0.94	94.1	99	140	87	76	180	No	No	181.032394
102	103	0.99	96.62	99	124	82	68	163.8	No	Yes	162.096588
93	97	0.96	96.62	96	150	95	93	108	No	No	112.058952
92	98	0.94	92.48	99	129	84	78	151.2	No	No	151.870651

Discussion

Principal Findings

ML algorithms can identify the patterns in a data set that may not be directly apparent. Thus, ML can provide helpful information and support to medical staff by identifying patterns that may not be obvious [30]. Comparison of the results found in this study to those in previous related works is crucial. Most previous studies have reported performance measurements as a function of classification accuracy, which may not be directly comparable to this study, which adopts a regression approach to build a predictive model for the continuous variable (ie, BGL).

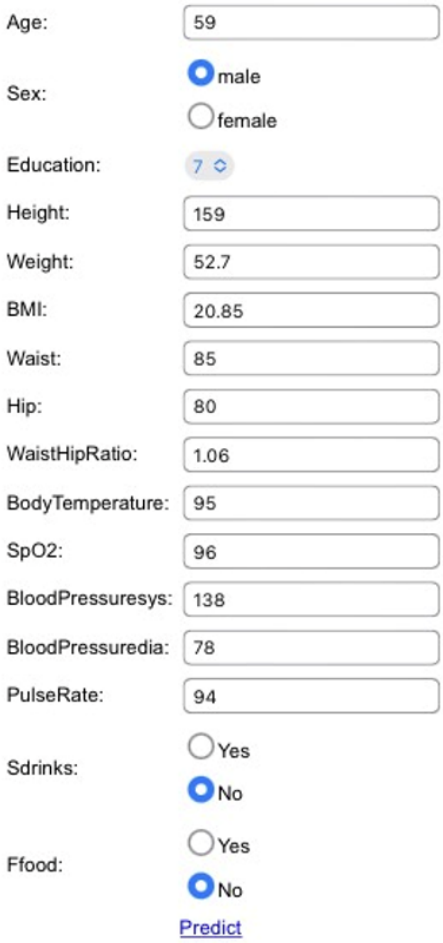
A previous study compared the performance of 3 ML models, namely logistic regression, ANN, and decision tree models, for predicting diabetes or prediabetes using 12 common risk factors (including only 1 clinical factor: BMI) in Guangzhou, China [31], and found accuracies of 77.87%, 73.23%, and 76.13% for the decision tree model, ANN, and logistic regression model, respectively.

The gradient boosting ML algorithm has been successfully used in clinical studies to predict cardiovascular diseases [12]. The gradient boosting decision tree method by Friedman [32] predicted BMI with an accuracy of 0.91 [33]. In the current study, decision tree regression was the best predictive model, followed by decision forest regression. Both of these are ensemble learning methods.

In this study, 5 ML prediction algorithms were evaluated to predict blood glucose values. The health records of 271 employees aged 34 to 77 years were collected and used in this

study. The data included well-known relevant factors of high blood glucose, such as age and BMI, as well as other factors with unknown associations with BGL. Specifically, 17 noninvasive health measurements, dietary information, and sociodemographic information were used for the prediction. This study used portable, cheap, and affordable devices for clinical data collection. The low-input dimensions provided the advantage of keeping the necessary time to train the models relatively small. Blood glucose was set as an output factor. Among the studied prediction algorithms, boosted decision tree regression was found to be the most effective with the best RMSE (2.3); this RMSE value was better than any reported in the literature. The developed model is a powerful tool for predicting blood glucose with limited medical resources and has been deployed on a website [14]. Figure 4 shows the web app. With this app, the patients of caregivers do not need to carry the blood glucose measuring instruments or be concerned with ensuring enough supply of test strips and lancet needles, as the predictor is able to predict BGL using external factors.

Figure 4. Screenshot view of the website to predict blood glucose value obtained by integrating the best performing boosted decision tree regression model into the application. BloodPressuresys: systolic blood pressure; BloodPressuredia: diastolic blood pressure; Bglucose: blood glucose level; Ffood: fast food; Sdrinks: sugary drinks.



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Conclusions

This study provides a measure for reducing NCDs and can be a good component in the national or global plan. We developed a blood glucose prediction model based on personal characteristics, dietary information, and some basic clinical measurements related to NCDs. Such a blood glucose prediction model is useful for reducing health management costs and improving awareness among high-risk individuals. Predicted glucose values can be used for early hypoglycemic or hyperglycemic alarms. These predictions can also help prevent complications associated with high BGLs. As a result, the developed model can help achieve the Sustainable Development Goals, ensuring universal and equal health coverage, and thus reducing overall morbidity and mortality.

However, there are several limitations to this study. First, the number of samples we studied was small; it must be expanded to train the prediction model in the future. Second, this study was limited to a particular area, specifically among employees working in a corporate office. We collected the training data from this specific area. We trained our model by using these data only. The data from other institutes do not confirm our

prediction model. Our findings may not be applicable to a broader population or different geographical locations. This is because the characteristics, behaviors, and dynamics of the population might differ significantly from one area to another. As a result, it becomes challenging to generalize the results beyond the confines of the chosen area and employee group. The specific area and employee group might possess unique cultural, economic, or contextual factors influencing their behaviors and responses. These factors might not hold true for other settings or groups, leading to skewed conclusions if applied outside the study's scope. The data from other institutes do not confirm our prediction model. However, the framework achieves high performance on Grameen Bank complex data. Thus, we believe this data-based strategy is also fit for predicting blood glucose in other communities. In future studies, additional features (eg, work stress, everyday physical activity, eating red meat) should be considered to improve the prediction accuracy. Nonetheless, this study served as a successful case.

Acknowledgments

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Authors' Contributions

MBS conceptualized the study, performed the formal analysis and investigation, designed the methodology, and wrote the manuscript. MBS, TB, MSR, NHBAA, MNH, and NAAA reviewed and edited the manuscript. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ANN: artificial neural network
BGL: blood glucose level
BMI: body mass index
DM: diabetes mellitus
LSTM: long short-term memory
MAE: mean absolute error
ML: machine learning
NCD: noncommunicable disease
PHC: portable health clinic
RMSE: root mean square error

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Original Paper

Barriers and Enablers to the Adoption of a Healthier Diet Using an App: Qualitative Interview Study With Patients With Type 2 Diabetes Mellitus

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Abstract

Background: Adopting a healthy diet is one of the cornerstones of type 2 diabetes (T2D) management. Apps are increasingly used in diabetes self-management, but most studies to date have focused on assessing their impact in terms of weight loss or glycemic control, with limited evidence on the behavioral factors that influence app use to change dietary habits.

Objective: The main objectives of this study were to assess the enablers and barriers to adopting a healthier diet using the Gro Health app in 2 patient groups with T2D (patients with recently diagnosed and long-standing T2D) and to identify behavior change techniques (BCTs) to enhance enablers and overcome barriers.

Methods: Two semistructured qualitative interview studies were conducted; the first study took place between June and July 2021, with a sample of 8 patients with recently diagnosed (<12 mo) T2D, whereas the second study was conducted between May and June 2022 and included 15 patients with long-standing (>18 mo) T2D. In both studies, topic guides were informed by the Capability, Opportunity, Motivation, and Behavior model and the Theoretical Domains Framework. Transcripts were analyzed using a combined deductive framework and inductive thematic analysis approach. The Behavior Change Wheel framework was applied to identify appropriate BCTs that could be used in future iterations of apps for patients with diabetes. Themes were compared between the patient groups.

Results: This study identified similarities and differences between patient groups in terms of enablers and barriers to adopting a healthier diet using the app. The main enablers for recently diagnosed patients included the acquired knowledge about T2D diets and skills to implement these, whereas the main barriers were the difficulty in deciding which app features to use and limited cooking skills. By contrast, for patients with long-standing T2D, the main enablers included knowledge validation provided by the app, along with app elements to help self-regulate food intake; the main barriers were the limited interest paid to the content provided or limited skills engaging with apps in general. Both groups reported more enablers than barriers to performing the target behavior when using the app. Consequently, BCTs were selected to address key barriers in both groups, such as simplifying the information hierarchy in the app interface, including tutorials demonstrating how to use the app features, and redesigning the landing page of the app to guide users toward these tutorials.

Conclusions: Patients with recently diagnosed and long-standing T2D encountered similar enablers but slightly different barriers when using an app to adopting a healthier diet. Consequently, the development of app-based approaches to adopt a healthier diet should account for these similarities and differences within patient segments to reduce barriers to performing the target behavior.

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KEYWORDS

behavior change techniques; diabetes; apps; smartphone; enablers; barriers; mobile phone

Introduction

Background

Type 2 diabetes (T2D) is a chronic noncommunicable disease, with an increasing prevalence in high-income countries such as the United Kingdom, where an estimated 4.2 million people live with the disease [1]. T2D care relies mainly on patient self-management, which encompasses behaviors such as monitoring blood sugar levels, engaging in physical activity, and adopting a healthy diet. With respect to adopting a healthy diet, tailoring the diet to individual patient needs is essential for T2D management, which implies taking into consideration the differences that exist between patients with recently diagnosed T2D (<1 y after diagnosis), who require an onboarding on dietary changes, and patients with long-standing T2D (>1 y after diagnosis), who may struggle to sustain dietary changes over time. In this context, apps have been used to support patients with T2D in adopting a healthy diet, demonstrating favorable effects in terms of improved glycemic control [2] and weight loss [3]. However, there is limited evidence on the behavioral enablers and barriers influencing user engagement with apps when adopting a healthy diet, as well as how these enablers and barriers may differ between patients with recently diagnosed T2D and those with long-standing T2D.

The Behavior Change Wheel (BCW) can be useful in this regard, offering a theoretically based, systematic framework to examine enablers and barriers to using a T2D app to adopt a healthy diet, which can then be linked to corresponding intervention strategies or behavior change techniques (BCTs) for optimization. Using BCW, we first highlighted the enablers and barriers to adopting a healthy diet before and when using an app in patients with recently diagnosed and long-standing T2D and then identified BCTs that specifically address the common and distinct barriers for both patient groups.

Current T2D Management

Diabetes care is primarily dependent on patient self-management, which, if not performed, increases the risk of premature death, blindness, and kidney failure [4]. T2D self-management consists of the development of knowledge or awareness to survive the complexity of diabetes in a social context, including behaviors such as monitoring of blood sugar, being physically active, improving medication adherence, and adopting a healthy diet [5].

A healthy diet plays a central role in the management of T2D in patients with a recent and long-standing diagnosis, as it contributes to common goals such as achieving glycemic targets (ie, inducing a reduction in hemoglobin A_{1c}) and weight loss in patients who are overweight and obese [6]. Although there is no single diet that is unanimously endorsed for patients with T2D, adapting and tailoring diets to their needs (especially the needs of patients with recently diagnosed T2D) is an essential first-line intervention for the management of T2D.

Multiple factors prevent patients with prediabetes and newly diagnosed T2D from changing their dietary patterns, whereas patients with a long-standing diagnosis struggle to maintain dietary changes over time. Pikkemaat et al [7] found several barriers to dieting among patients with recently diagnosed T2D, including a lack of knowledge about the correct diet to adopt, absence of self-regulatory skills (eg, low self-control and lack of self-monitoring skills), low motivation, low self-efficacy, and lack of social and medical support. In the case of patients with a long-standing diagnosis, an important factor that affects the sustainability of lifestyle behavioral changes is the time since diagnosis (ie, duration of time living with diagnosis); receiving a diagnosis from a health care professional may increase patients' awareness and motivation for lifestyle changes, but this motivation may fade over time [8]. In addition, sustainable lifestyle changes must be adopted and endorsed by patients, coopted into their social setting (ie, endorsed by family and friends), and supported by health care professionals [9]. In view of these factors, it is paramount to have effective early behavior change interventions and target the underlying influences that prevent patients with recently and long-standing T2D from adopting or maintaining a healthier diet. Among these, digital technologies are increasingly being used to remotely support patients with T2D in their lifestyle management.

Digital Behavior Change Interventions

Delivering theory- and evidence-based, cost-effective, highly available, flexible, and engaging real-life interventions has become a focus of T2D intervention development [10]. Consequently, digital behavior change interventions (eg, *apps*) have become increasingly popular and stand to bridge the gaps in health care outreach, particularly among underserved populations, who can be readily accessed via the web [11]. The use of apps has been demonstrated to improve glycemic outcomes in people with type 1 diabetes and T2D [2]. A meta-analysis also reported that apps for T2D management have a positive effect on weight loss, with 14 studies that enrolled 2100 patients showing apps that could significantly reduce body weight, particularly among patients who were obese [3]. To date, most studies have focused on assessing the impact of using an app for T2D management in terms of weight loss or glycemic control outcomes, but there is limited evidence on the behavioral enablers and barriers to change dietary habits using an app, which is an important element to understand when promoting effective behavior change.

Few studies to date have evaluated T2D apps from a behavioral perspective, and they have focused on identifying the BCTs that have been included in T2D apps. Hoppe et al [12] conducted a review of 10 diabetes apps, assessing the number of BCTs included, and found that the average number of BCTs was 4.4, out of a possible maximum of 26 BCTs, as proposed by a taxonomy of BCTs [13]; the most common BCTs were "self-monitoring of behavior," "intention formation," "goal setting" and "feedback on performance." Consistent with these findings, Priesterroth et al [14] assessed 56 diabetes apps using a taxonomy of BCTs, which is modified from the taxonomy given by Michie et al [15], and found that an average of 7.4 BCTs were implemented in each app, including "self-monitoring of behavior," "feedback on behavior," as well as "self-monitoring of outcomes of behavior" among the most frequently used BCTs. Although these findings provide insights into the BCTs used in T2D apps, these studies have neither

systematically identified which BCTs could best support self-management behaviors, such as adopting a healthy diet using an app, nor reported findings for individual apps.

Among the numerous commercially available T2D apps, only a limited number have been formally evaluated in terms of their impact on user engagement outcomes (and published in peer-reviewed journals) or have regulatory clearance [16]. Engagement with digital health interventions, such as T2D apps, has been defined as both an objective measure of use, such as the amount, frequency, duration, and depth of the app accessed, and a subjective experience characterized by attention, interest, and affect [17]. According to Kebede et al [18], in 2018, the most commonly used apps across English- and German-speaking countries included mySugar, MyFitnessPal, OneTouch Reveal, and accu-chek. Most of these apps included self-monitoring and feedback features to track blood glucose levels and keep a diary of dietary intake and physical activity. More recently, however, new apps have been developed that seek to integrate these features; one of them is the Gro Health app, which is the focus of this study. The Gro Health app was selected among other apps because its content considers behavioral change evidence and is endorsed by real-world outcomes reported in 2 studies [4,19], which made it an appropriate app for further research from a behavioral lens.

The Gro Health App

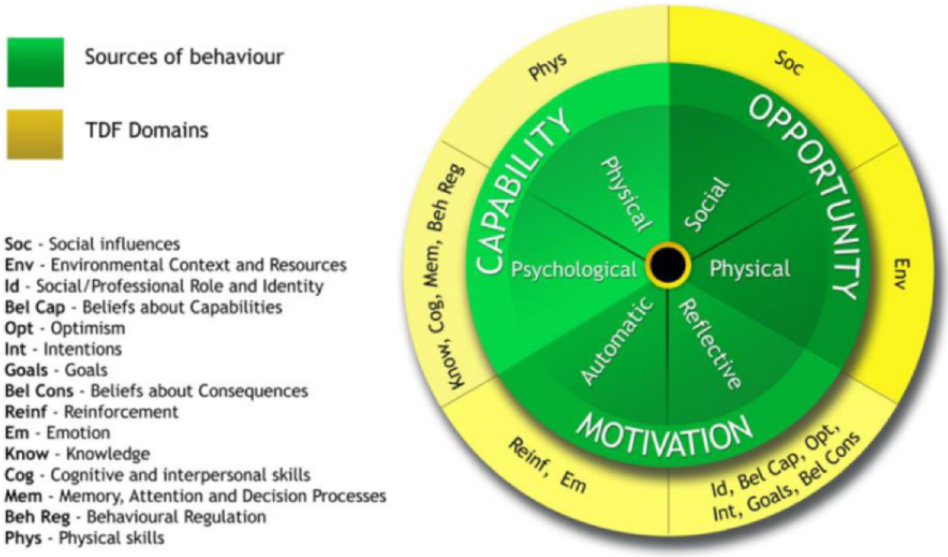
The Gro Health app is an evidence-based behavior change platform consisting of a dedicated website and an app developed by DDM (previously known as Diabetes Digital Media). The app supports diabetes management by addressing 4 key pillars of health: nutrition, mental well-being, sleep, and physical activity [20]. In terms of nutrition, the app provides nutrition programs, resources, and meal plans personalized to the disease, budget, dietary preferences, and cultural and social norms. In addition, it includes features such as blood glucose tracking, a food diary to track macro- and micronutrients, lifestyle education guides, peer support in a moderated community, and behavior change coaching from health coaches. Within the nutritional programs available, the app offers a Low-Carb program, which is a 12-session, educational behavior change intervention for glycemic control and weight loss for adults with prediabetes and T2D. This program had been evaluated through a real-world 12-month outcomes study that demonstrated improvement in terms of glycemic control and weight loss among participants who completed 9 core lessons of the program [4]. Despite these established benefits, further research is required to better understand the factors that influence the adoption of a healthy diet using the app from a behavioral perspective; a more comprehensive understanding of such factors could be achieved through a systematic theory-based approach using BCW.

The BCW Approach

The BCW approach was developed through the synthesis of 19 frameworks of behavior change to aid behavior change intervention design and to improve the process of intervention evaluation and theory development [21]. The BCW approach includes 4 behavioral science tools and demonstrates how they interlink and can be applied to understand behavior and design behavior change interventions. The 4 tools include the Capability, Opportunity, Motivation, and Behavior (COM-B) model, the Theoretical Domains Framework (TDF) [22], the BCW, and the Behavior Change Techniques Taxonomy (BCTTv1). The COM-B model and TDF guide the understanding of behavior, whereas the BCW and BCTTv1 guide the development and content of behavior change interventions [23]. By using COM-B, researchers can better understand behavior in the context where it occurs, determining which aspects in terms of capability (psychological and physical), opportunity (physical and social), and motivation (automatic and reflective) act as enablers or barriers to behavior change. The TDF provides a more granular understanding of the COM-B components (Figure 1 [24]) by further detailing the factors that influence behavior. The COM-B and TDF identify what needs to shift for the desired behavior to be achieved and therefore what to target in an intervention, whereas the BCW identifies intervention functions and supporting policies that are likely to be effective in bringing about change [21].

An expert consensus allows the mapping of the COM-B components and TDF domains with the BCW intervention functions. This leads to the next step of the BCW approach, which consists of identifying intervention content in terms of which BCTs best serve intervention functions and the appropriate mode of delivery to implement the intervention [21]. The BCTTv1 serves as a standardized language for describing distinct BCTs, which serve as the active ingredients in interventions; it lays the foundation for the reliable and systematic specification of behavior change interventions [15]. The appropriateness of an intervention and BCT can be assessed by applying the affordability, practicability, effectiveness/cost-effectiveness, acceptability, side effects/safety, and equity (APEASE) criteria, which acknowledge contextual factors that may influence implementation and have been previously used in the development of health apps to ensure app design simplicity and user-friendliness [25].

Figure 1. Capability, Opportunity, Motivation, and Behavior model and Theoretical Domains Framework (TDF) domains, from Atkins et al [24] which is published under the Creative Commons Attribution 4.0 International License (CC-BY) [26].



Objectives and Research Questions

The adoption of a healthy diet is essential for ensuring a better prognosis; however, it remains challenging for patients with prediabetes and newly diagnosed T2D as well as for patients with a long-standing diagnosis. The Gro Health app has shown promise as a tool for users to achieve better T2D self-management by incorporating features and BCTs, such as meal plans, information sheets, and a recipe library [4]. However, further research is needed to better understand how users engage with the app's features and then offer strategies for improvement.

Using the BCW approach, this study aimed to identify the enablers and barriers to adopting a healthier diet before and after the use of the Gro Health app in patients with prediabetes, newly diagnosed T2D, and long-standing T2D. A comparison of the enablers and barriers before and after the use of the Gro Health app can help distinguish the features of the app that contribute to the adoption of a healthy diet. In addition, patients with recently diagnosed T2D and those with long-standing T2D are evaluated in separate studies to identify similarities and differences in terms of patient acceptability of app features and to propose BCTs that are best suited to address the specific engagement barriers of each group.

This study used the BCW approach to answer 3 key research questions (RQs):

- RQ1: per COM-B and TDF, what are the enablers and barriers to adopting a healthier diet in patients with recently diagnosed T2D or those with prediabetes before and after the use of the Gro Health app?
- RQ2: per COM-B and TDF, what are the enablers and barriers to adopting a healthier diet in patients with long-standing T2D, diagnosed for >1.5 years, before and after the use of the Gro Health app?
- RQ3: Do barriers and enablers to adoption differ between patients with recently diagnosed T2D (<12 mo) and those with long-standing (>1.5 y) T2D?
- RQ4: What BCTs could support the Gro Health app, or any other app developed specifically for patients with T2D, in overcoming barriers to promote the adoption of a healthier diet in each patient subgroup?

Methods

Study Design

Two studies were conducted. The first was a semistructured qualitative interview study encompassing in-depth interviews with patients with newly diagnosed T2D (<1 y after diagnosis), conducted between June and July 2021. The second study was also a semistructured qualitative interview study focusing on patients with a long-standing diagnosis (>1.5 y after diagnosis), conducted between May and June 2022.

Semistructured qualitative interviews were selected in both studies because little is known about the behavioral enablers and barriers to adopting a healthier diet using an app in patients with newly diagnosed and long-standing T2D. This study design allowed the researchers to probe in greater detail to obtain better insight into the required content of BCTs to support the Gro Health app (in support of RQ4).

Recruitment

Study 1: Patients With Newly Diagnosed T2D

In this study, participants were eligible to participate if they (1) were newly diagnosed (<1 y) with T2D or prediabetes, (2) had received a recommendation from their health care provider to adopt a healthier diet, (3) were aged >18 years, (4) were fluent English speakers, (5) owned a smartphone, and (6) were willing to interact with an app for 2 weeks to adopt a healthier diet.

A total of 16 participants were recruited via a Diabetes UK advertisement to their users (email and communities) and diabetes-related social media groups (eg, via Facebook) in the United Kingdom, with 8 participants completing the interviews. The advertisement was live and reposted several times over 2 months (June to July 2021), offering 1-year access to the Gro

Health app and inviting patients with newly diagnosed (<12. mo) T2D or prediabetes who were advised by their health care team to adopt a healthier diet; the patients were asked to use the app for 2 weeks and share their experiences during interviews. A QR code directed potential participants to a screening questionnaire embedded in the University College London (UCL) REDCap (Research Electronic Data Capture; Vanderbilt University) safe haven to guarantee anonymity. For participants meeting the aforementioned eligibility criteria, basic demographic information (eg, age and gender) and patients' specific diagnosis (T2D or prediabetes; Table S1 in Multimedia Appendix 1) were collected. Participants consented to the study by reading and signing an e-document containing the necessary information, after which an email was automatically sent with instructions for the 2-week app use and interview scheduling.

Study 2: Patients With a Long-Standing Diagnosis

In this study, participants were eligible if they had been diagnosed with T2D for >1.5 years, and met screening criteria 2 to 6 given in the *Study 1: Patients With Newly Diagnosed T2D* section. The 1.5 years postdiagnosis criterion was defined as the minimum period between initiating study fielding and the time of initial T2D diagnosis to ensure that patients would have been diagnosed before the COVID-19 pandemic (before March 2020), thus minimizing the impact that the pandemic could have had on patient diagnosis and follow-up.

In this study, a web-based advertisement was posted via the on the Diabetes UK Twitter account to recruit potential participants between May and June 2022, offering 6-month access to the Gro Health app. Five hundred respondents expressed initial interest and completed a web-based REDCap survey. Participants were included or excluded based on the responses gathered. In addition, as part of the survey, participants who met the inclusion criteria were asked to provide demographic information such as age, gender, employment status, and educational background; this information was used to select eligible participants while ensuring that there was a balanced distribution in terms of age and gender. Finally, the recruited and interviewed sample (n=15) included participants who had been diagnosed with T2D, met the inclusion criteria, and equitably represented different age and gender groups (Table S1 in Multimedia Appendix 1). Participants who completed the interview were offered £10 (US $12.60) compensation by UCL, as well as extended free access to the app for a total of 6 months, as a token of appreciation for their time.

Procedure

In both studies, eligible participants were granted free access to the Gro Health app through a voucher provided by the app developers and engaged in a 2-week app use period. The duration of these studies was aligned with the duration of a prior study evaluating a T2D app, which lasted 4 weeks [27], but further reduced to 2 weeks considering the time limitations for fielding in the case of this research project.

Semistructured interviews were conducted via the web by the researchers, owing to the geographic distance between the researcher and participants (located around the United Kingdom) and, to a lesser extent, the COVID-19 restrictions; interviews were held via Teams (Microsoft Corporation). Interviews lasted between 30 and 45 minutes were audio recorded and transcribed verbatim. The participants provided consent to be interviewed and audio recorded before data collection. Upon completion of the interview, participants could continue using the app for the duration of the voucher, which lasted 1 year in study 1 and 6 months in study 2.

Measures

The interview schedule in both studies was organized into 3 sections, which comprised COM-B– and TDF-aligned questions along with exploratory questions (Table 1), which are designed to explore participants' barriers and enablers in adopting a healthier diet before and after app use. The first section explored participants' lifestyle choices after diagnosis and before using the app, which provided information on dietary habits, as well as prior enablers and barriers to adopting a healthier diet. Patients with long-standing T2D were further prompted to discuss prior dietary experiences because they had been living with T2D for a longer period. The second section focused on the participants' experiences during the 2-week period using the app, assessing their perception of the features included in the app and how they perceived these had supported them, or not, in adopting a healthier diet. The third, shorter section of the interview probed participants' willingness to continue using the app after the 2-week period and if participants would recommend the app to other patients with T2D.

Semistructured and open-ended questions allowed the exploration of the main COM-B and TDF components in a structured manner while ensuring that specific topics could be further explored in detail. This is consistent with the approach used in other studies that evaluated apps for diabetes self-management and typically used semistructured interviews. The author created questionnaires to assess criteria such as app usability, acceptability, and behavioral impact [28]. The full interview schedules can be found in Multimedia Appendix 1.

Table 1. Example questions from the interview schedules.

Interview section and example questions	COM-B[a] component	TDF[b] domain
Eating habits before engaging with the app		
When where you diagnosed and who diagnosed you?	Exploratory	Exploratory
What were the main recommendations given to you by your doctor or health care team?	Psychological capability	Knowledge skills
Before using the app, what were your main struggles when trying to adopt a healthier diet?	Reflective motivation	Beliefs about capabilities
In particular, what changes have you made regarding your nutritional habits?	Psychological capability	Behavioral regulation
Experience engaging with the app		
Which features of the app did you use more often?	Exploratory	Exploratory
What made these features particularly useful to you?	Reflective motivation	Beliefs about consequences
Have you changed anything in your eating routine since using the app?	Psychological capability	Behavioral regulation skills
Any particular aspect of using the app that preempted you from changing your eating routine? Or external aspects not discussed so far?	Physical opportunity	Environmental context and resources
Future outlook		
In the mid to long term, are you planning to keep using the app?	Reflective motivation	Intentions
Is there anything else that we have not covered so far that you would like to discuss?	Exploratory	Exploratory

[a]COM-B: Capability, Opportunity, Motivation, and Behavior.

[b]TDF: Theoretical Domains Framework.

Data Analyses

Analyses of Interviews

In both studies, interview transcripts were analyzed in a stepwise approach: a deductive framework analysis was followed by inductive thematic analysis, based on the guidance for data analysis using COM-B and TDF provided by Atkins et al [24].

Step 1: Deductive Framework Analysis

To address RQ1 and RQ2, the data were coded against COM-B and TDF to generate the framework for content analysis. In study 1, 2 transcripts were reviewed by a second coder, and an agreement rate of 92% was obtained. In study 2, 2 pilot transcripts were reviewed by a second coder, reliability checks were carried out on the transcripts, and an agreement rate of 82.46% was achieved; these pilot transcripts served to develop a codebook that was used to guide subsequent coding.

Step 2: Inductive Thematic Analysis

To further understand the enablers and barriers influencing behavioral change in this context, the data were also assigned an inductive code. Data were analyzed following Braun and Clarke's [29] thematic analysis process: (1) transcripts were read and reread to allow content familiarization; (2) text relevant to the RQ was highlighted in Word (Microsoft Corporation), coded to COM-B components and TDF domains, and pasted into Excel (Microsoft Corporation); (3) within the identified TDF domains, similar codes were grouped into potential themes and classified as either a barrier or an enabler to the target behavior before or after app use; (4) all themes and domains were reviewed to ensure that all relevant data were analyzed and corresponded to the COM-B components; and (5) main domains or components and themes were tabulated and ranked. To identify which theoretical model domains were the main barriers to and facilitators of healthier diet adoption, both before and after the use of the Gro Health app, they were arranged according to the incidence of mentions and then by the frequency of respondents who stated them.

In study 1, the analysis was validated by a second coder who read 20% of the transcript data, with a high level of code agreement (92%) [30]. In study 2, the codes and grouping in subthemes were checked with a second coder to ensure the reliability and validity of coding; discrepancies were discussed until agreement was reached.

Comparison of Findings Between Studies

To address RQ3, the enablers and barriers to adopting a healthy diet before and after using the app were qualitatively compared by the first author to assess how these differed between patients with recently diagnosed T2D and those with long-standing T2D.

Identifying Intervention Strategies Using the BCW

To address RQ4, the enablers and barriers (coded to COM-B and TDF) were mapped against BCTs using BCTTv1 according to the approach described by Johnston et al [31] to facilitate linking the TDF domains to the relevant BCTs. This allowed the identification of potential types of BCTs that may optimize Gro Health app content. The APEASE criteria, as described by Michie et al [21], were applied to the identified BCTs to determine their appropriateness for implementation by app users and developers (for BCTs that require app design or content changes per se).

Data Exclusion

In study 1, 2 patients decided not to use the app after accessing it for the first time. For these participants, the data analysis focused on the first interview section "eating habits before engaging with the app."

Ethical Considerations

Ethics approval was granted for both studies by the Departmental Research Ethics Committee of the UCL (20027/001 and 22417.001). Personal identifiers were removed, and the data were stored securely.

Results

Enablers and Barriers to Adopting a Healthier Diet

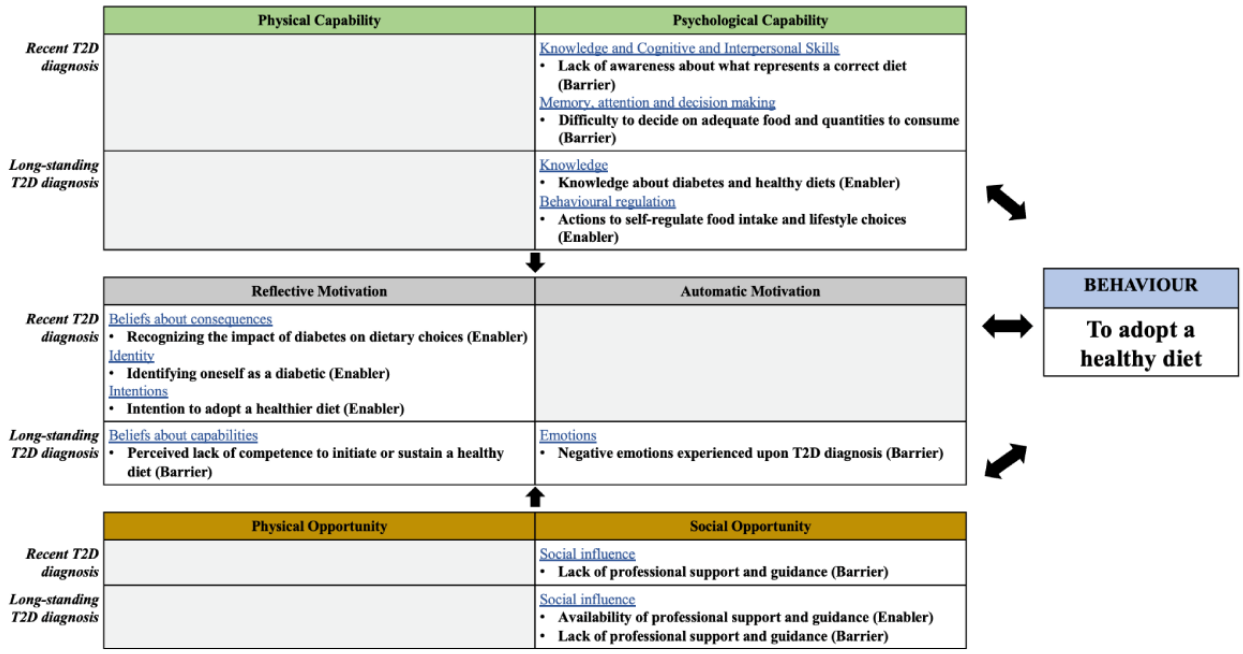
The enablers and barriers influencing the adoption of a healthier diet were identified across the COM-B components and TDF domains before and after the participants engaged with the app.

Before Using the Gro Health App

Overview

Six core themes were identified from the interviews in each study, corresponding to the most frequently mentioned statements by participants, identified as either enablers or barriers, and categorized according to the COM-B model and the TDF (Figure 2). Tables S2-S5 of Multimedia Appendix 2 show the rank order and main themes of the enablers and barriers identified for patients with recently diagnosed T2D and those with long-standing T2D before using the Gro Health app, respectively. As indicated by the arrows in Figure 2, the themes within the COM-B components of capability, opportunity, and motivation interact to generate the behavior in scope, which in turn influences these components (ie, enacting the behavior can in turn alter capability, motivation, and opportunity).

Figure 2. Map of the main themes before using the app in both patient groups, indicating Capability, Opportunity, Motivation, and Behavior (COM-B; overarching) themes; Theoretical Domains Framework (TDF; secondary) themes; and inductive subthemes. T2D: type 2 diabetes. Overarching COM-B themes are indicated by shaded boxes, and TDF secondary themes are indicated by blue underlined text. The inductive themes are indicated in bold. Word in brackets indicate whether each subtheme was identified as an enabler or a barrier. Arrows show the COM-B interactions. The gray boxes correspond to COM-B components for which no main themes were identified.



Enablers to Adopting a Healthy Diet in Patients With Recently Diagnosed T2D: Reflective Motivation

The main enablers identified were coded within this COM-B component, among which, recognizing the impact of diabetes on dietary choices (TDF domain: *beliefs about consequences*) was identified as a key enabler to adopt a healthy diet:

> *Well, you have to learn how to manage it [diabetes], because I think once you're diabetic, the doctor says you're diabetic for life.* [P2]

In addition, identification as a person with diabetes or prediabetes in need of help (TDF domain: *Identity*) was identified as a catalyst for behavior change among various patients, whereas some of the patients stated that they had taken a conscious decision to adopt a healthy diet (TDF domain: *intention*):

> *And it's in my hands now. And so just doing that it's a case of right, I'm going to educate myself and get a bit healthier.* [P4]

Barriers to Adopting a Healthy Diet in Patients With Recently Diagnosed T2D: Psychological Capability

Barriers coded within this COM-B component comprised three of the 14 TDF domains: (1) *knowledge*; (2) *cognitive and interpersonal skills;* and (3) *memory, attention, and decision-making.*

Within the TDF domain of *knowledge*, patients cited that they had difficulty understanding what constitutes a correct "low-carb" diet:

> *What is the right low carb diet? What percentage of my diet should be proteins, carbs, and fats? I had no idea.* [P4]

In terms of *cognitive and interpersonalskills*, patients mentioned their struggle to adopt such a diet:

> *It's not that I don't know how to diet, I've done it many times before, but not as a for life kind of thing, just for a few weeks or months.* [P2]

In terms of the TDF domain of *memory, attention, and decision-making*, patients who had lacked the ability to find missing information resorted to web-based search engines and social media and found the amount and diversity of information overwhelming. The lack of understanding on which "low-carb" diet to choose or what to trust was outlined as a barrier to adopting a healthy diet:

> *So I go off, and I'm reading just about every website and thing I can find that will sort of advise me. Now I find by doing that, you get quite a bit of conflicting information. So that just generates more questions.* [P14]

Barriers to Adopting a Healthy Diet in Patients With Recently Diagnosed T2D: Social Opportunity

Within this COM-B component, the identified barriers correspond to the TDF domain *social influences*. The lack of support from health care professionals was unanimously reported as the main reason for not being able to adopt a healthier diet. Most patients reported only being told the diagnosis, without further assistance:

> *I was left to my own luck. I received a call from my GP saying I've looked into your tests, and you have Diabetes. There was no "you should stop eating this or cut down on that," no nothing.* [P2]

Enablers to Adopting a Healthy Diet in Patients With Long-Standing T2D: Social Opportunity

Within this COM-B component and the TDF domain *social influences*, the main enabler was the "availability of professional support and guidance," provided mostly by general practitioners and diabetic nurses, to help patients with T2D better understand the nutritional changes that they needed to make and sustain.

Enablers to Adopting a Healthy Diet in Patients With Long-Standing T2D: Psychological Capability

In terms of this COM-B component and the TDF domain *knowledge*, the central theme was the "knowledge about diabetes and healthy diets" that participants had, which enabled them to initiate or maintain a diet; this knowledge was acquired by accessing books, flyers, web-based resources, and courses. In terms of the TDF domain *Behavioral regulation*, the key enabler identified corresponded to the "actions that participants took in terms of self-monitoring their food intake":

> *For me it's about, in my head, always calculating how much carbohydrates I've had so far, to determine what I will have.* [P6]

Barriers to Adopting a Healthy Diet in Patients With Long-Standing T2D: Social Opportunity

Within this COM-B component, and in terms of the TDF domain *social influences*, the "lack or limited professional support" was often mentioned as the main barrier to adopt a healthier diet:

> *I was just told to check labels. The diabetic nurse just said anything under 5g of sugar you can take, anything over 5g don't eat that. That was it. That was the sum and total of the support.* [P9]

Barriers to Adopting a Healthy Diet in Patients With Long-Standing T2D: Automatic Motivation

A key barrier that was coded within the TDF domain *emotions* comprised the "negative emotions experienced upon diagnosis," such as anger, shock, or surprise, which may have temporarily hindered patient motivation to change nutritional habits.

Barriers to Adopting a Healthy Diet in Patients With Long-Standing T2D: Reflective Motivation

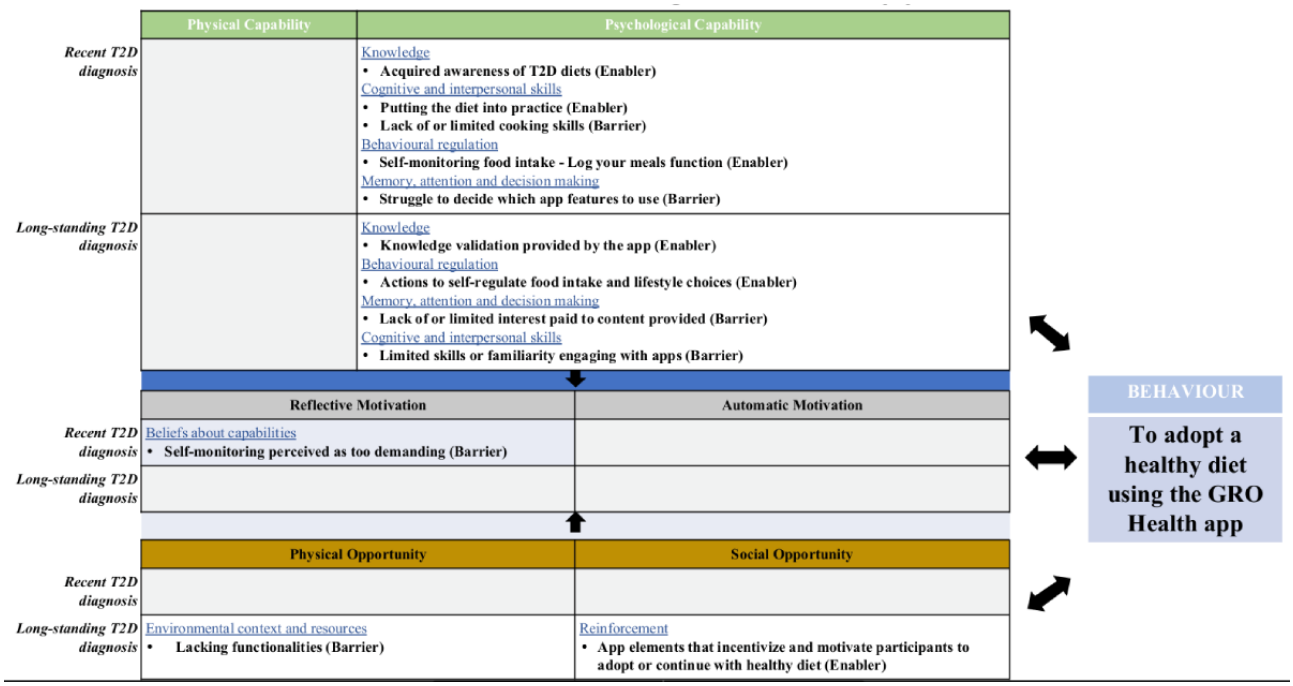
Within the TDF domain *beliefs about consequences*, the "perceived lack of competence to initiate or maintain a healthy diet" was often mentioned as a barrier for behavior change:

> *I also personally don't have the capability for eating meat. That really seems to be required on things like Atkins and keto diets. I eat meat, but I don't eat it in the quantities that they recommend.* [P14]

After Using the Gro Health App

After engaging with the app, 6 core themes were identified in each study as the most common enablers or barriers (Figure 3). Tables S6-S9 in Multimedia Appendix 2 show the rank order and main themes of the enablers and barriers identified for patients with recently diagnosed T2D and those with long-standing T2D after using the Gro Health app, respectively.

Figure 3. Map of the main themes after using the app in both patient groups, indicating Capability, Opportunity, Motivation, and Behavior (overarching) themes, Theoretical Domains Framework (secondary) themes; and inductive subthemes. T2D: type 2 diabetes.



Enablers to Adopting a Healthy Diet in Patients With Recently Diagnosed T2D: Psychological Capability

The main enablers were categorized within this COM-B component; among these, patients reported that using the app increased their knowledge of an ideal T2D diet and clarified prior dietary misconceptions (TDF domain: *knowledge*):

> *I always thought I would have to stop eating a bunch of things I can't live without, but then I've learned is more about portion control and compensations, and there is no such a thing as prohibited foods.* [P17]

In addition, all patients reported translating their acquired knowledge into new skills (TDF domain: *cognitive and interpersonal skills*), actively lowering their carbohydrate consumption, managing portion sizes, including more fruits and vegetables in their meals, and making new recipes.

Patients unanimously mentioned using at least 1 self-monitoring tool for tracking progress with the app, with food logging being the most frequently used**,** demonstrating the TDF domain *behavioral regulation*. Increased food intake self-monitoring was cited as an important driver for adopting a healthier diet:

> *Yes, logging my meals is very helpful. With that I can plan myself, because it shows me how much of each nutrient I have eaten and what is the ideal amount for the day.* [P11]

Barriers to Adopting a Healthy Diet in Patients With Recently Diagnosed T2D: Psychological Capability

Most of the identified barriers to the adoption of a healthier diet using the app were within this COM-B component, particularly within the TDF domains of (1) *memory, attention, and decision-making* and (2) *cognitive and interpersonal skills*.

Although all participants reported that their dietary capabilities improved using the app, many experienced, at some point in time, a cognitive overload (TDF domain: *memory, attention, and decision-making)* because of the considerable amount of information available simultaneously, which made navigation of the app cumbersome and counterintuitive:

> *It can get quite busy with all the articles and videos...there is no order for you to follow and sometimes I would feel like there is so much going on at the same time here.* [P9]

In addition, some participants cited having difficulty understanding how to measure food, highlighting a lack of cognitive skills, which limited the use of the food logging tool and reduced motivation. Similarly, patients also complained about not finding suitable replacements and stated that they did not have the skills needed to cook some of the proposed recipes, presenting a barrier to diet change.

Barriers to Adopting a Healthy Diet in Patients With Recently Diagnosed T2D: Reflective Motivation

Some patients found the app's self-monitoring tool *log your meals* demanding or difficult to use, stating that it made them less willing to log meals after a few days:

> *When I eat something I can't find on the app's list to log, I just don't do it. It's too much work to try to guess what is on the food you ordered. But I do admit that not putting on the app makes me lose track of things and probably eat more carbs than I should.* [P14]

This highlighted a barrier within the TDF domain *beliefs about capabilities*, with some participants feeling less confident about dieting, whereas others believed that they had slipped further out of a healthier diet.

Enablers to Adopting a Healthy Diet in Patients With Long-Standing T2D: Psychological Capability

In terms of the enablers within this COM-B component, the main TDF domains identified include *knowledge* and *behavioral regulation* (Figure 3), consistent with the findings observed before using the app. In terms of *knowledge*, the app mainly validated preexisting information that participants had previously encountered to further their understanding of T2D and its dietary requirements. With regard to *behavioral regulation*, the app allowed users to more broadly undertake various actions to self-regulate their food intake, using elements such as the *meal plans* and *log your meals* functionalities, and this helped participants to better plan their meals and self-monitor their food intake:

> *I went back to monitoring what I cooked for a while, but altered the proportions and the amounts. And from that I started to realize that carbs were too high and needed to come down.* [P7]

Enablers to Adopting a Healthy Diet in Patients With Long-Standing T2D: Automatic Motivation

An additional enabler often identified corresponds to the TDF domain *Reinforcement*, which encompassed the combination of "app elements that incentivized and reinforced patients in their conviction to adopt or continue with a healthy diet":

> *The range of the planning of the weekly plans plus the variety of recipes make it more fun, it's more motivating.* [P3]

Barriers to Adopting a Healthy Diet in Patients With Long-Standing T2D: Physical Opportunity

Most of the barriers identified fell within this COM-B component, particularly within the TDF domain *environmental context and resources*. The "lacking functionalities" was the most recurring theme mentioned by patients, in particular the lack of meal options in the weekly planners and ingredients in the *log your meal* function and the inability to synchronize data exchange with other apps or blood glucose meters.

Comparison of Enablers and Barriers Between Patients With Recently Diagnosed T2D and Those With Long-Standing T2D

The comparison between the 2 patient groups (Table 2) showed that in proportion to the total number of statements coded, the patients with recently diagnosed T2D reported more barriers to adopting a healthy diet than patients with a long-standing diagnosis before using the app (69% vs 47%, respectively). Conversely, after using the app, patients with recently diagnosed T2D reported more enablers than barriers compared with patients with a long-standing diagnosis (81% vs 63% respectively).

In terms of TDF domains, there were differences in the enablers and barriers before using the app between the 2 patient groups (Figure 2), with no overlapping domain between groups, except for *knowledge*. The *knowledge* domain was noted as a barrier for recently diagnosed patients, in contrast to long-standing diagnosis patients who referred to it as an enabler. In contrast, when using the Gro Health app, both patient groups coincided in terms of most of the TDF domain enablers (*knowledge* and *behavioral regulation*) and barriers (*memory, attention, and decision processes* and *cognitive and interpersonal skills*), although the underlying themes differed. For instance, referring to the barriers within the TDF domain *memory, attention and decision processes* patients with a recent diagnosis referred to their "struggle to decide which app features to use," whereas patients with a long-standing diagnosis expressed a "lack of/limited interest paid to the content provided."

Table 2. Relative frequency of enabler and barrier statements before and after using the app between patients with recently diagnosed type 2 diabetes (T2D) versus those with long-standing T2D.

Patient group	Before using app (%)			After using Gro Health app (%)		
	Enablers	Barriers	Total	Enablers	Barriers	Total
Recently diagnosed with T2D	31	69	100	81	19	100
Long-standing T2D	53	47	100	63	37	100

Recommended BCTs

BCTs to Support the Gro Health App in Overcoming Barriers

A mixture of enablers and barriers to adopting a healthier diet using the Gro Health app were identified across various TDF domains and represented targets for behavioral change interventions. Working through the BCW intervention development process, including the APEASE criteria, the most appropriate BCTs were identified to address the main barriers identified among patients with recently diagnosed T2D (Table S10 in Multimedia Appendix 2) and those with long-standing T2D (Table S11 in Multimedia Appendix 2). The APEASE criteria, as described by Michie et al [21], were applied to the identified BCTs to determine their appropriateness for implementation by app users and developers (in the case of BCTs requiring app design or content changes per se).

Regarding the recommended BCTs, both studies suggested the use of the following: "restructuring the physical environment," "instruction on how to perform a behavior," and "conserving mental resources"; however, the studies differed in terms of other BCTs to consider. Patients with a recent diagnosis were suggested BCTs that were predominantly aimed toward addressing *beliefs about capabilities* barriers (eg, "demonstration of the behavior"), whereas those with a long-standing diagnosis were suggested BCTs to enhance their skills and prompt them to engage with the app.

Comparison of the Recommended BCTs Versus Existing BCTs in the Gro Health App

The proposed BCTs from both studies were further compared with the BCTs already included in the Gro Health app. The individual BCTs in the Gro Health app were coded against the BCTTv1, resulting in 33 BCTs being identified out of the 93 in the BCTTv1 (refer to Table S12 in Multimedia Appendix 3); comparing the outcomes of this coding assessment with the proposed BCTs (Table S13 in Multimedia Appendix 3) suggested that most of the latter (10/11, 91%) were not entirely new BCTs and likely served to supplement the existing BCTs within the app, whereas a minority of the BCTs (1/11, 9%) were not currently leveraged by the app and represented a new approach toward the target behavior change.

Discussion

Principal Findings

Overview

This qualitative study identified key enablers and barriers to adopting a healthier diet using an app (Gro Health) among patients with recently diagnosed T2D and those with long-standing T2D. We outlined the similarities and differences between patient groups and proposed BCTs to address these barriers. The main enablers for patients with recently diagnosed T2D in terms of TDF domains were *knowledge*, *cognitive and interpersonal skills*, and *behavioral regulation*, whereas the main barriers were *memory, attention, and decision processes*; *cognitive and interpersonal skills*; and *beliefs about capabilities*. For patients with long-standing T2D, the main enablers were similar and included TDF domains *knowledge* and *behavioral regulation*. However, in contrast to patients with a recent diagnosis, these patients identified *reinforcement* as a key enabler. The main barriers were also similar to those of recently diagnosed patients and included *memory, attention, and decision processes* and *cognitive and interpersonal skills*. However, for this patient group, *environmental context and resources* were identified as key barriers. In further comparing findings between patient groups, both groups reported more enablers than barriers to performing the target behavior when using the app, with overlap in most of the enablers and barriers encountered. Consequently, BCTs such as *restructuring the physical environment*, *instruction on how to perform a behavior* and *conserving mental resources* were recommended as relevant BCTs to address key barriers in both groups.

Enablers and Barriers to Adopt a Healthier Diet Before Using the Gro Health App

This study's results are consistent with the findings of other studies that reported enablers and barriers to adopting healthier diets among patients with T2D, with or without the support of apps. Some of the main enablers identified before using the app, namely, *behavioral regulation*, *knowledge*, and availability of low-carbohydrate food options, are consistent with the findings by Cradock et al [32], who identified various facilitators of healthy diet behaviors among patients with T2D in Ireland (with similar demographics to this study), such as home and work food planning, education to assist in adopting and maintaining a healthy diet, and availability of healthy food choices when shopping.

In terms of barriers, this study identified the lack of professional guidance and support in providing the information patients needed as a prominent barrier to behavior change. This is consistent with the findings by Hynes et al [33], whereby the absence of trusted guidance from health care professionals impaired the patients' self-management skills and motivation to implement lifestyle modifications. Pikkemaat et al [7] reached the same conclusion but also connected the resultant lack of structured primary care education to low self-efficacy, low self-confidence, increased stress, and feelings of loneliness among patients with a new diagnosis. This also aligns with the negative emotions reported by the study participants, particularly in patients with long-standing T2D.

Enablers and Barriers to Adopting a Healthier Diet Using the Gro Health App

In terms of the main enablers of adopting a healthier diet using the Gro Health app, patients in both studies unanimously considered the information on the Gro Health app to be both trustworthy and credible, which improved their knowledge and self-management skills. This finding concurs with the results of a systematic review of 28 studies evaluating the adoption of T2D apps by patients [34]. *Knowledge* is consistently reported as an enabler, particularly information about T2D, new insights into self-management, and the latest research findings [34,35]. In addition, elements considered within *behavioral regulation*, such as the log your meals and weekly meal planning functions, were praised by both patient groups, consistent with the findings by Trawley et al [36], who also identified these features among the preferred and most useful ones within T2D apps. Finally, with regard to *reinforcement* among patients with a long-standing diagnosis, the benefits of prompts or reminders are documented to a lesser extent than those of the aforementioned enablers, but Jeffrey et al [37] also identified weekly reminders supporting patient self-management as useful features for app users.

By contrast, with regard to the barriers to performing the target behavior, this study reports barriers similar to those identified in the literature, while also identifying some less frequently encountered ones. Common barriers in terms of *environmental context and resources* include "lacking functionalities" and the "perceived complexity of the app design," which resonate with other studies that identify these app-specific elements as common barriers to engaging with a T2D app [34,37].

Within the domains of *memory, attention, and decision processes*, the cognitive overload reported by patients with a recent diagnosis due to the app providing too much simultaneous information. This has also been reported by Katz et al [38] in their evaluation of type 1 diabetes apps, highlighting the importance of reducing cognitive demands in terms of use requirements. In addition, the "lack of/limited interest paid to the content provided" among patients with long-standing T2D is consistent with previous findings, suggesting that if patients are confident of their lifestyle management decisions without using apps and do not perceive a benefit from T2D apps, they are unlikely to use them for T2D self-management [34,36].

Highlighting the added benefits that the Gro Health app may offer, in addition to other self-management initiatives, may be an approach to better engage patients with long-standing diabetes, as these individuals have usually tried various self-management approaches before trying an app. Further research on this topic is recommended.

Finally, in terms of *beliefs about capabilities*, patients with a recent diagnosis considered self-monitoring using the app to be too demanding, whereas in terms of *cognitive and interpersonal skills*, they highlighted the "lack of/limited cooking skills" as a main barrier to adopting a healthier diet. Within the same TDF domain, patients with a long-standing diagnosis mentioned the "limited skills or familiarity engaging with apps" as a key barrier. Altogether, the barriers identified in these domains are consistent with the findings from previous studies that highlight patient self-perception of technological literacy as a key barrier to engaging with T2D apps [37], which can be addressed by providing training on how to use an app [34]. To address these barriers, further understanding of the similarities and differences between patients with recently diagnosed T2D and those with long-standing T2D could be beneficial to inform the customization of the app for specific user requirements.

Comparison of Enablers and Barriers Between Patients With Recent and Those With Long-Standing Diagnoses

Differences in terms of the types of enablers and barriers and their respective frequency of mentions were identified between the 2 patient groups before using the app; however, after engaging with it, both patient groups reported more enablers and similar types of enablers and barriers, contrary to the expectations of the researchers. These findings may be explained by understanding the motivational predictors to initiate or maintain T2D dietary changes in each patient group. The 2 studies assessed the predictors of dietary self-care in these populations; among the newly diagnosed group, changes in dietary self-care are associated with perceived self-efficacy, self-evaluation (ie, self-monitoring), and controlled motivational behaviors, which occur when patients are pressured either by their interpersonal environment or by guilt or fear [39] (refer to Multimedia Appendix 4 [38] for a description of the constructs used). In contrast, in patients with long-standing T2D, changes in dietary self-care are mostly associated with self-efficacy and autonomous motivation, that is, behaviors that are self-initiated because they are important to the individual and tie into their values and goal system [40]. The association with self-efficacy in both groups may explain why they concur on enablers such as *knowledge* and *behavioral regulation*, whereas the difference in terms of motivation may partly explain the differences in barriers: among patients with a recent diagnosis, factors related to the TDF domains of *social influence* and *beliefs about capabilities* were identified as key barriers in study 1, whereas among patients with a long-standing diagnosis, factors related to *environmental context and resources* were identified as main barriers for the target behavior.

The similarities and differences identified in terms of enablers and barriers between patient populations lead to the identification of BCTs that may benefit both populations or only 1.

BCTs to Support the Gro Health App in Enhancing Enablers and Overcoming Barriers

The proposed BCTs further build on the existing behavioral components included within the Gro Health app. This app includes a relatively high number of BCTs (32 out of the 93 BCTs in the BCTTv1), whereas the average number reported by Priesterroth et al [14] was 7.4 BCTs in other diabetes apps. This implies that the Gro Health app already includes a considerable number of BCTs, although these were not exclusively included to support the adoption of a healthier diet but were considered in a more holistic manner to support various self-management behaviors (eg, physical activity, sleep, and mental well-being). In this context, the BCTs suggested in this study may enhance the app by further tailoring its nutritional self-management content to achieve the target behavior.

The suggested BCTs not only are consistent with those that have been previously identified in studies evaluating T2D apps but also include novel BCTs that have not been often reported in these apps. As reported in other studies [12,14], "self-monitoring of behavior," "prompts/cues," and "conserving mental resources" are consistently identified BCTs in T2D apps, which have already been included, to some extent, in the Gro Health app design, likely due to these BCTs having a clear link with diabetes self-management tasks. In contrast, other BCTs suggested in this study, such as antecedents (eg, "restructuring the physical environment" and "avoidance/reducing exposure to cues for the behavior"), shaping knowledge ("instruction on how to perform the behavior"), and repetition and substitution BCTs ("graded tasks"), have either been reported in <10% of T2D apps [14] or not reported at all in previous studies, despite supporting rationale for their inclusion.

The following have been used as constituent BCTs in randomized controlled trials that evaluate interventions to change dietary activity in patients with T2D: "instruction on how to perform the behavior," "avoidance/reducing exposure to cues for the behavior," and "graded tasks." The results of those trials suggest that the presence of these BCTs is associated with reductions in hemoglobin A_{1c}, although these results were not statistically significant [32]. Although the study by Cradock et al [32] did not focus on the use of T2D apps, it is indicative of the potential of the aforementioned BCTs to positively impact the adoption of a healthier diet, either by directly influencing dietary activity or by further engaging users with the app. Further studies, ideally using experimental designs, are required to evaluate how these BCTs impact the adoption of a healthier diet using T2D apps to validate their potential.

Although the BCTs described so far are applicable to both groups of patients, certain BCTs may be best suited for one population or the other. For instance, patients with a long-standing diagnosis may benefit more from "prompts/cues" that serve as reminders to adopt a healthier diet, helping them better manage environmental factors such as time restrictions, which in turn may lead them to forget checking the app; in contrast, patients with a recent diagnosis further benefit from BCTs that enhance their *beliefs about capabilities*, such as "feedback on behavior." This finding has further implications

for app developers in terms of the customization and support provided by the apps.

Implications for Practice

This study identified enablers and barriers, as well as BCTs, to ultimately support patients with T2D in adopting a healthier diet with an app. The enablers identified reemphasize the need for T2D app developers to include app features that provide further knowledge to users regarding T2D and nutrition, allow for self-monitoring and action planning *(TDF domain: behavioral regulation)*, and reinforce prior actions taken by users to adopt a healthier diet. In addition, app developers should be cognizant of particular barriers that patients with recently diagnosed and long-standing diabetes encounter in terms of the app per se (eg, cognitive overload and perceived complexity of app functionalities), the external environment (eg, lacking functionalities), and the skills that users need to have to either use the app or implement its suggestions. The BCTs suggested in this study not only build on those already included in the Gro Health app but also represent new options to consider in terms of app design (eg, including "graded tasks" and "feedback on the outcomes of behaviors" BCTs to encourage engagement with the app). Although the APEASE criteria inform the appropriateness of these BCTs, further validation through additional studies is required to corroborate BCT appropriateness and its impact on the target behavior.

This study also identified the commonalities and differences faced by patients with recently diagnosed T2D versus those with long-standing T2D when it comes to performing the target behavior. The Gro Health app does not currently customize its content according to the duration of diabetes. This implies the need to further customize certain app features to better respond to the differing needs of these patient populations and to address the different barriers they may encounter. The extent to which such customization should be implemented requires further research, given that this study has limitations in terms of the generalizability of its results across populations.

Limitations

This study has several limitations. The results correspond to a particular app (Gro Health) that was evaluated in a small sample size, potentially limiting the generalizability and applicability of this study's findings to other apps and the broader population; however, it is worth noting that the overall supply of T2D apps changes continually, which hinders potential comparison to other apps. In addition, it was not possible to monitor app use patterns during the 2-week period; this might have led to social desirability bias among participants during the in-depth interviews when asked about the frequency with which they used the app.

In terms of the BCW approach, the researchers and second coders are trained in the approach and confident in the interpretation of results; nonetheless, there is scope for potential bias during the analysis process, particularly when coding deductively and inductively, and other researchers may have categorized data in a different manner. In addition, the TDF approach also has some inherent limitations. McGowan et al [41] highlighted that the TDF offers a structured approach that may result in findings becoming self-contained within the relevant domains identified, leading to important factors being overlooked. However, this risk has been mitigated in this study by following the guidance of Atkins et al [24] and by conducting an inductive analysis to generate themes considered in relation to the TDF domains. This allowed for the lack of specificity of some TDF domains, such as *cognitive and interpersonal skills*, to be addressed using descriptive inductive coding (eg, "lack of/limited cooking skills" and "limited skills or familiarity engaging with apps"), which ultimately allowed to identify more adequate BCTs.

A final limitation is that this study did not measure actual behavioral change over time as an outcome (ie, the percentage of patients with T2D who adopted or maintained a healthy diet using an app for 6 mo or 1 y). Instead, the enablers identified when using the app and the BCTs already incorporated into the app served as proxies for effectiveness. Despite this limitation, the results from this study provide a foundation for further evaluation of the effect of the suggested BCTs on the behavior in scope.

Conclusions

Adopting and maintaining a healthy diet is a challenge for patients with T2D, which can partially be addressed by the use of digital apps. This study used the BCW approach to assess the enablers and barriers to adopting a healthier diet using the Gro Health app for patients with recently diagnosed T2D and those with long-standing T2D. The main enablers identified among both populations in terms of TDF domains included *knowledge* and *behavioral regulation*, whereas the main barriers included *memory, attention, and decision processes* and *cognitive and interpersonal skills*. Thematic analysis identified key themes that provided additional insights into the specific enablers and barriers (notably, enablers such as "knowledge validation" and self-regulating and self-monitoring actions and barriers including "lacking functionalities" and "struggle to decide which app features to use") that could be addressed using BCTs. Consequently, BCTs were identified (per the BCTTv1) with the potential to address the key barriers (eg, "restructuring the environment," "instruction on how to perform a behavior," and "conversing mental resources"). Findings from this study revealed similar enablers between patients with recently diagnosed T2D and those with long-standing T2D, with slight differences in terms of barriers to performing the target behavior. These results highlight the importance of understanding enablers and barriers in patients with T2D and suggest that future research is needed to further understand enablers and barriers within patient groups, as well as to implement and validate the effectiveness of the proposed BCTs.

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DDM Health provided participants with free access to the app during the study duration and for a total period of 6 months (study 2) or 1 year (study 1) after initial use to participants who completed the interviews.

We confirm that all patient and personal identifiers have been removed or disguised; therefore, the patients or persons described are not identifiable and cannot be identified through the details of the story.

Authors' Contributions

JMM, BD, OP, and LMG conceived the study. JMM and BD recruited the participants, conducted interviews, and analyzed the data. JMM drafted the first version of the manuscript. All authors reviewed and edited the manuscript and approved its final version.

Conflicts of Interest

OP acts as an unpaid scientific adviser to the Smoke Free app. The other authors have no competing interests to declare. The funders played no role in the design, conduct, or analysis of the study or in the interpretation and reporting of the study findings. The views expressed are those of the authors, and not necessarily those of the funders.

Multimedia Appendix 1
Demographics of study participants.
[DOCX File , 22 KB - diabetes_v8i1e49097_app1.docx]

Multimedia Appendix 2
Rank order of enablers and barriers to adopt a healthier diet for recently diagnosed patients with type 2 diabetes.
[DOCX File , 48 KB - diabetes_v8i1e49097_app2.docx]

Multimedia Appendix 3
Behavior change techniques included in the GRO Health App, based on the Behavior Change Techniques Taxonomy.
[DOCX File , 41 KB - diabetes_v8i1e49097_app3.docx]

Multimedia Appendix 4
Constructs used by Nouwen et al [39].
[DOCX File , 16 KB - diabetes_v8i1e49097_app4.docx]

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Abbreviations

APEASE: affordability, practicability, effectiveness/cost-effectiveness, acceptability, side effects/safety, and equity
BCT: behavior change technique
BCTTv1: Behavior Change Techniques Taxonomy
BCW: Behavior Change Wheel
COM-B: Capability, Opportunity, Motivation, and Behavior
REDCap: Research Electronic Data Capture
RQ: research question
T2D: type 2 diabetes
TDF: Theoretical Domains Framework
UCL: University College London

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Original Paper

Clinician Experiences With Hybrid Closed Loop Insulin Delivery Systems in Veterans With Type 1 Diabetes: Qualitative Study

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Abstract

Background: Hybrid closed loop (HCL) insulin pumps adjust insulin delivery based on input from a continuous glucose monitor. Several systems are FDA approved and associated with improved time in range, reduction in hemoglobin A_{1c}, and decreased incidence of hypoglycemia. Major diabetes guidelines differ in their strength of recommendations regarding the use of HCL systems. Overall, limited information about the factors that influence HCL pump clinical decision-making is available, especially among endocrinology clinicians.

Objective: The study objective is to describe the knowledge and attitudes, network support, and self-efficacy regarding HCL insulin delivery systems among endocrinology clinicians in one Veterans Affairs (VA) Healthcare System in the Midwest.

Methods: Following a descriptive approach, this qualitative study used semistructured interviews and inductive thematic analysis. All endocrinologists, endocrinology fellows, and nurses in the endocrinology and metabolism department at one VA Healthcare System in the Midwest were invited to participate in one-on-one phone interviews. Thematic analysis explored clinician perspectives on HCL insulin pump systems.

Results: Participants (n=11) had experience within VA and university health care system endocrinology clinics. From their experiences, 4 themes were identified involving the evaluation and assessment of insulin pump candidates, prescribing challenges, clinical benefits of HCL pumps, and overall clinician confidence.

Conclusions: Findings suggest that clinicians believe HCL systems have significant glycemic benefits but are not appropriate for all patients, especially those with cognitive impairment. HCL pump initiation is a multi-step process requiring an interdisciplinary team of health care clinicians to ensure patient and pump success. Furthermore, HCL systems improve clinician confidence in overall diabetes management.

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KEYWORDS

automated insulin delivery; hybrid closed loop; type 1 diabetes; endocrinology; qualitative study; insulin delivery; digital health intervention; thematic analysis; diabetes management

Introduction

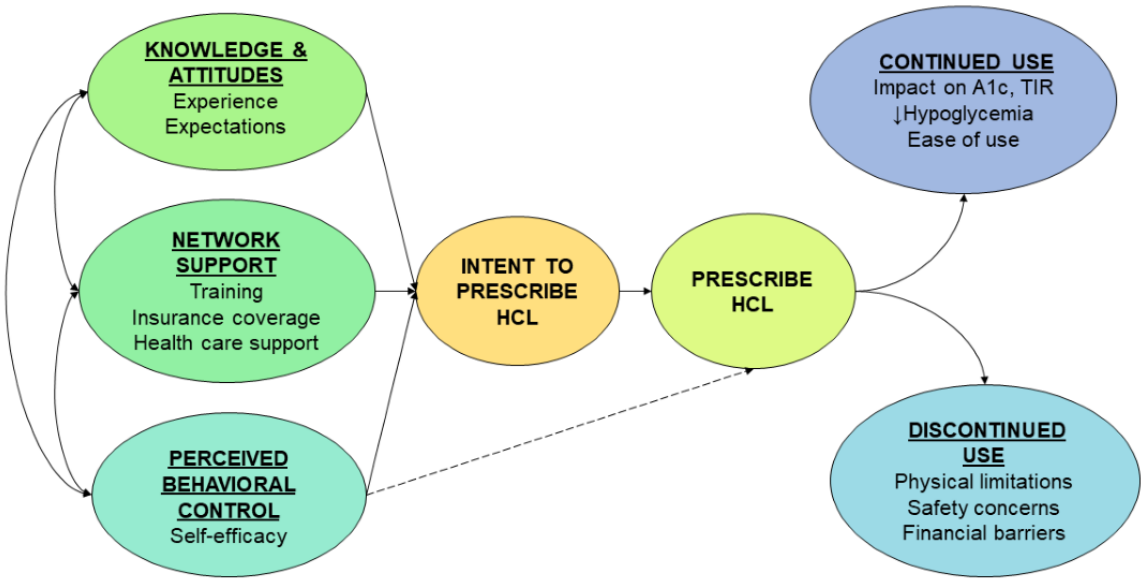
In 2016, the first commercial "artificial pancreas" or hybrid closed loop (HCL) insulin delivery system was made available [1]. HCL systems use a continuous glucose monitor (CGM) and control algorithm to automatically adjust insulin delivery based on current and predicted sensor glucose values [2]. HCL systems can either adjust basal insulin delivery, provide small correction boluses, or both; however, mealtime boluses are not automated and rely on the patient to count and input carbohydrate data. Currently, 3 HCL systems are approved by the US Food and Drug Administration (FDA). The MiniMed 670G with Guardian 3 CGM system (Medtronic PLC) was the first HCL system, becoming available in September 2016. The t:slim X2 pump with Dexcom G6 CGM (Tandem Diabetes Care, Inc) has been available since December 2019. The Omnipod 5 with Dexcom G6 CGM (Insulet Corp) was approved by the FDA in January 2022.

Several studies have reported many glycemic benefits to the use of HCL systems [3,4]. These studies demonstrate that HCL systems increase time-in-range (TIR) up to 10% overall and 15% overnight compared to older insulin pump technology. Data also suggests an additional reduction in hemoglobin A_{1c} (HbA_{1c}) by about 0.5% with an HCL pump versus regular or sensor-augmented insulin pumps alone. Use of an HCL system for 6 months was associated with an approximately 1% decrease in time spent in clinically significant hypoglycemia (ie, level 2 hypoglycemia, defined as a blood sugar level below 54 mg/dL). The improvements in HbA_{1c} and TIR are presumed to translate to a reduction in microvascular complications [5,6].

Due to these clinical advantages to HCL pump use, diabetes clinical practice guidelines routinely recommend the use of HCL systems for both adults and youth with type 1 diabetes. The American Diabetes Association (ADA) guidelines state automated insulin delivery systems of HCL pump systems may be offered for diabetes management in all adults and youth with type 1 diabetes (grade A: clear evidence from randomized trials) and other types of insulin-deficient diabetes (grade E: expert consensus) [7]. Similarly, the recently published American Association of Clinical Endocrinology (AACE) guidelines recommend automated insulin delivery systems for "many" patients with type 1 diabetes (grade A: high strength of evidence; best evidence level) [8]. As both guidelines emphasize, there are a variety of insulin delivery modalities, and the use of HCL systems depends on a variety of factors, including patient preference, caregiver preference (if applicable), provider preference, patient and clinic resources, and payer considerations [7,8]. Recent studies demonstrating racial and ethnic disparities in diabetes technology for type 1 diabetes highlight the importance of understanding why discrepancies in the use of HCL systems exist [9].

Although endocrinologists are experts in diabetes care and use of diabetes technology, there is limited literature available regarding the factors that influence their decisions regarding HCL systems in type 1 diabetes. Previous qualitative studies regarding diabetes technology examined the perspectives of certified diabetes care and education specialists, research nurses, diabetes nurse specialists, and dieticians; very few included information from endocrinologists [10-12]. These studies also lacked rigorous methodology in that they were not rooted in known behavioral theory, or they used survey data alone, which lack the richness and complexity of semistructured interviews, considered the gold standard for qualitative research [13]. Additionally, data on HCL systems is especially lacking in veteran populations with type 1 diabetes. To address these gaps, this study aims to describe the knowledge and attitudes, network support, and self-efficacy regarding HCL insulin pump systems among endocrinology clinicians at one Veterans Affairs (VA) Healthcare System in the Midwest based on the modified Theory of Planned Behavior, as shown in Figure 1 [14].

Figure 1. Conceptual model based on modified Theory of Planned Behavior [14]. HCL: hybrid closed loop; A_{1c}: hemoglobin A_{1c}; TIR: time-in-range.



Methods

Ethics Approval

This study was approved by the VA Ann Arbor Institutional Review Board and Research and Development Committees (1618650).

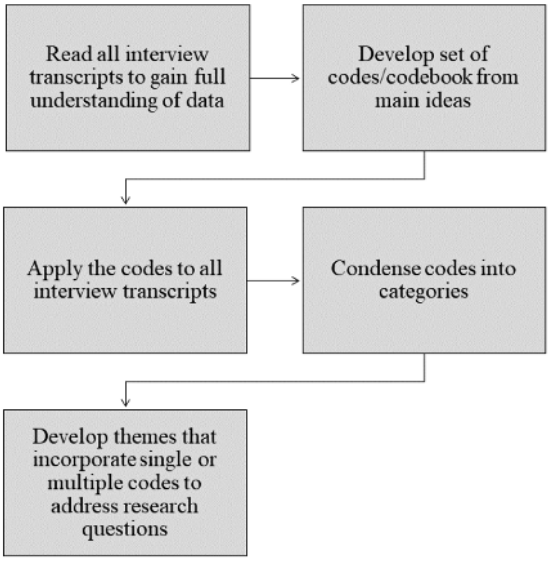
Data Collection

Semistructured interview guides were developed to assess the knowledge and attitudes, network support, and self-efficacy of endocrinologists based on the Theory of Planned Behavior [14] (Multimedia Appendix 1). All the endocrinology physicians and nurses (N=13) from one VA Healthcare System in the Midwest were invited to participate in the interviews via email. Upon expressing interest in participating, they were provided with a copy of the study cover letter and informed consent document. One author (HMT) conducted interviews by phone from December 2021 through February 2022. Although the interviewer followed the interview guide, semistructured interviews are adaptable and allow for a loose, flexible structure to aid in discussion and insight into participant perspectives. This facilitates a deeper exploration of participant thoughts and experiences while gathering detailed information [13]. The interviewer completed a reflection form immediately following each interview that included the main ideas and initial thoughts on the interview process. Interviews were audio recorded with 2 types of recording system, Audacity (Audacity Team) and the Olympus 9500 DVR (Olympus Corp), in case of technical failure. Immediately after each interview was completed, the recording was uploaded to a secure server, where it was then deidentified and transcribed verbatim into Microsoft Word (Microsoft Corp) to prepare for data analysis by the research team.

Data Analysis

As described in Figure 2, thematic analysis was used for the interview transcripts. NVivo (version 12; QSR International) was used for data management and organization. We inductively developed a coding template that reflected participant responses during the interview (Multimedia Appendix 2), which was initially used to code each transcript, though codes were iteratively modified and updated throughout the coding process to ensure all concepts were represented. Codes were further condensed into themes and participant quotes were used to support identified themes. One author (HMT) initiated coding of all transcripts and organization of themes. Themes were developed and discussed in detail with all authors to reach agreement and conclusions. Data analysis was completed as an ongoing process as the scheduled interviews were completed with each provider. Throughout the process the research team documented aspects of the qualitative study design using the COREQ (Consolidated Criteria for Reporting Qualitative Research) guidelines (Multimedia Appendix 3) [15].

Figure 2. Inductive thematic analysis process.



Results

Overview

Interviews were conducted at one VA Healthcare System in the Midwest among endocrinology and metabolism clinic staff, the majority of whom also had a dual appointment at the University of Michigan. Of the 13 approached physicians and nurses, 11 (for a response rate of 85%) agreed to participate in the interviews. Clinician characteristics are displayed in Table 1. Interviews lasted a mean 37 (SD 9.15) minutes.

Overall, participants provided insight into their experiences at both the Midwestern VA Healthcare System and the affiliated university health care system. From the interviews, 4 themes were identified to encompass the knowledge and attitudes, network support, and self-efficacy of clinicians regarding the use of HCL systems, as shown in Textbox 1.

Table 1. Participant characteristics.

Characteristics	Participants (n=11)
Gender, n (%)	
Male	5 (45)
Female	6 (55)
Clinician type, n (%)	
Endocrinologist	4 (36)
Endocrinology fellow	5 (46)
Diabetes nurse	2 (18)
Practice site, n (%)	
Veterans Affairs health system only	2 (18)
Veterans Affairs and university health system	9 (82)
Clinical experience (years), mean (SD)	16.5 (11.80)
Clinician confidence rating in diabetes technology (scored from 1 to 10), mean (SD)	7.9 (1.13)

Textbox 1. Summary of themes for endocrinology perspectives on hybrid closed loop systems in type 1 diabetes.

Ongoing hybrid closed loop (HCL) candidacy

Initial and continued assessment for HCL appropriateness is important for optimal use.

HCL initiation barriers

Challenges persist in initial procurement, education, and training, despite insurance coverage.

HCL benefits in real-world use

Clinical benefits include improved glycemic control and reduced hypoglycemia.

Improved clinician confidence

Enhanced clinical decision-making and overall confidence in providing care for patients with type 1 diabetes.

Ongoing HCL Candidacy

Clinicians felt strongly that HCL systems are not a one-size-fits-all approach to diabetes care. Instead, patients should be carefully considered for these systems to ensure overall appropriateness and optimal clinical benefit. Participants felt that patients who are comfortable with technology and are highly motivated to manage their diabetes make suitable candidates for HCL technology. Additionally, several clinicians reported that the HCL systems are most beneficial for patients with variability in their day-to-day schedules, especially regarding meals.

> *I think patients who have a lot of variability in their schedule, and whether that sort of work, sleep schedule, or whether that's like, when do they exercise, when are they active, I think those patients are a group that really benefits.* [Endocrinologist 3]

Clinicians also felt there are patients who are not ideal HCL-system candidates. Some of the most common examples included patients with limited dexterity, patients with impaired cognition, and patients who are not technology savvy, as they might be significantly more likely to be frustrated by complex technology. Clinicians also commonly brought up the example of patients who still struggle with carbohydrate counting and noted that this is a significant limitation to HCL pump use, since these systems still require patients to enter carbohydrate values to receive input for food boluses. Clinicians were surprised that patients who have very high expectations and demand perfect blood sugar control struggle with a system that provides so much real-time data. They described how these patients may become overly concerned about their blood glucose readings, leading to inadequate boluses of meal-time insulin and the inability to trust the HCL system when necessary.

> *Patients are often not used to seeing what their blood sugars look like at all times of day and my experience is that they tend to get nervous a little bit more.* [Endocrinologist 3]

Participants in our study described how each patient must be continuously assessed to ensure appropriate use, even if the clinicians believed they were an appropriate candidate. If at any point the clinician felt that the pump was potentially harmful, the patient was transitioned back to a multiple-daily-injection insulin regimen. Across participants interviewed, the most common reason for any previous pump discontinuation was development of cognitive decline or dementia, as summarized here:

> *Probably the most common reason we have to take people off a pump or take it away from them is dementia, altered mental status where they just*

> *become incapable of managing the pump anymore...* [Nurse 1]

One endocrinologist offered valuable insight into their streamlined approach for initial patient evaluation and assessment. By using a stepwise approach, the clinician slowly added on different components of the HCL system to ensure the patient felt comfortable with each aspect of the technology.

> *For somebody who is doing insulin injections but is [already] monitoring their glucose using a continuous glucose monitor, that may be an easier transition to a pump with a hybrid closed loop system because they already know one piece of the technology.* [Endocrinologist 3]

Overall, the provider assessment and evaluation of patients for HCL candidacy was highly individualized, reflecting their years of clinical experience and different examples of patients they had cared for during various clinic encounters.

HCL Initiation Barriers

Clinicians commonly commented on the frequent challenges they experienced when first prescribing an HCL system. Most clinicians interviewed had experience at the VA and university health system and could easily discuss key differences between the 2 practice sites. For example, clinicians described the differences in insurance coverage for patients in the 2 systems, noting the added complexities of describing HCL pumps in the university health system.

> *[One of the challenges is] whether this will be covered by a patient's insurance or not and what their copay would be and then maybe the time that it takes for a patient to schedule all the appropriate appointments and learn about the pumps. So, it's sort of time consuming.* [Fellow 5]

Surprisingly, clinicians conducting clinic visits directly with patients and monitoring or adjusting their insulin therapy were not the same clinicians who placed orders for HCL pumps within either health system. In both health systems, HCL ordering is more complex than a typical prescription, and although a physician signature is required, the actual order process is completed by clinic support staff. At the VA, the nurse manager for the endocrinology clinic typically places all insulin pump orders to ensure a consistent process. In the university health system, medical assistants typically placed the orders for the insulin pump and supplies, but clinicians described the specific and detailed documentation that was required from their end for HCL pump approval.

> *At the University we go through our diabetes educators, and they will do the insurance authorization, the teaching, and once they've done those things, they'll send a script for us to sign, and they try to mimic kind of their basic setting based on a current regimen.... It's similar at the VA via the pharmacist.* [Fellow 1]

Another frequent and key difference that was mentioned by clinicians was the difference in resources available between the VA and university clinics. Unique to this specific VA facility, the endocrinology service offers a clinic a half day per week that is dedicated to just HCL pump management. This clinic offers interdisciplinary health care professionals, including a clinical pharmacist, nurses, and an insulin pump company representative, in addition to the endocrinologists, to provide support, answer patient questions, and provide initial education and training to new insulin pump patients. In contrast, the university health system has a team comprising certified diabetes educators that deliver the initial pump education, training, and monitoring.

Additionally, clinicians discussed various challenges patients face while initiating use of an HCL insulin pump. Most of the difficulties originate from the acclimation process. In some instances, patients are completely inexperienced in using any continuous insulin-infusion devices. In other cases, patients have to adjust to the differences between the HCL system and their older pump technology. It is also challenging for patients to begin to trust the technology and adjust to the availability of monitoring blood glucose in real time via a CGM system that communicates directly with the insulin pump.

> *Trusting the technology, a lot of patients have had diabetes for a very long time and they're just very used to controlling their own blood sugars and kind of giving up a lot of that control to a little machine, I think some patients do have a little difficulty with that, especially some of the older folks.* [Endocrinologist 4]

Other challenges included difficulties with obtaining and ordering pump supplies and the infusion sets and with sensors appropriately adhering to the patients' skin. Determining initial insulin rates could also be difficult, especially if a patient was new to the clinic or health system in addition to being new to insulin pump technology.

To mitigate these challenges, clinicians often reported relying on assistance from interdisciplinary team members for support and troubleshooting of malfunctioning devices or technology glitches. Other nonclinic resources that were reported as beneficial to patients included YouTube videos and direct patient contact, usually via telephone or website, with the insulin pump company or manufacturer.

HCL Benefits in Real-World Settings

Another theme that clinicians commonly discussed was the clinical benefits of HCL insulin pumps. In general, clinicians noticed improved glucose control with less variability and fluctuations in patient blood sugars. Importantly, clinicians noted the reduction in hypoglycemia, especially nocturnal hypoglycemia and hypoglycemia surrounding physical activity.

> *Much-improved nocturnal control with much fewer fluctuations especially less hypoglycemia or unexplained hypoglycemia at night and tends to be better postprandial, I see more control in most patients, so variability in it goes down; some moderate, modest to moderate improvement of overall A_{1c}, and fewer hypoglycemia events.* [Endocrinologist 2]

> *I think the hypoglycemia incidence seems to be improved and just kind of like the yo-yo of going up*

and down or the variability of it just seems to be improved for patients. [Fellow 3]

Many other clinicians interviewed also mentioned an overall improvement in hemoglobin after HCL initiation.

Besides the clinical improvements in glycemic control, HCL systems also have social benefits. Clinicians reported these insulin pumps allowed for greater convenience and flexibility for patients, especially in the timing and content of meals throughout the day.

The flexibility is...you're not chained to having to eat a certain amount at a certain time. I think that's the greatest thing that it does for the patients. It sort of allows them to you know have brunch on Sunday, they don't have to [know] what time dinner is, they don't have to worry about bottoming out because of their NPH [insulin] that they took earlier. [Endocrinologist 1]

While overall attitudes toward HCL pumps were positive, clinicians also discussed several clinical and social limitations. Clinicians recognized the pump algorithm was not perfect and could sometimes lag when correcting patients' hyperglycemia, especially postprandially. Other clinicians suggested it would be beneficial if there were more customizable features to the pumps, such as setting individualized glucose targets.

I would like to see in a system, at least for the physicians, to have more latitude in setting the target glucose. They largely have one main target glucose and then there's sort of an activity type target you can set temporarily, but I would like to see it more customizable. [Endocrinologist 3]

Note the recent FDA-approved Omnipod 5 system does include software with adjustable glucose targets; however, no clinicians that participated in interviews had patients on this system. Social limitations discussed consistently by the cohort of clinicians interviewed included challenges with pump alarms and device adhesion. Clinicians reported some patient dissatisfaction with being attached to a device for all hours of the day. Patients also reportedly struggled with sensors falling off or malfunctioning, thereby interrupting or diminishing their ability to use the HCL functionality of the pump. Other problems included the frequency of alarms with certain systems, as well as the number of calibrations with a glucometer that were required while using a particular HCL system. One provider commented on the importance of educating patients before they started a pump on the impact fingerstick blood glucose checks may still have on their lives.

I try to include that conversation that [CGM] is not a replacement of finger sticks and that it's really just going to reduce the frequency that you'd have to finger stick, but I do think that the calibration of the [certain hybrid closed loop] systems is something that's not as attractive for patients. [Fellow 3]

Improved Clinician Confidence

Clinicians interviewed had an average self-reported confidence rating in prescribing and managing diabetes technology of 8 (on a 1 to 10 scale, with 1 being the least confident to 10 being the most confident). However, upon further discussion of overall knowledge and competence in diabetes management, all clinicians reported HCL insulin systems added to their confidence. Clinicians highlighted that much of their confidence was due to these pumps often resulting in less hypoglycemia, a potentially dangerous side effect of poor insulin management, leading to a perception of safer care for patients.

You feel a little bit better that the pump is helping me and the patient when if maybe I haven't programmed or had a chance to figure out their settings perfectly because I just don't have enough time with them yet. You know when they're new to me or I don't have a lot of experience with their diabetes or when the patient's just not doing everything exactly as they're supposed to. So, I think it gives me some confidence that they're less likely to get into trouble. [Endocrinologist 3]

I think I feel more comfortable because I'm thinking that it will help prevent hypoglycemia, which is something scary in diabetes, so I think it's keeping patients safer. [Fellow 4]

Since these systems not only contain a CGM device, but also include the capability for that device to communicate with the insulin pump in real time, increased data are available to help make clinical decisions based on underlying physiology and patient behaviors. It is well-known that glucose trends available from CGM devices facilitate shared decision-making and goal setting in patients with diabetes [16]. However, HCL devices also augment insulin delivery in real time in response to glucose trends and provide information on patient bolusing behaviors. Clinicians attributed their increased confidence and competence in diabetes management to this increased amount of information, which could be used to identify patterns and guide clinical decision-making.

I feel like it's definitely helped me understand patterns more and understand where we can make changes and how to make those changes. It kind of helps give more guidance with all the data that it provides too.... What's nice is when you see when the basal rates change, especially if there's an acute change, it kind of tells you, "oh that means more insulin is needed for their meals because their basal shot up all of a sudden," or it's really dropping down, "oh, that's because they're having tight sugars or low sugars at the point of the night or day." So, seeing that also kind of tells you what's actually going on underneath. [Fellow 2]

In general, the attitudes of this cohort of endocrinology clinicians were positive toward the use of HCL insulin-delivery devices. Clinicians reported that they enjoyed working with the devices, despite their limitations, to continue to provide the best possible diabetes care to their patients.

Discussion

Principal Findings

This study sought to describe the knowledge and attitudes, network support, and self-efficacy of endocrinology clinicians regarding HCL insulin delivery systems within a VA health care system. Key themes identified included the evaluation and selection criteria used by professionals for HCL candidacy, prescribing challenges, perceived clinical benefits, and clinicians' confidence in diabetes management. Although other qualitative analyses have detailed similar results in survey studies, this study is unique in the patient population (veterans with primarily adult-onset type 1 diabetes), provider population (specifically endocrinology physicians and nurses), and technologies assessed.

Our data support findings from Lawton et al [17] made after interviewing 12 diabetes nurses and 6 dieticians; they also perceived that, in general, insulin pumps offered better self-management to patients. However, the staff used a variety of clinical and patient-specific personal and psychological attributes as criteria to select patients for pumps, and this affected the staff's perceptions of the benefits of HCL pump technology. In line with our findings, patients with unpredictable or highly physically active lifestyles and those who were technology savvy were more likely to be selected for HCL systems, while a history of poor adherence to self-monitoring or medications or an expectation that the pump would take over all aspects of diabetes management predicted unsuccessful outcomes with an HCL system. This is concerning, as studies have demonstrated the utility of HCL systems for individuals across the HbA_{1c} and control spectrum. This could lead to inadvertent differential access to technology, which in turn could affect clinical outcomes. Efforts are needed to ensure equitable access to HCL systems regardless of HbA_{1c} or patient characteristics [9].

We also found that access to technology in general was an important resource for HCL use, which is similar to findings from an Australian study of semistructured telephone interviews that identified themes related to access to HCL system technology and available support [12]. Limited qualitative data are available about HCL insulin pumps, especially regarding clinician attitudes and experiences with their use. In contrast to previous studies, interviews from this study provide insight on a wide range of attitudes and experiences, including clinical benefits, prescribing trends, HCL candidacy, and overall provider confidence in diabetes technology.

Consistent with our findings, a study that included multidisciplinary health care professionals in the United Kingdom found that financial resources and insurance coverage were critical for HCL device use [18]. Importantly, these prior studies were conducted in countries with significantly different health care systems and access to care. This study found that clinicians practicing within a United States VA health care system perceived that HCL system access for appropriate patients was better than at a major university hospital system, likely due to the elimination of insurance barriers.

Additionally, clinicians interviewed in our study frequently discussed the multiple benefits of these systems, such as improved glucose control, reduced glucose variability, and a lower incidence of hypoglycemia. These results mirror the clinical benefits seen in HCL clinical trial data [3,4]. Each provider had individual screening mechanisms, in addition to predefined VA criteria for use, when determining if a patient would make an adequate pump candidate.

Strengths and Limitations

This study had several strengths. The first is that a theory-based assessment was used, which adds to the overall rigor of the study. This study is also novel in that the interviewees were all endocrinology clinicians, the majority of whom practice in both academic and VA heath care systems, which adds to the generalizability of our findings. While only 11 clinicians were interviewed, they represented 85% of all the eligible endocrinologists (ie, all but 2 clinicians invited elected to participate). Additionally, clinicians had experience with all HCL insulin pump systems that were available to patients at the time the study was conducted.

Limitations include that the study took place at a single-center VA health care system. Other VA health systems or endocrinology practices may have different processes, use different HCL systems, or have alternative clinical personnel to execute tasks such as insulin pump starts. Another limitation is that few data were gathered and analyzed regarding the familiarity of the clinicians with each HCL system used, their preferences for specific HCL systems, or differences in roles and training in each clinician group: endocrinologists, endocrinology fellows, and nurses. However, the purpose of this study was not to look for explicit differences, but instead look for similarities in experiences of the various clinicians on a care team. Future research could further examine whether there are differences between groups, which would require access to a larger sample of diabetes care team members.

Conclusion

This qualitative analysis of semistructured interviews provides insight into the knowledge and experiences of clinicians practicing in an endocrinology clinic in a VA health care system. Our study is the first to include US VA clinicians such as endocrinologists and fellows that are prescribing and monitoring patients on these devices. Our findings suggest that HCL systems have significant glycemic benefits but are not appropriate for all patients, especially those with dementia or other degrees of cognitive impairment. HCL pump initiation is a multistep process requiring an interdisciplinary team of health care clinicians to ensure patient and pump success. Furthermore, HCL systems improve clinician confidence, knowledge, and competence in diabetes management. Additional studies are needed describing non–endocrinology provider knowledge and attitudes, as well as patient experiences, to provide a complete assessment of HCL system access and impact on diabetes care and quality of life.

Acknowledgments

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Conflicts of Interest

JML is a member of the medical advisory board of GoodRx and a consultant for Tandem Diabetes. No other authors declare conflicts of interest.

Multimedia Appendix 1
Endocrinology clinician semistructured interview script.
[DOCX File , 20 KB - diabetes_v8i1e45241_app1.docx]

Multimedia Appendix 2
Codebook based on the modified Theory of Planned Behavior.
[DOCX File , 18 KB - diabetes_v8i1e45241_app2.docx]

Multimedia Appendix 3
Consolidated Criteria for Reporting Qualitative Research (COREQ): a 32-item checklist for interviews and focus groups.
[DOCX File , 20 KB - diabetes_v8i1e45241_app3.docx]

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Abbreviations

AACE: American Association of Clinical Endocrinology
ADA: American Diabetes Association
CGM: continuous glucose monitor
COREQ: Consolidated Criteria for Reporting Qualitative Research
FDA: US Food and Drug Administration
HbA_{1c}: Hemoglobin A_{1c}
HCL: hybrid closed loop
TIR: time-in-range
VA: Veterans Affairs Healthcare System

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Original Paper

The Promising Success of Project Extension for Community Healthcare Outcomes (ECHO) Diabetes: Case Series

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Abstract

Background: In the United States, there are over 37 million people with diabetes but only 8000 endocrinologists. Therefore, many people with diabetes receive care exclusively from primary care providers (PCPs). To democratize knowledge regarding insulin-requiring diabetes through tele-education, Stanford University and the University of Florida developed Project Extension for Community Healthcare Outcomes (ECHO) Diabetes.

Objective: ECHO Diabetes uses a Hub and Spoke model connecting specialists (the "Hub") with PCPs (the "Spokes"). One-hour, weekly sessions include Hub diabetes didactic presentations and Spoke deidentified case presentations. Lessons learned during these sessions target provider knowledge and confidence surrounding diabetes management and patient care.

Methods: Spokes were asked to provide short descriptions of people with diabetes whose diabetes management improved directly or indirectly from their providers' participation or their involvement with a Diabetes Support Coach (DSC). We provide a case series to describe individuals and outcomes. Because this study was not a randomized controlled trial and was a prospective observation of patients with the intervention delivered to providers, the trial is not registered in a public trials registry.

Results: A case series of 11 people with diabetes was compiled from 10 PCPs and 1 DSC from California and Florida between 2021 and 2022. The principal impact of ECHO Diabetes is the education amplified from PCPs and DSCs to people with diabetes. In all cases, people with diabetes reported increased engagement and improved diabetes management. Several cases reflected increased access to diabetes technology, improvement in glycemic outcomes, and positive trends in mental health measures.

Conclusions: This case series elucidates the potential value of the ECHO Diabetes program to people with diabetes who receive their diabetes care from PCPs. Those matched with a DSC saw clinically significant improvements in hemoglobin A_{1c} and mental health outcomes.

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KEYWORDS

type 1 diabetes; care delivery; primary care; community health care

Introduction

While more than 37 million Americans live with diabetes [1], there are only around 8000 endocrinologists, 1 for every 4625 people with diabetes, in the United States [2]. Furthermore, as endocrinologists are not distributed equitably and many do not provide care for people with diabetes [3], numerous people with diabetes receive care exclusively from primary care providers (PCPs). The Extension for Community Healthcare Outcomes (ECHO) model created at the University of New Mexico empowers PCPs through the use of tele-education. The model uses videoconferencing technology to connect community PCPs to subject matter experts at an academic medical center. Rather than patients remotely connecting to a specialist, the model facilitates education from specialists to PCPs in rural and underserved communities on topics related to chronic disease management in the form of regular, 1-hour didactic presentations and building a community of practice. Additionally, PCPs have opportunities to present case presentations on their own patients and receive feedback and support from both the subject matter experts and the peer providers who attend the sessions. PCPs develop subspecialty expertise over time and can become valuable resources in their communities for people with chronic medical conditions. The model aims to amplify and democratize specialty knowledge to improve health equity and outcomes in the communities it serves. Figure 1 highlights the ECHO model and its reach from academic medical centers, to community PCPs, to patients with complex chronic medical conditions. The Project ECHO model was designed to improve management practices and the overall quality of life (QOL) for people who lack access to specialists or routine care in underserved or rural communities and has been adapted in many disease types including hepatitis C, chronic pain, rheumatologic disorders, and behavioral health [4,5]. Stanford University and the University of Florida have partnered with Project ECHO to develop this model for democratizing specialty knowledge regarding insulin-requiring diabetes [6-11]. Through this program, the multidisciplinary Project ECHO Hub team offers real-time support and frequent presentations on topics related to diabetes treatment to PCPs.

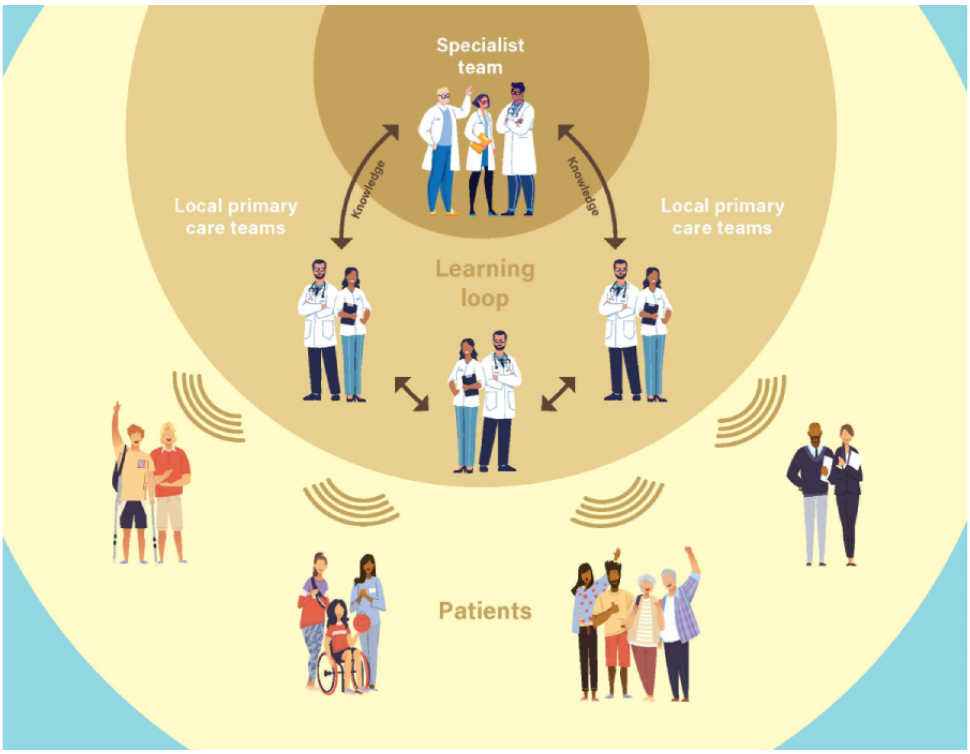
Project ECHO Diabetes conducted outreach to primary care clinics and Federally Qualified Health Centers in high-need catchment areas in California and Florida, the locations of the respective universities. To identify these high-need catchment areas, the Neighborhood Deprivation Index was used along with geocoding of PCPs and endocrinologists in each state to identify areas with low access to endocrinology providers and high health risk or poverty [9]. Site visits, advertisements in family medicine publications, and informational web-based sessions were conducted with interested clinics. To participate, clinics needed to have at least 15 patients with type 1 diabetes and at least 15 patients with type 2 diabetes on insulin. Clinics were invited to participate by signing a Spoke Collaboration Agreement, submitting clinic-level outcomes data, and asking PCPs to attend web-based education sessions and submit cases for case presentations. Notably, clinics were provided a stipend for participation in ECHO Diabetes.

ECHO Diabetes uses a Hub and Spoke model digitally connecting specialists (the "Hub") with PCPs (the "Spokes"). During weekly, 1-hour ECHO Diabetes sessions conducted via secure video communication (Zoom Video Communications Inc), the Hub team presents a brief didactic topic, and the remainder of the session is for 1 Spoke to discuss a specific diabetes case from their clinic. A sample of the Project ECHO Diabetes curriculum is provided in Textbox 1. In this all teach-all learning model, PCPs from the Spoke sites were encouraged to lead the discussion by asking clarifying questions and providing their own recommendations. Only after the Spoke site PCPs met or exceeded their level of comfort in managing the case did the Hub team experts weigh in. This model encouraged independent thinking and best practice sharing among peers while still providing expert-level guidance. In addition to the ECHO Diabetes sessions, the Hub team offered real-time support to the PCPs at the Spoke sites through individual telemedicine or telephone consultations.

Perhaps most importantly and as a unique aspect of the ECHO Diabetes programs, a Diabetes Support Coach (DSC) was hired to work directly with each Spoke, its PCPs, and people with diabetes in the community. Providers were invited to identify well-managed patients from their clinic who either lived with diabetes (type 1 or type 2 on insulin) or cared for a loved one with diabetes to serve as DSC. These individuals were already familiar with the clinics and providers, and experts in their local community and its resources. Additionally, the personal connection each DSC had to diabetes was invaluable for the role. Individuals were invited to apply for these paid positions and interviewed by the Hub teams. Stanford and the University of Florida employed the DSC teams and provided supervision and specialized peer coach training by the ECHO Diabetes Hub team. Required training for DSCs included Association of Diabetes Care and Education Specialists' Diabetes Paraprofessional Level I certification, the University of California San Francisco Center for Excellence in Primary Care's health coach training, and all training required by the respective institutions, such as Health Insurance Portability and Accountability Act and institutional review board (IRB) trainings. DSCs met weekly with Hub teams, attended weekly ECHO Diabetes clinic sessions, and attended ongoing trainings from health psychologists and social workers. Providers could refer any patient with type 1 or type 2 diabetes (using insulin) to use a DSC though participation from the people with diabetes was voluntary. Many DSCs held hours inside of the physical clinic location, but providers could also connect people with diabetes via phone or email to DSCs. DSCs provided one-on-one support for people with diabetes seen for care at the Spoke sites, hosted regular social events (web-based and in-person), and created local resource guides specific to the community. DSCs encouraged people with diabetes as they worked toward their individual diabetes goals, and worked to address disparities in diabetes care. This unique role helped to fill a gap in health care delivery and connect people with diabetes with a trusted cultural insider from their own community to support them in their diabetes management. Challenges and limitations of the DSC model include (1) funding, as the DSCs were hired and paid by the academic institutions; (2) integration of the DSCs into external Spoke sites, as DSCs often needed extra training or certifications to be able to access electronic health records and clinic space; and (3) work-related stress and burnout as a result of this challenging role [10].

Herein, we provide a case series of people with diabetes who received Project ECHO Diabetes services, including access to DSCs, in an effort to highlight descriptive outcomes from the ECHO Diabetes intervention.

Figure 1. Project Extension for Community Healthcare Outcomes overview.



Textbox 1. Project Extension for Community Healthcare Outcomes Diabetes curriculum (T1D: type 1 diabetes; T2D: type 2 diabetes).

- The Pillars of Success: Knowledge, Community, & Resilience
- Continuous Glucose Monitoring
- Glycemic Targets and Glucose Monitoring
- T2D Management in Established Atherosclerotic Cardiovascular Disease
- T2D Management in Heart Failure and Chronic Kidney Disease
- T2D Management: Promoting Weight Loss
- T2D Management: Strategies to Minimize Hypoglycemia
- Using and Interpreting Data from CGMs
- Initiating Insulin and Dose Calculations for T1D and T2D
- T2D Management: When Medication Cost Becomes a Barrier
- Types of Analog Insulin
- Initiating Insulin and Dose Calculations in T1D and T2D: A Case Based Approach
- Initiating Insulin Pump Therapy
- Introducing Diabetes Technology to Patients
- Screening for Depression and Diabetes Burnout
- Carbohydrate Counting and Dietary Management in T1D
- Making a Diagnosis of Diabetes in Primary Care
- Diabetes and Hypertension Management
- Dyslipidemia and Diabetes
- Exercise Strategies in Diabetes
- Motivational Interviewing
- Diabulimia and Disordered Eating
- Diabetes Complications and Screenings
- Sick Day Management and Severe Hyperglycemia

Methods

Study Design

Spokes were asked to provide short descriptions of people with diabetes who benefited either directly or indirectly from PCP participation in Project ECHO Diabetes. Cases were collected, and reports were standardized, summarized, and analyzed.

Ethics Approval

The ECHO Diabetes intervention and assessment was approved by the Stanford University IRB (54198) and University of Florida IRB (UF IRB201800382) and conducted in compliance with the standard of Good Clinical Practice and Declaration of Helsinki. Participating Spokes and PCPs signed a “Spoke Articulation Agreement” that outlined expectations for participation, including the expectation that all cases shared are deidentified to protect confidentiality. Each Hub’s IRB granted a Health Insurance Portability and Accountability Act waiver or waiver of consent so that participating PCPs could share eligible cases as part of the project. No protected health information was included in the write-ups. Providers were given instructions to anonymize the cases and to not include any identifying information on their submissions. Research coordinators further reviewed the case submissions to ensure confidentiality was protected. Because this study was not a randomized controlled trial and was a prospective observation of patients with the intervention delivered to providers, the trial is not registered in a public trials registry.

Results

Overview

A total of 10 PCPs (including physicians, nurses, nurse practitioners, social workers, and Certified Diabetes Care and Education Specialists) and 1 DSC from California and Florida provided write-ups for 11 different diabetes cases between 2021 and 2022 are summarized in Table 1.

Table 1. Summary of cases and primary care provider interaction with Project ECHO[a] Diabetes.

Case	Age (years), sex	Diabetes type × duration	Comorbidities	Interaction with Project ECHO Diabetes	Outcome
1	32, female	T2D[b] × 18 years	Anxiety, depression, retinopathy, peripheral neuropathy	Introduced to CGM[c] and educated on how to use it	HbA_{1c}[d] 11.5% to 5.3% in under 1-year, healthy pregnancy
2	63, male	T2D—new diagnosis	Hypertension, dyslipidemia, cardiovascular disease, right ischemic stroke with left-sided hemiparesis	Educated on lifestyle modifications, PCP[e] received guidance on insulin titration	HbA_{1c} now 5.4%
3	33, male	T1D[f] × 20 years	Polyneuropathy with a history of toe amputation, retinopathy, poor mental health, and chronic kidney disease on hemodialysis	Increased engagement, education, and fostered collaborative team approach	HbA_{1c} 14.0% to 7.8% after a year, the person with diabetes reports improved mental health and confidence
4	37, female	T1D × 26 years	Gastroparesis, chronic kidney disease, severe hypoglycemia	Helped solidify a plan to give rapid-acting insulin post meal	HbA_{1c} 10.4% to 7.6%, reports increased sense of safety
5	22, male	T1D × 8 years	Depression, anxiety, fear of hypoglycemia secondary to traumatic car accident and device mistrust	PCP education on diabetes technology resulted in person with diabetes using AID[g]	HbA_{1c} 12% to the mid-8% range in 2 years, now making insulin adjustments independently
6	48, male	T1D × 20 years	Frequent hypoglycemia resulting in safety concerns, and mood imbalance	Started on CGM, educated on how to use his CGM to help prevent lows before they happened	HbA_{1c} 7.3% to 6.4% with decreased hypoglycemia, reports improved health and QOL[h] for himself and his family
7	63, female	T2D × 18 years	Concern for burden of insulin use, limited nutrition knowledge	Matched with a DSC[i] who invited her to Diabetes Hour gatherings where she gained comfort with insulin and received education on diet	HbA_{1c} 8.7% to 6.7% within 2 years, feeling comfortable with insulin use
8	26, female	T1D × 14 years	Depression, anxiety, above target HbA_{1c} early in pregnancy	Matched with a DSC who helped with lifestyle modifications and improved her mental health	HbA_{1c} 12.8% to 7.1% over the course of the pregnancy, delivered a healthy baby
9	68, male	T2D—new diagnosis	Hypertension	Matched with a DSC who educated him about diet, alcohol intake, insulin use, and blood sugar monitoring	HbA_{1c} >14% to 10.8% in 1 month, now prioritizing health
10	70, male	Prediabetes × 7 years; T2D—new diagnosis	Class III obesity	Matched with a DSC and nursing case management team who educated him on physical activity requirements and medication use	HbA_{1c} 7.2% to 5.3% in 1 year, with reduction in medication doses
11	54, male	T2D × 10 years	Anxiety, hyperlipidemia, alcohol abuse complicated by acute pancreatitis	Matched with a DSC for carbohydrate counting education and general support, and was started on CGM	HbA_{1c} 10% to 7.9% within 2 years with increased health care engagement

[a]ECHO: Extension for Community Healthcare Outcomes.

[b]T2D: type 2 diabetes.

[c]CGM: continuous glucose monitor.

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

[e]PCP: primary care provider.

[f]T1D: type 1 diabetes.

[g]AID: automated insulin delivery.

[h]QOL: quality of life.

[i]DSC: Diabetes Support Coach.

Case 1

Case 1 highlights a 32-year-old woman living with type 2 diabetes since the age of 14 years. Both of her parents died due to complications from diabetes while in their 50s. She struggled to take care of her family growing up without working parents, shifting attention away from her own health. With no health insurance, she rarely had proper health care treatment, which contributed to her worsening anger, depression, and anxiety. Prior to recent intervention, she lost vision in 1 eye due to

diabetes-related retinopathy and had constant pain in both lower legs due to peripheral neuropathy. In 2021, her PCP was introduced to ECHO Diabetes, which was able to provide her with samples of continuous glucose monitor (CGM). ECHO Diabetes didactics taught the PCP how to take full advantage of CGM technology, and the PCP was able to share insights with the person with diabetes. She was also connected to a DSC through the program, who supported her with lifestyle changes and use of CGM. From April 2021 to August 2021, her hemoglobin A_{1c} (HbA_{1c}) improved from 11.5% to 7.0%, without significantly increased time below range, which was the lowest HbA_{1c} she had ever achieved. She felt that the combination of CGM and peer coaching provided through ECHO Diabetes helped her optimize her glycemic management. Positive lifestyle changes continued, followed by a healthy pregnancy in late 2021. As of January 2022, she had an HbA_{1c} of 5.3% and a healthy pregnancy at 20 weeks gestation.

Case 2

Case 2 highlights a 63-year-old man recently hospitalized for 5 days due to a right ischemic stroke. He was not previously diagnosed with diabetes and had not seen a health care provider for over 20 years. He was diagnosed with type 2 diabetes, hypertension, dyslipidemia, left-sided hemiparesis, and cardiovascular disease. The person with diabetes was also placed on 30 units of insulin (ie, 70/30 premixed insulin) twice daily. His HbA_{1c} was unknown at insulin initiation, but his blood glucose was monitored at the skilled nursing facility in which he was placed. He was uninsured and could not access endocrinology care, and relied on his PCP for diabetes management and oversight. After participating in ECHO Diabetes, his PCP felt much more confident managing diabetes. The PCP learned about tapering insulin and received feedback from the learning network on how to safely and effectively taper insulin use based on the needs of this person with diabetes. The PCP, along with the Diabetes Nurse Educator at the clinic, provided additional ECHO Diabetes supported education to help him feel empowered in diabetes management after the stroke. The PCP learned about the psychological impacts of diabetes and focused on providing patient-centered care and psychological support. The person with diabetes made several lifestyle changes to his diet, frequency of physical activity, physical therapy, and began regularly taking his medication as prescribed as a result. His insulin was titrated down on multiple occasions, and his dosage was lowered to 15 units of insulin 70/30 twice daily, after accessing real-time support from the ECHO Diabetes Hub team. His most recent HbA_{1c} was 5.4% on this regimen after 9 months of seeing this PCP.

Case 3

Case 3 highlights a 33-year-old man with type 1 diabetes. The person with diabetes was diagnosed when he was 13 years old. He had numerous vascular complications including polyneuropathy, toe amputation, retinopathy, and was on hemodialysis. He presented with a multitude of psychosocial barriers to health care including lack of health insurance, financial hardship, food insecurity, and limited support system. He had a history of alcohol dependence, severe visual impairment, chronic pain, and poor mental health. ECHO Diabetes was especially helpful to his PCP as access to local endocrinology specialists was extremely limited in their area, and the person with diabetes had many other social barriers to accessing specialty care. The PCP used strategies learned through ECHO Diabetes including patient-centered care, motivational interviewing, a collaborative team approach, participation in case presentations, learnings from educational lectures, and real-time support with the Hub team to address medication dose adjustments and complication management. The PCP appreciated the information on psychosocial impacts of diabetes, and considered this when caring for the person with diabetes. He also began using CGM, which provided valuable data to assist with insulin dose adjustments and overall diabetes education. ECHO Diabetes gave the PCP additional skills and allowed for more active engagement and likely contributed to a marked improvement in his diabetes management skills. Prior to the ECHO Diabetes intervention, he was not engaged in the management of his diabetes and had an HbA_{1c} of 14.0%. One year following ECHO Diabetes intervention, his HbA_{1c} was 7.8%.

Case 4

Case 4 highlights a 37-year-old woman with type 1 diabetes diagnosed at age 11 years and complicated by gastroparesis and chronic kidney disease. Her case was presented during an ECHO Diabetes clinic session when her HbA_{1c} was measured at 10.4% in June 2020. She had frequent episodes of severe hypoglycemia (<50 mg/dL), one of which required administration of glucagon by paramedics. These hypoglycemic episodes commonly occurred when she gave herself rapid-acting insulin before meals but was unable to finish the meal due to her gastroparesis. The ECHO Diabetes team helped to solidify a plan to give her rapid-acting insulin after she completed meals, which prevented over-bolusing and significantly reduced the rates of severe hypoglycemia after meals. The person with diabetes previously lacked confidence with counting carbohydrates, and based on feedback from the case presentation, the PCP also learned to empower her to bolus with a set insulin dose based on the size of the meal (eg, small meal and large meal). The discussion during the case presentation was particularly helpful to the PCP, who worked toward a creative, patient-centered solution that addressed issues related to gastroparesis specifically and positively impacted the person with diabetes. She was also connected with a DSC through the ECHO Diabetes program for peer support outside of the clinic. The DSC worked to support her around the changes implemented in the diabetes management plan, identify and support goals, and empower her around mealtime insulin boluses. She reported feeling supported by the DSC and more confident in her diabetes management. Due to the PCP's participation in ECHO Diabetes and the connection to the DSC, the person with diabetes was able to reduce her HbA_{1c} to 7.6% by May 2022.

Case 5

Case 5 highlights a 22-year-old man who was diagnosed with type 1 diabetes at the age of 14 years. He presented to his current PCP at age 20 years. At the time, the person with diabetes was struggling with significant depression and anxiety and had an HbA_{1c} of 12.0%. Prior intervention had failed because he had

a severe distrust of diabetes devices and had a fear of hypoglycemia, exacerbated by a traumatic car accident, challenges in managing his glucose levels, and difficulty obtaining his insulin and medical support for his diabetes. After trialing an insulin pump and CGM, he was willing to discuss using an automated insulin delivery (AID) system. In February 2020, his PCP presented the case to ECHO Diabetes for assistance with the transition to AID technology. The ECHO Diabetes Spoke sites and Hub team gave the PCP recommendations to get started on a new AID system. In December 2020, he was using the system with continued distrust and fear, and his HbA_{1c} at the time was 10.6%. After further help from the ECHO Diabetes Hub team and at the request of the person with diabetes to host follow-ups every 2-3 weeks, he became more confident in his diabetes management. By June 2022, his HbA_{1c} was reduced to 7.8%, and he began making insulin adjustments independently. He reported higher job satisfaction and improved mental health with the help of his PCP and ECHO Diabetes.

Case 6

Case 6 highlights a 48-year-old man living with type 1 diabetes for nearly 20 years. The person with diabetes lived in rural communities for the last 15 years and did not have access to an endocrinologist or diabetes technology. He often struggled with low blood sugar and mood lability. He and his wife almost lost their lives in a car accident due to a hypoglycemic event that he experienced while driving. After his PCP joined ECHO Diabetes, they felt more comfortable in prescribing CGM. Within the first month of CGM use, the device provided alarms for hypoglycemia prompting him to stop driving several times. The device also alerted him and his wife of nocturnal hypoglycemia. With the help of ECHO Diabetes and recommendations from the Hub team and Spoke sites, the PCP taught him how to use the glucose rate of change information to prevent hypoglycemia episodes before they occurred. The CGM data also provided valuable insight to the PCP into his insulin needs, and the PCP adjusted his insulin doses appropriately. Prior to receiving CGM, his HbA_{1c} was 7.3% with frequent episodes of severe hypoglycemia. His most recent HbA_{1c} was 6.4%, and the frequency of severe hypoglycemia (along with episodes of hyperglycemia) has decreased significantly. He recently reported improved QOL for his entire family and increased safety with the use of the CGM. The PCP also reported feeling more comfortable prescribing and managing CGM technology.

Case 7

Case 7 highlights a 63-year-old woman living with type 2 diabetes, diagnosed when she was 45 years old. The person with diabetes was fearful of taking insulin because she frequently traveled out of the country and felt like it would be a burden having to transport insulin and supplies. She also felt confused about her diet and did not know what foods to eat, as she did not want to exacerbate her condition or blood glucose levels. Through ECHO Diabetes, the PCP matched her with a DSC that was able to alleviate her concerns and help her better manage her diabetes. The DSC invited her to the "Diabetes Hour" weekly web-based social gatherings and a few local social events. Through these gatherings, the person with diabetes learned how to travel with her insulin supplies and she learned about how to better manage her diet. After being in contact with her PCP and the DSC for a couple of months, she felt much better about her condition and she felt confident that she could manage it properly using new technologies introduced to her through ECHO Diabetes. Her HbA_{1c} improved from 8.7% to 6.7% after 18 months of ECHO Diabetes engagement by her PCP. She continued to be engaged with her DSC to optimize her treatment and management.

Case 8

Case 8 highlights a 26-year-old woman living with type 1 diabetes since the age of 12 years. She started to meet with a DSC that she was paired with through ECHO Diabetes because she wanted to be healthier for her family. Six weeks after their introduction, the person with diabetes found out that she was pregnant and became very stressed about her glucose management. After working on lifestyle modifications with the DSC and her PCP, her HbA_{1c} decreased from 12.8% to 8.9% in just 8 weeks. She continued to meet with her PCP, her DSC, and her obstetrician throughout the course of her pregnancy. The DSC helped her create a plan to support a lower HbA_{1c}, including discussion of healthy meal planning and regular exercise. The DSC remained in close contact with her throughout the pregnancy to remind her of upcoming appointments, accompany her to appointments, discuss blood glucose changes and ways to prevent severe hypoglycemia and hyperglycemia, and offer ongoing support. The DSC also lives with type 1 diabetes and experienced 2 pregnancies herself, which gave the person with diabetes unique insight and comfort into her own experience. She reported feeling relieved having the support of someone who could relate to her. She confided in the DSC about her past struggles with depression and reported that their relationship helped improve her mental health. At 38 weeks, the person with diabetes delivered a healthy 7-pound, 14-ounce baby. Her most recent HbA_{1c} was 7.1%, which her health care team attributed in part to their participation in ECHO Diabetes.

Case 9

Case 9 highlights a 68-year-old man recently diagnosed with type 2 diabetes. During his last clinic visit prior to engaging with ECHO Diabetes, he had a fasting blood sugar of 415 mg/dL, with symptoms of polyuria and polydipsia, and he had lost 23 pounds. His HbA_{1c} was over 14% at the time of diagnosis, and his blood pressure was 156/84 mm Hg. His PCP matched him with a DSC who helped support him with the transition to using insulin. He received education about his diet, alcohol intake, how to test blood glucose, and how to inject insulin. Within a week, his glycemic control improved. Over the course of the next month, his insulin needs dropped. His DSC continued to advise him, and he made strict dietary changes, including abstinence from alcohol. The person with diabetes prioritized his diet and overall health, and he saw drastic changes in just the first month. Specifically, within a month of receiving ECHO Diabetes support, his HbA_{1c} decreased to 10.8%, and his insulin dose was further reduced. The PCP was

confident that his HbA_{1c} would continue to improve thanks to the PCP's participation in ECHO Diabetes and the close connection between the person with diabetes and the DSC.

Case 10

Case 10 highlights a 70-year-old man with a history of prediabetes since 2015. He was assigned a DSC through the ECHO Diabetes program after he was diagnosed with type 2 diabetes in 2021. He had an HbA_{1c} of 7.2% at the time and had a BMI of 40 kg/m^2. The person with diabetes had no social support system, limited financial resources, and low health literacy, which made it challenging for him to manage his blood sugar levels. After starting on a glucose-lowering medication (ie, metformin), he was next seen in the clinic 4 months later. His fasting blood glucose was 551 mg/dL with polydipsia and polyuria, and he was immediately started on insulin glargine. He was reconnected with support coaching and nursing case management and had weekly coaching calls to help manage his medications and treatment. He maintained marked improvements in his diabetes self-management and began a gentle exercise routine that included resistance band exercises and stretching at home for 15-20 minutes per day, 5-6 days per week. His weight decreased, his insulin doses were reduced, and his HbA_{1c} 9 months later had improved to 5.3%. The person with diabetes attributed his success and improved health to ECHO Diabetes and the help of his DSC.

Case 11

Case 11 highlights a 54-year-old man who was diagnosed with type 2 diabetes at age 44 years. He had a history of anxiety, hyperlipidemia, and alcohol abuse complicated by acute pancreatitis in January 2019. Before his PCP's clinic started participating in ECHO Diabetes, he used metformin and sulfonylureas and reported frequent hypoglycemia. His HbA_{1c} fluctuated between 9% and 10%. After starting ECHO Diabetes, his PCP matched him with a DSC for carbohydrate counting education and general support. He was also prescribed CGM and educated on how to use it by the DSC. His HbA_{1c} improved to 7.9%, and his glucose time in range improved significantly over the year since his PCP's interaction with ECHO Diabetes. He continued to engage in his treatment and remained in contact with his DSC weekly.

Discussion

These 11 cases volunteered by Spoke PCPs and a DSC reflect the promise of the Project ECHO Diabetes intervention and specific examples of how individuals with diabetes benefited. The principal impact of ECHO Diabetes is the education amplified from PCPs and DSCs to people with diabetes. In all cases, the people with diabetes reported increased engagement with their diabetes care team and health literacy. Those matched with a DSC not only saw clinically significant improvements in their HbA_{1c} but also reported mental health benefits. Additional impact included increased knowledge and confidence from PCPs treating people with diabetes. PCPs reported that the ECHO Diabetes didactics and case presentations, along with recommendations and guidance from the Hub team and other Spoke sites, provided value and helped them to solve problems creatively to improve care and help people with diabetes reach their goals.

While there are clear benefits for the individual participants presented herein, there are several limitations to making conclusions based on a case series. Since this case series was not a randomized controlled trial and did not include a control group, the efficacy of the overall Project ECHO Diabetes program cannot be assessed in this manner. That said, a rigorous formal analysis of patient-level outcomes is planned. The small sample in only 2 states in the United States may not be generalizable to the entire population. PCP's interaction with the ECHO Diabetes Hub team is variable, and some writers submitted multiple cases. Cases were self-reported and selected on the basis of success as assessed by the author of the vignette, introducing a potential selection bias. Cases with limited or no change in outcomes were not submitted. It should be noted that since the inception of Project ECHO Diabetes, there have been no reported adverse events or negative impact from provider participation. Most commonly, challenges with implementation or management changes are related to the health insurance coverage and financial insecurity of people with diabetes in the rural and underserved communities that the program serves. While the writers universally attributed success to ECHO Diabetes, it is unknown if innovations in diabetes technology and pharmacology would have naturally found their way into the PCP's practice. Moreover, we focus on quantitative A_{1c} improvements and more subjective QOL benefits.

Project ECHO Diabetes aimed to address the ethical tenets of medical care such as autonomy, beneficence, justice, and nonmaleficence. Importantly, the ECHO model has been evaluated in multiple settings, and the safety and efficacy of the approach have been uniformly supported [5]. Related to autonomy, in Project ECHO, the primary doctor-patient relationship (PCP to people with diabetes) is maintained, and providers retain care of their own patients. In an effort to support beneficence for all patients within a Spoke site, ECHO Diabetes creates learning loops to strengthen PCPs' subspecialty expertise and effectively democratizes specialty knowledge. In support of the notion of justice, ECHO Diabetes increases equity and aims to improve health access, as many people with diabetes lack access to regular specialty care. Some of the participating Spokes are in locations many hours away from the nearest endocrinologist. One potential ethical concern is related to long-term access to the resources provided by Project ECHO Diabetes. Without consistent financial support from state and federal governments or payers, the program is unsustainable, and PCPs are left with limited or no access to the knowledge and resources of the program. Finally, Project ECHO Diabetes addressed privacy concerns regularly and ensured deidentification of case presentations.

Given the supply-demand mismatch of people with diabetes to endocrinologists and the success of Project ECHO Diabetes thus far, there are opportunities for expansion of this project to improve health equity and outcomes in diabetes care. PCPs care for a large number of people with diabetes, and more programs like Project ECHO Diabetes could improve patient outcomes with a broader reach. Nevertheless, funding for ECHO Diabetes

programs will likely need to be provided by state and federal agencies or payers to ensure the long-term sustainability of these programs.

A formal evaluation of Project ECHO Diabetes is currently in progress. The study used a rigorous stepped-wedge design and will assess outcomes at the patient, PCP, and Spoke levels. A total of 872 people with insulin-requiring diabetes were recruited and consented to participate in ECHO Diabetes across 2 recruitment phases in the summer and winter of 2021 across the states of California (n=495) and Florida (n=377). The outcomes of the study will inform future directions including possible expansion of the program, gaps and limitations, and its impact on individual people with diabetes. Future directions for this program include efforts to develop a national ECHO Diabetes program to increase reach. “Super Hubs” could be developed to train other academic medical centers to act as regionalized Hubs with local Spoke sites across the country.

In summary, these 11 cases highlight (1) the benefit of PCP education, (2) PCP receptiveness and engagement in diabetes tele-mentoring or tele-education, (3) improved PCP knowledge and confidence in complex diabetes care, and (4) improved outcomes for people with diabetes after participation from PCPs in Project ECHO Diabetes programs at Stanford University and the University of Florida. To best serve the increasing population of people with diabetes, including those without access to specialty care, novel methods to disseminate knowledge, tools, and experience [11] to improve care for all people with diabetes are needed. Project ECHO Diabetes is one such method, and these 11 case studies provide personal examples of people with diabetes who saw improved outcomes after their PCP’s participation in the program. Future directions include expanded tele-education to reach more PCPs and, by extension, more people with diabetes to improve overall health outcomes.

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Conflicts of Interest

LF, AA, IJ, CAZ, PM, CDC, CS, BCF, KC, TR, CS, EM, LC, CB, MH, EPS, AB, SCW, KKH, MB, SLF, MJG, and AFW have no disclosures. NC has consulted for The Leona M. and Harry B. Helmsley Charitable Trust and Cecelia Health. DMM has consulted for Abbott, the Helmsley Charitable Trust, Sanofi, Eli Lilly, and Novo Nordisk, and has served on an advisory board for Insulet. MJH has consulted for SABiotherapeutics, Sanofi, and Mannkind. RAL has consulted for Abbott Diabetes Care, Biolinq, Capillary Biomedical, Deep Valley Labs, Morgan Stanley, Gluroo, and Tidepool. DPZ has received speaker’s honoraria from Medtronic Diabetes, Ascensia Diabetes, and Insulet Canada, and is also on the Dexcom Advisory board.

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Abbreviations

AID: automated insulin delivery
CGM: continuous glucose monitor
DSC: Diabetes Support Coach
ECHO: Extension for Community Healthcare Outcomes
HbA_{1c}: hemoglobin A1c
IRB: institutional review board
PCP: primary care provider
QOL: quality of life

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Original Paper

Glycemic Variability and Fluctuations in Cognitive Status in Adults With Type 1 Diabetes (GluCog): Observational Study Using Ecological Momentary Assessment of Cognition

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Abstract

Background: Individuals with type 1 diabetes represent a population with important vulnerabilities to dynamic physiological, behavioral, and psychological interactions, as well as cognitive processes. Ecological momentary assessment (EMA), a methodological approach used to study intraindividual variation over time, has only recently been used to deliver cognitive assessments in daily life, and many methodological questions remain. The Glycemic Variability and Fluctuations in Cognitive Status in Adults with Type 1 Diabetes (GluCog) study uses EMA to deliver cognitive and self-report measures while simultaneously collecting passive interstitial glucose in adults with type 1 diabetes.

Objective: We aimed to report the results of an EMA optimization pilot and how these data were used to refine the study design of the GluCog study. An optimization pilot was designed to determine whether low-frequency EMA (3 EMAs per day) over more days or high-frequency EMA (6 EMAs per day) for fewer days would result in a better EMA completion rate and capture more hypoglycemia episodes. The secondary aim was to reduce the number of cognitive EMA tasks from 6 to 3.

Methods: Baseline cognitive tasks and psychological questionnaires were completed by all the participants (N=20), followed by EMA delivery of brief cognitive and self-report measures for 15 days while wearing a blinded continuous glucose monitor. These data were coded for the presence of hypoglycemia (<70 mg/dL) within 60 minutes of each EMA. The participants were randomized into group A (n=10 for group A and B; starting with 3 EMAs per day for 10 days and then switching to 6 EMAs per day for an additional 5 days) or group B (N=10; starting with 6 EMAs per day for 5 days and then switching to 3 EMAs per day for an additional 10 days).

Results: A paired samples 2-tailed *t* test found no significant difference in the completion rate between the 2 schedules (t_{17}=1.16; *P*=.26; Cohen d_z=0.27), with both schedules producing >80% EMA completion. However, more hypoglycemia episodes were captured during the schedule with the 3 EMAs per day than during the schedule with 6 EMAs per day.

Conclusions: The results from this EMA optimization pilot guided key design decisions regarding the EMA frequency and study duration for the main GluCog study. The present report responds to the urgent need for systematic and detailed information on EMA study designs, particularly those using cognitive assessments coupled with physiological measures. Given the complexity of EMA studies, choosing the right instruments and assessment schedules is an important aspect of study design and subsequent data interpretation.

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KEYWORDS

ecological momentary assessment; type 1 diabetes; cognitive variability; digital neuropsychology; digital technology; remote assessment; continuous glucose monitoring; cognition; diabetes; physiological; behavioral; psychological; cognitive; adults; glucose; data; study design; assessment; sample; hypoglycemia

Introduction

Ecological Momentary Assessment

Ecological momentary assessment (EMA) is a methodological approach used to study intraindividual variation over time, using repeated assessments of behavioral, physiological, and psychological processes during regular daily activities using electronic devices [1]. In recent years, the increasing reach of technology, have dramatically increased the feasibility and sophistication of approaches that use EMA [2,3]. The use of EMA overcomes many limitations of traditional study designs, such as retrospective response bias and undetected environmental influences on behavior, as well as allowing for real-time intervention [4,5]. However, as a relatively recent methodology, there are some challenges to the use of EMA, including the relative scarcity of specific evidence-based methodological guidelines for conducting studies. Moreover, few studies have described EMA methodology in sufficient detail for replication [6]. This lack of methodological guidance is particularly notable in the assessment of cognitive performance via EMA.

EMA for Individuals With Type 1 Diabetes

Individuals with type 1 diabetes (T1D) are a particularly important target population for EMA study designs given their vulnerabilities to and interactions among multiple dynamic physiological, behavioral, and psychological processes. T1D is a chronic autoimmune disease characterized by the destruction of insulin-producing β-cells in the pancreas, causing hyperglycemia [7] and requiring the use of exogenous insulin. Variations in blood glucose, which occur over the course of minutes to hours, are associated with short-term cognitive variability [8-12] in controlled studies and may indirectly impact psychological and other physiological states [13-15]. We are aware of 3 other ongoing studies that are using continuous glucose monitoring (CGM) coupled with EMA in adults with T1D: The Function and Emotion in Everyday Life with T1D study [16], Hypoglycaemia – Redefining Solutions for better lives project [17], and Towards a Better Understanding of Diabetes Distress, Depression and Poor Glycaemic Control study [18]. One of these studies does not include ambulatory cognitive assessment [18], and the other 2 have not yet reported results [16,17].

The primary goal of the Glycemic Variability and Fluctuations in Cognitive Status in Adults with Type 1 Diabetes (GluCog) study is to characterize the relationship between glycemic excursions and cognitive functioning in adults with T1D, with the secondary goal of determining how psychological state and diabetes-related factors mediate and moderate this relationship. The study, led by principal investigators Dr Laura Germine of McLean Hospital and Dr Naomi Chaytor of Washington State University, uses the EMA of cognitive performance and self-report data, coupled with blinded CGM. Four endocrinology centers (SUNY Upstate Medical University, University of Pennsylvania, Mayo Clinic, and AdventHealth Diabetes Institute), with central clinical site coordination by the Jaeb Center for Health Research, are currently recruiting participants for this study.

Aims of the Study

Here, we report the results of an initial EMA optimization pilot study of 20 participants with T1D. This optimization pilot was conducted before the finalization of the GluCog protocol to determine the appropriate EMA frequency for the detection of hypoglycemia and EMA completion rate and to refine our cognitive EMA battery. We describe how the initial optimization pilot results guided the design of the main GluCog study, which was launched in September 2020 and is ongoing. Although this study collected CGM data in adults with T1D, similar methodological considerations are applicable to any semicontinuous physiological or behavioral data collection coupled with discrete EMA data (eg, actigraphy, heart rate, and continuous electroencephalogram monitoring). To establish the optimal EMA frequency, we evaluated 2 EMA schedules (6 EMAs per day for 5 days vs 3 EMAs per day for 10 days) to determine which schedule (1) captured the highest number of hypoglycemic episodes within 60 minutes before each EMA and (2) resulted in higher EMA completion rates. We focused on EMA after hypoglycemia (rather than hyperglycemia) because of the established association with cognitive performance in controlled studies and given that hypoglycemia is less frequent than hyperglycemia [19,20].

Methods

Participants

In total, 20 adults with T1D were enrolled in the optimization study between February 2020 and May 2020 from SUNY Upstate Medical University based on the inclusion criteria that they must: be ≥25 years of age, be diagnosed with T1D, have T1D for >1 year, be fluent in English, have understood the EMA protocol and agreed to comply with it to the best of their ability, and have 24-hour access to a personal smartphone with reliable internet access. Exclusion criteria included the following: inability to complete cognitive assessments owing to significant visual, motor, hearing, or cognitive impairment; any medical or psychiatric condition or treatment that was determined by the principal investigators to interfere with the completion of the study; current use of real-time CGM; inability to complete EMA assessments during the study period (eg, night shift work, planned travel across time zones, or occupation that does not reliably allow time to complete assessments within a reasonable period).

Materials

Baseline Assessment

Baseline cognitive tasks and psychological questionnaires were completed by all the participants via their smartphones, tablets, or computers through a secure website (TestMyBrain.org [21]; TMB) managed by the study staff at McLean Hospital. The baseline assessment duration was approximately 60 minutes. Tasks were selected based on the recommendations from the Core Neuropsychological Measures for Diabetes and Obesity Trials [22]. Full-length versions of all cognitive EMA (see below) were also included. For a complete list of the baseline assessments and constructs measured, see Textbox 1.

Textbox 1. Baseline assessments and constructs measured.

Baseline questionnaires, approximately 40 minutes

- General questionnaire
  - Demographic characteristics, employment, sleep and wake times in a typical week, and work time
- Mental Health Questionnaire
  - Questionnaire assessing cross-cutting symptoms for psychopathology based on the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition [23,24]. This is a 6-item questionnaire assessing possible broad psychopathology. It takes approximately 2 minutes.
- Pittsburgh Sleep Quality Index [25]
  - Questionnaire assessing sleep duration and quality over a 1-month interval. It takes approximately 5 minutes.
- Snoring, tiredness, observed apnea, high BP, BMI, age, neck circumference, and male gender (STOP-Bang) Questionnaire [26]
  - Questionnaire assessing obstructive sleep apnea risk consisting of 8 questions that take approximately 2 minutes. STOP-BANG sensitivity is of 93% and 100% for detecting moderate and severe sleep apnea [27].
- Functional Activities Questionnaire [28]
  - Questionnaire assessing instrumental activities of daily living consisting of 10 items and administered to an informant
- Patient Health Questionnaire-8 (PHQ-8) [29]
  - An 8-item questionnaire assessing depression symptoms that takes approximately 5 minutes
- Generalized Anxiety Disorder (GAD-7) [30]
  - A 7-item self-report scale assessing generalized anxiety symptoms that takes approximately 5 minutes
- Global perceived stress scale [31]
  - Questionnaire assessing the chronic experiences of stress. It is a 10-item scale measuring the degree to which situations are appraised as stressful. It takes approximately 5 minutes.
- World Health Organization Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST) [32]
  - Screening for alcohol consumption, smoking, and other substance use throughout lifetime and during the latest 3 months at the time of assessment. It takes approximately 3 minutes.
- Quality of Life in Neurological Disorders (Neuro-QoL)—Cognitive Function Short Form [33]
  - An 8-item questionnaire assessing self-reported cognitive problems in daily life. Neuro-QoL provides a common metric for use across patient groups in different studies [34]. It takes approximately 5 minutes.
- Coronavirus Health Impact Survey (CRISIS) [35]
  - Questionnaire covering key domains relative to mental distress and resilience, which assess self-reported impact owing to the COVID-19 pandemic. It was demonstrated to have good feasibility, reliability, and construct validity in large pilot samples in the United States and United Kingdom [35]. It takes approximately 10 minutes.

Baseline cognitive assessment, approximately 30 minutes

- TestMyBrain.org (TMB) Matrix Reasoning
  - Cognitive test assessing general cognitive ability and nonverbal reasoning. Participants solve a series of visual puzzles.
- TMB Vocabulary
  - Cognitive test assessing verbal reasoning. Participants indicate which of 5 words is the closest in meaning to a target word.
- TMB Simple Reaction Time
  - Cognitive test assessing basic psychomotor speed. Participants press a button every time a green square appears on screen.
- TMB Letter-Number Switching
  - Cognitive test assessing cognitive flexibility and task switching. Participants indicate which response fits the instruction cue shown on screen.

- TMB Visual Paired Associates Memory
  - Cognitive test assessing visual memory. Participants learn a set of picture pairs and have to indicate which pictures go together based on the set they learned.
- TMB Delay Discounting
  - Cognitive test assessing decision-making. Participants indicate whether they would prefer differing amounts of hypothetical money now or in the future.

Baseline full-length cognitive ecological momentary assessment tests, approximately 10 minutes

- TMB Flicker Change Detection (Flicker)
  - Cognitive test assessing visual working memory. Participants view a series of visual scenes with blue and yellow dots. One of the dots is changing color from blue to yellow. Participants are asked to indicate the dot that is changing color.
- TMB Multiple Object Tracking (MOT)
  - Cognitive test assessing visuospatial working memory. Participants track dots as they move across the screen.
- TMB Paced Serial Addition Test (PSAT)
  - Cognitive test assessing sustained attention. Participants indicate whether last 2 numbers add up to >10 or <10.
- TMB Gradual Onset Continuous Performance Test (GradCPT)
  - Cognitive test assessing sustained attention. Participants see a series of city or mountain scenes and are asked to press a button whenever they see a city scene and withhold a response whenever they see a mountain scene.
- TMB Digit Symbol Matching (DSM)
  - Cognitive test assessing psychomotor processing speed. Participants have to match a set of symbols to the numbers 1, 2, or 3 based on a key presented on screen.
- TMB Choice Reaction Time (Choice RT)
  - Cognitive test assessing psychomotor processing speed

Cognitive EMA

Cognitive tasks selected for the optimization pilot were based on prior TestMyBrain [21] website-collected data showing good sensitivity and internal reliability for ultrabrief versions (reliability of 0.4 or higher for one 30-60-second testing occasion [36]) across alternate forms suitable for EMA, theoretical association with blood glucose excursions, and prior use in brain health research [37,38] (refer to Multimedia Appendix 1 for a complete list of the EMA questions and cognitive tasks [37-44]; Cognitive EMA selection in the *Results* section). Two tests of processing speed (Brief TMB Choice Reaction Time and Brief TMB Digit Symbol Matching [DSM]), cognitive control or sustained attention (Brief TMB Gradual Onset Continuous Performance Test [GradCPT] and Brief TMB Paced Serial Addition Test), and visual working memory (Brief TMB Multiple Object Tracking [MOT] and Brief TMB Flicker) were selected for evaluation during the optimization phase. To maintain a total EMA duration of <5 minutes, 3 tests (1 from each cognitive domain) were administered during each EMA and counterbalanced across EMAs to ensure equal exposure to all tasks across each EMA frequency period (ie, 3 and 6 EMAs per day). Participants who completed <50% of the total EMAs were excluded from the data analyses.

For all the tasks described in Multimedia Appendix 1, 21 alternate forms were generated based on validated algorithms to minimize practice effects. Versions differed in trial order or items to be remembered but not in any substantive characteristics (eg, task length, parameters, and stimuli). The cognitive EMA tasks were performed on a personal smartphone using a dedicated mobile TestMyBrain [21] study site.

Blinded CGM

A blinded Dexcom G6 Personal CGM System (Dexcom CGM). The CGM system (Food and Drug Administration–approved) was inserted and worn for a minimum of 10 days and a maximum of 20 days (a second sensor was sent home with the participant). The CGM system consisted of a sensor (plus an additional sent home for insertion after 10 days), transmitter, and receiver (set to blinded mode before assigning to the participant). Participants with <3 days of CGM data (72 h) were excluded from the data analyses.

Hypoglycemia Criteria

CGM data were coded for the presence of hypoglycemia within 60 minutes before the start of each EMA. This time frame was chosen based on insulin clamp studies demonstrating cognitive recovery within 40 to 90 minutes of return to euglycemia [45]. On the basis of recent consensus criteria recommendations [46], we operationalized *hypoglycemia* as >15 consecutive minutes

with a sensor glucose value of <70 mg/dL. At least 2 sensor values <70 mg/dL that are ≥15 minutes apart, plus no intervening values of >70 mg/dL, are required to define a hypoglycemic event. The end of the hypoglycemic event is defined as a minimum of 15 consecutive minutes with a sensor glucose concentration of >70 mg/dL. At least 2 sensor values of >70 mg/dL that are ≥15 minutes apart, with no intervening values of <70 mg/dL, are required to define the end of an event. We chose the sensor glucose value of <70 mg/dL to maximize the likelihood of these events occurring within 60 minutes of EMA. Hypoglycemic events were excluded if there were missing values or discontinuous jumps between adjacent measures (indicating potential sensor error) [47].

Passive Measures

The metadata of the browser, screen size, and operating system were captured to assist in the interpretation of cognitive data, as data quality is critically dependent on the accurate capture of device characteristics that can confound smartphone–based cognitive assessments [48].

Ethics Approval

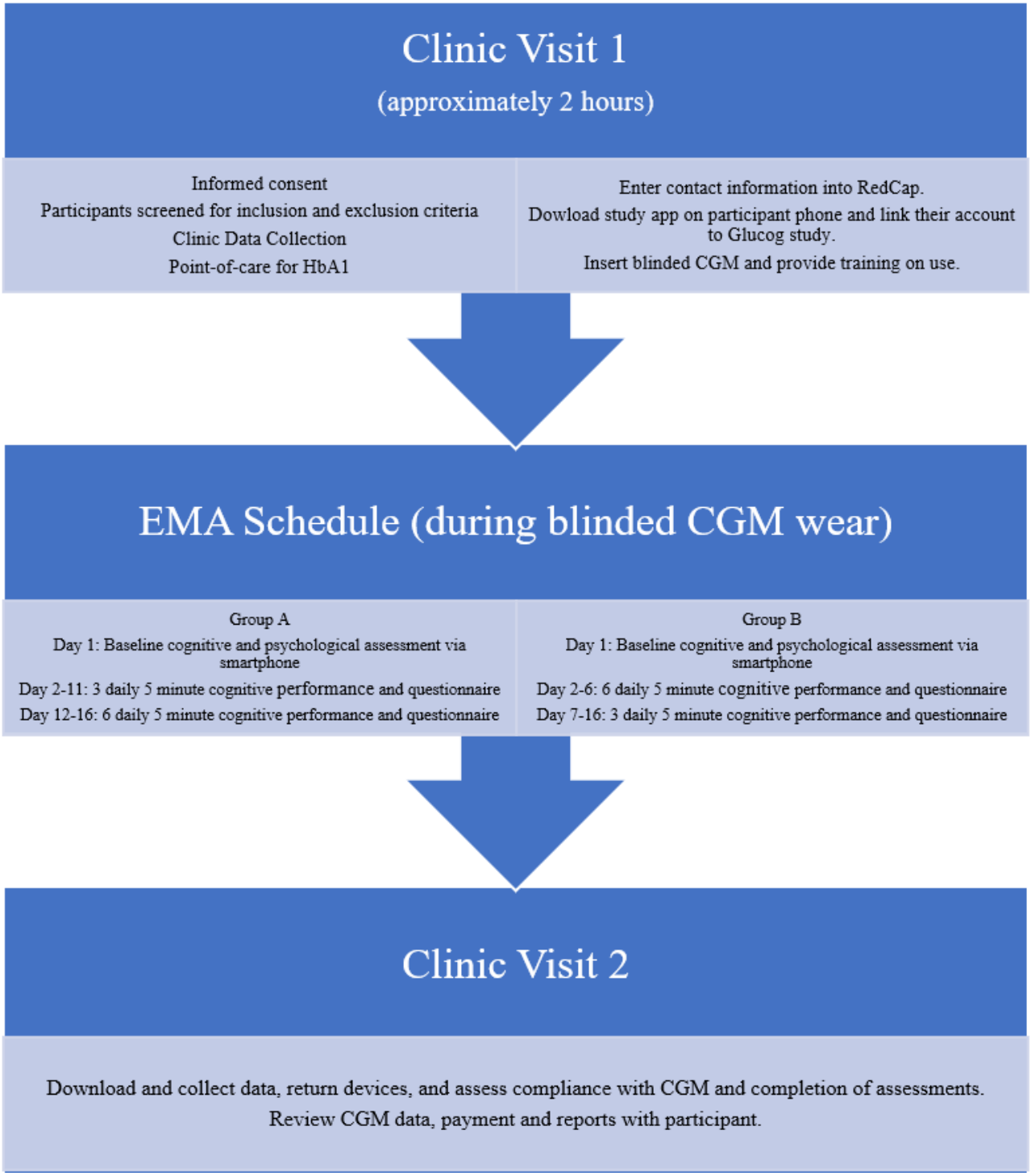
The GluCog optimization pilot study was conducted in compliance with ethical principles that have their origin in the Declaration of Helsinki, including Regulations for the Protection of Human Participants of Research, and the standards of Good Clinical Practice. This study was approved by the Jaeb Center for Health Research Institutional Review Board. All the participants provided written informed consent.

Procedure

Overview

For schematic of the overall study design, see Figure 1. Clinic data collection consisted of physical exam (height, weight, blood pressure, heart rate, and waist and neck circumference) conducted by a medical provider; demographic and socioeconomic information; medical record review and patient-reported diabetes history, including age at diagnosis, severe hypoglycemia history, and diabetic ketoacidosis history; current diabetes and other medications; insulin administration method; hypoglycemia awareness assessment scale; and other medical conditions. Hemoglobin A1c was newly collected if not done clinically within 3 months. Participants were reimbursed for completion of the following study components: clinic visit 1, baseline assessment, each EMA (up to a maximum of US $30), an extra bonus for completion of >80% EMA and clinic visit 2). To be included in data analysis, the participant must have completed ≥50% of EMAs.

Figure 1. Schematic of study design. CGM: continuous glucose monitoring; GluCog: Glycemic Variability and Fluctuations in Cognitive Status in Adults with Type 1 Diabetes study; HbA_{1c}: hemoglobin A_{1c}.



EMA Schedule Randomization

To evaluate the impact of EMA administration schedules on completion rates, detection of hypoglycemia, and cognitive variability, we randomized participants (1:1) into one of two counterbalanced EMA frequency groups. Group A began with low-frequency or long-duration EMA (3 EMAs/day over 10 days), followed by high-frequency or short-duration EMA (6 EMAs/day over 5 days). Group B began with high-frequency or short-duration EMA (6 EMAs/day over 5 days), followed by low-frequency or long-duration EMA (3 EMAs/day over 10 days). All EMAs were delivered between 9 AM and 9 PM local time to minimize the effects of varying sleep schedules and sleep inertia on performance. Each of the 6 mobile tests was administered 30 times to each participant (15 times in the 6 EMA/day schedule and 15 times in the 3 EMA/day schedule), with each EMA occasion including one of two tests from each of the 3 cognitive domains.

EMA Schedule

The participants completed all the EMAs on their personal smartphones. On day 2 of the CGM sensor wear, following

completion of the baseline assessment, participants were sent a smartphone notification to complete an onboarding EMA consisting of detailed instructions and practice trials for the cognitive EMA tasks. Figures 2 and 3 show a diagram of the 3 EMAs per day coupled with CGM. Each EMA consisted of patient-reported questions and brief cognitive tasks with a total duration of 5 minutes, occurring 3 to 6 times a day (refer to EMA Schedule Randomization) on days 3 to 18. The formal EMA schedule began in the morning of day 3 after wearing CGM sensor for 2 days, followed by multiple daily assessments for 15 days. Each participant was sent push notifications containing a link to the EMA battery. Notifications were sent at random within prespecified time windows (for the 3 EMA/day schedule, a notification was sent between 9:00 AM and 12:59 PM, 1 PM and 4:59 PM, and 5 PM and 9 PM; for the 6 EMA/day schedule, a notification was sent between 9 AM and 10:59 AM, 11 AM and 12:59 PM, 1 PM and 2:59 PM, 3 PM and 4:59 PM, 5 PM and 6:59 PM, and 7 PM and 9:00 PM). Participants had up to 30 minutes to start each EMA from the time the notification was delivered. Participants received a reminder text message when 25 minutes had elapsed, stating that it was the final chance to complete the EMA.

Figure 2. Cognitive ecological momentary assessment (EMA) coupled with continuous glucose monitoring (CGM)—for example, schedule with 3 EMAs per day. CGM data collected every 5 minutes. Smartphone icons represent hypothetical 3 times a day EMA assessment.

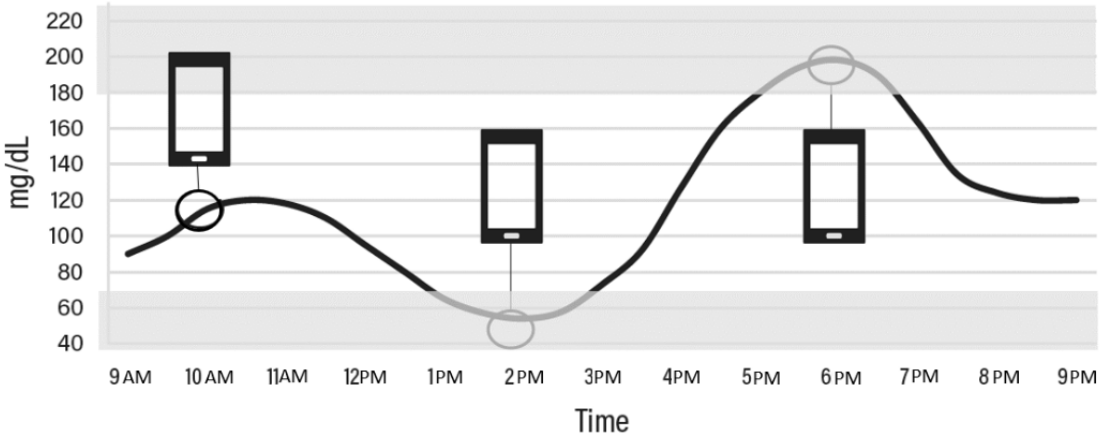
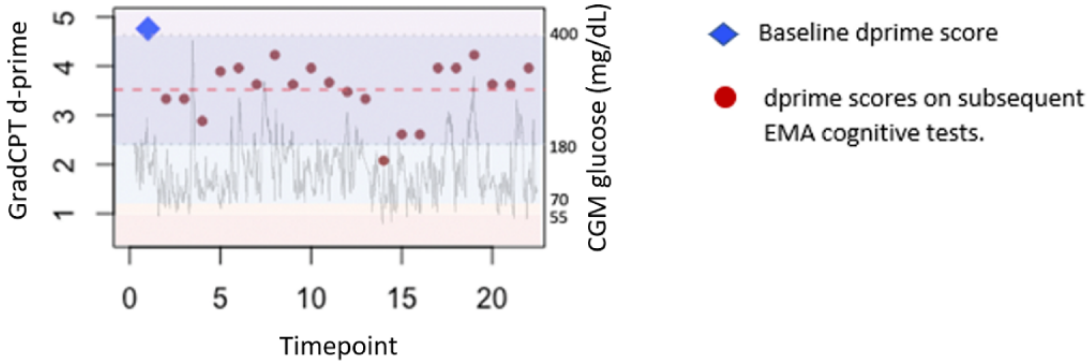


Figure 3. Example of ecological momentary assessment (EMA) coupled with continuous glucose monitoring (CGM) data for a single participant. GradCPT: Gradual Onset Continuous Performance Test.



Technical Support

Technical support was provided during working business hours, that is, 9 AM to 5 PM Eastern Time from Monday to Friday. In addition to the general availability to answer questions, technical support staff monitored participant assessment completion and intervened during the initial days following study enrollment. On days 1 and 2 of the study, participants were expected to complete a baseline assessment (link sent through email) and onboarding assessment (sent through app notification). If the participants had not completed both assessments by 3 PM Eastern time on day 2, they were sent a text reminder to complete these assessments as soon as possible. In this reminder, participants were told to contact us via Google Voice SMS and laboratory phone number if they experienced any technical problems. Technical problems such as an error in a survey link, issues in loading the webpage, and session timeout errors would result in a clinical research assistant troubleshooting with the participant via Google SMS. If the issue could not be resolved over SMS text messaging, a phone call was made to the participant and the participant's clinic coordinator and the issue was elevated to the team's software engineer. In general, problems typically arose within the first 48 to 72 hours of study enrollment and could usually be resolved over SMS text messaging. In rare cases where the issue could not be resolved, such as smartphone capability issue, a participant could be unenrolled from the study. For the remainder of the study, on days 4, 8, and 12, participants received standard status updates regarding their completion rate and follow-up on previously reported issues.

Test Selection for Main Study: Psychometric Analyses of Pilot Data

Individual cognitive tests were evaluated for inclusion in the main study based on three sequential criteria: (1) completion rates and usability (eg, minimal participant burden or technical barriers), (2) minimal restriction of range, and (3) good between-person reliability in mobile format.

To calculate the between-participant reliability of each mobile cognitive test, we separately calculated the test scores for even and odd trials. For each test, unconditional multilevel mixed models were used to predict performance on each half of each mobile test, with random effects of EMA numbers nested within participants. Fitting these models allowed partitioning of variance to between- and within-person effects, which we entered into the following equation [36]:

where Var (BP) is the total variance in scores between participants, Var (WP) is the variance in scores within participants (ie, variance between EMA sessions and residual variance), and n is the total number of measurements. For each test, we set n equal to the average number of measurements per participant, with a maximum possible n of 60 (a measurement of each half of the 30 mobile tests). CIs for the between-person reliability of each test were calculated using 10,000 bootstrap samples, with resampling at the participant level. Task psychometrics were compared across tasks and 3 EMA/day and 6 EMA/day schedules.

Results

Cognitive EMA Selection

Here, we present the results that led to the choice of cognitive EMA tests used during the optimization pilot phase. Table 1 is based on the previous data collected from the TestMyBrain.org [21] website showing good sensitivity and internal reliability (see Multimedia Appendix 2 for score distribution across tests). All tests exceeded our reliability threshold of 0.4 for a single 30-to-60-second testing occasion. For clarity, the EMA versions of the TMB tests are designated as *brief*.

Table 1. Initial reliability data for brief cognitive tests, based on the data collected from the digital research platform TestMyBrain.org [21].

Outcome	TestMyBrain.org sample		
	n	Mean (SD)	Reliability of the EMA[a] length test[b]
Brief TMB[c] Choice RT[d]—median RTc (ms)	12,939	961 (342)	0.93
Brief TMB DSM[e]—median Tc (ms)	7095	1005 (374)	0.81
Brief TMB Flicker—medianRTc (ms)	11,869	4873 (2461)	0.62
Brief TMB GradCPT[f]—d-prime	5039	2.92 (0.94)	0.82
Brief TMB MOT[g]—accuracy	10,703	69.4 (11.6)	0.67
Brief TMB PSAT[h]—accuracy	9900	72.8 (18.8)	0.75

[a]EMA: ecological momentary assessment.

[b]To calculate internal reliability, we fit unconditional multilevel mixed models predicting performance on each half of the test with a random effect of participants. The variance between and within participants was again entered into the same equation, with n=2 for the TestMyBrain.org sample (ie, the 2 halves of the single testing session). Note that for the TestMyBrain.org sample, this produces the same reliability value as the Spearman-Brown corrected split-half reliability of the even and odd trials.

[c]TMB: TestMyBrain.org.

[d]RT: Reaction Time.

[e]DSM: Digit Symbol Matching.

[f]GradCPT: Gradual Onset Continuous Performance Test.

[g]MOT: Multiple Object Tracking.

[h]PSAT: Paced Serial Addition Test.

Optimization Pilot

The optimization pilot sample (N=20) was recruited from a single clinic site (SUNY Upstate Medical University) from February 2020 to April 2020. Initially, 30% (6/20) of participants were enrolled before the widespread COVID-19 lockdowns. We modified the protocol, obtained International Review Board approval for fully remote study visits, and enrolled the remaining optimization study sample participants remotely. Subsequently, 50% (10/20) of participants were randomized into EMA group A (starting with 3 EMAs per day for 10 days and then switching to 6 EMAs per day for an additional 5 days), and 50% (10/20) of participants were randomized to the EMA group B (starting with 6 EMAs per day for 5 days and then switched to 3 EMAs per day for an additional 10 days). However, of the 10 participants, 2 (20%) participants in group A were excluded from the analyses as they completed <50% of the EMAs (prespecified minimum EMA completion). One participant reported sleeping through all morning EMAs, and the other participant declined to troubleshoot technical issues.

Completion of the remaining sample (N=18) was good across both EMA frequency schedules (3 and 6 EMAs per day) and

randomization groups—groups A and B (Table 2). The reported mean for each test was calculated by first computing the mean of each participant across all completed EMA tests and then calculating the average and SD of those participant-level means.

Between-participant reliability was greater for the GluCog optimization pilot sample than for the TestMyBrain.org [21] sample (Table 1), consistent with the repeated testing approach of the EMA design, increasing the measurement precision of between-participant differences relative to a single testing session.

The psychometric characteristics of the mobile cognitive tests were similar across both EMA schedules (Table 3).

Table 2. Means, SDs, and reliability of all tests across ecological momentary assessment schedules.

Test	GluCog[a] optimization sample		
	N	Mean (SD)	Mean reliability (range)
Brief TMB[b] Choice RT[c]—medianRTc (ms)	18	731 (114)	0.99 (0.93-0.99)
Brief TMB DSM[d]—medianRTc (ms)	18	839 (135)	0.99 (0.97-0.99)
Brief TMB Flicker—medianRTc (ms)	18	3768 (1771)	0.98 (0.90-0.99)
Brief TMB GradCPT[e]—d-prime	18	3.06 (0.36)	0.91 (0.81-0.94)
Brief TMB MOT[f]—accuracy	18	71.7 (7.1)	0.96 (0.92-0.98)
Brief TMB PSAT[g]—accuracy	18	83.4 (23.7)	0.99 (0.91-0.998)

[a]GluCog: The Glycemic Variability and Fluctuations in Cognitive Status in Adults with Type 1 Diabetes.

[b]TMB: TestMyBrain.org.

[c]RT: Reaction Time.

[d]DSM: Digit Symbol Matching.

[e]GradCPT: Gradual Onset Continuous Performance Test.

[f]MOT: Multiple Object Tracking.

[g]PSAT: Paced Serial Addition Test.

Table 3. Performance for each cognitive test, ecological momentary assessment (EMA) completion rate, and hypoglycemia episodes captured during the 3 EMA per day schedule and the 6 EMA per day schedule.

Outcome	3 EMAs per day			6 EMAs per day		
	N	Mean (SD)	Reliability	N	Mean (SD)	Reliability
Brief TMB[a] Choice RT[b]—medianRTc (ms)	—[c]	728 (116)	0.98	—	733 (124)	0.99
Brief TMB DSM[d]—medianRTc (ms)	—	833 (146)	0.99	—	844 (142)	0.98
Brief TMB Flicker—medianRTc (ms)	—	3809 (1606)	0.95	—	3727 (2146)	0.98
Brief TMB GradCPT[e]—d-prime	—	3.04 (0.45)	0.90	—	3.08 (0.30)	0.67
Brief TMB MOT[f]—accuracy	—	72.5 (7.4)	0.94	—	71.0 (7.0)	0.92
Brief TMB PSAT[g]—accuracy	—	83.6 (24.0)	0.98	—	83.3 (23.8)	0.98
EMA completion rate	—	85.7 (10.6)	—	—	81.7 (14.9)	—
Total hypoglycemic events (whole sample)	102	5.7 (5.6)	—	35	1.9 (2.1)	—
EMA-captured hypoglycemic events	43	2.4 (2.4)	—	16	0.9 (1.0)	—

[a]TMB: TestMyBrain.org.

[b]RT: Reaction Time.

[c]Not available.

[d]DSM: Digit Symbol Matching.

[e]GradCPT: Gradual Onset Continuous Performance Test.

[f]MOT: Multiple Object Tracking.

[g]PSAT: Paced Serial Addition Test.

Paired samples 2-tailed *t* tests indicated that MOT accuracy was significantly better (P=.008) during the 3 EMA/day schedule than during the 6 EMA/day schedule (t_{17}=2.96; P=.009; Cohen d_z=0.70). For the other 5 cognitive tests, performance did not significantly differ between the 3 EMA/day and 6 EMA/day schedules (ChoiceRT medianRTc, P=.71; DSMmedianRTc,

P=.57; FlickermedianRTc, *P*=.72; GradCPTD-Prime, *P*=.55; PSAT Accuracy, *P*=.75). The GradCPT reliability was much lower on the 6 EMA/day schedule than the 3 EMA/day schedule. This was because of the much higher between-person variance in scores (SD of scores) for the 3 EMA/day schedule than the 6 EMA/day schedule. However, the reason 3 EMA/day schedule captured more between-person variance in scores was unclear from our data.

EMAs were considered complete if the participants finished all 3 cognitive tests comprising the EMA. A paired samples 2-tailed *t* test found no significant difference in EMA completion rate between the 3 EMA/day schedule and the 6 EMA/day schedule (t_{17}=1.16; *P*=.26; Cohen d_z=0.27), with both schedules producing >80% EMA completion.

Another goal of the optimization pilot was to determine which EMA frequency schedule would be associated with more EMAs delivered within 60 minutes of a hypoglycemic event. Hypoglycemic episodes were considered only within 1 hour from the hours when EMAs were administered, that is, between 8 AM and 10 PM each day Hypoglycemia episodes were considered "captured" (overlapping with an EMA) if they met any of the following criteria: (1) any point of the hypoglycemic episode occurred within 60 minutes before the start of the EMA (2) the hypoglycemic episode began during the EMA, or (3) the hypoglycemic episodes began within 15 minutes following the end of the EMA. Of the 18 participants, 3 (17%) participants had no daytime hypoglycemic events during the entire pilot period (either 3 or 6 EMA/day periods, combined duration of wearing CGM for 15 d). During the 3 EMA/day period (10-day duration), 67% (12/18) of participants had 43 unique EMA-captured episodes of hypoglycemia (of 102 CGM-detected episodes). Two participants had no EMA-captured events despite having more than one event during the 10-day period. During the 6 EMA/day period (5-day duration), 50% (9/18) of participants experienced 16 unique EMA-captured episodes of hypoglycemia (out of 35 CGM-detected episodes). One participant had no EMA-captured events despite having >1 event during the 5-day period. When comparing periods within individual participants, 50% (9/18) of participants had more EMA-captured hypoglycemic events during the 3 EMA/day period compared to that of 6 EMA/day period, while only 11% (2/18) of participants had more EMA-captured events during the 6 EMA/day period. Overall, 39% (7/18) of participants had the same number of EMA-captured events in both periods.

A paired samples *t* test revealed that more hypoglycemic episodes occurred during the 3 EMA/day schedule than during the 6 EMA/day schedule (t_{17}=3.00; *P*=.008; Cohen d_z=0.71) as expected, given that the 3 EMA/day schedule spanned twice the amount of time as the 6 EMA/day schedule. Furthermore, more hypoglycemia episodes were captured by an EMA during the 3 EMA/day schedule (mean 2.4, SD 2.4) than during the 6 EMA/day schedule (mean 0.9, SD 1.0); t_{17}=2.57; *P*=.02; Cohen d_z=0.61 (Table 3).

Discussion

Implications for the Main GluCog Study

The optimization pilot was incorporated into the planned study design for the GluCog study to determine the EMA frequency that would (1) result in higher EMA completion and (2) capture more hypoglycemic events, which are critical factors in the success of the main study. On the basis of comparable EMA completion and greater EMA capture of hypoglycemic episodes, we selected 3 EMA/day schedule over the 6 EMA/day schedule for the main GluCog study.

The optimization pilot also allowed us to evaluate the psychometric and usability properties of the cognitive EMA measures. Given the paucity of cognitive EMA studies on which to base test selection, we initially selected 6 cognitive EMA measures within 3 cognitive domains and alternated tasks within each domain at each EMA (to reduce the total EMA duration). The data from the optimization pilot allowed us to select one test within each cognitive domain that had the greatest likelihood of producing usable data for the main GluCog study. For the processing speed domain, the Brief TMB DSM and Brief TMB Choice Reaction Time had comparable reliability and usability. We selected the Brief TMB DSM owing to greater familiarity among clinicians and the use of Digit Symbol Matching tasks in prior studies of cognition in T1D. For the sustained attention domain, we selected the Brief TMB GradCPT owing to less restriction of range when compared with the Brief Paced Serial Addition Test. For the working memory domain, we selected the Brief TMB MOT because some participants had technical issues with touch sensitivity on their devices during the Brief TMB Flicker task. Specifically, some participants had issues with screen taps not immediately registering on the device and as a result, had longer reaction times.

The optimization pilot also revealed technical difficulties in the implementation of the EMA via the app-based notification system. Some participants had trouble installing and setting up the app, as well as keeping track of push notifications. To address this, in the main GluCog study, we switched to a system that did not involve installation of an app and relied on text messages rather than push notifications. This system required less technical support throughout the study.

Many aspects of EMA study design can affect adherence to the research protocol [49,50]. The optimal assessment strategy for capturing sufficient glycemic variability and ensuring adequate EMA completion rates was unknown before initiating the GluCog study. The EMA cognitive tasks that we selected were also refined via an optimization pilot. We found no difference in the completion rates between the 2 EMA frequencies. However, we found that a longer sampling duration (10 d) with less frequent EMAs (3 EMAs per day) resulted in more EMAs in close proximity to hypoglycemic episodes compared with short duration of testing (5 days) with high-frequency EMAs (6 EMAs per day). Our findings may guide future studies that include events of interest with relatively infrequent occurrence (mean=0.51, SD =0.44 events per day; range 0-1.47), such as hypoglycemia.

Other Considerations for the Main GluCog Study Procedure

Given that the onset of the COVID-19 pandemic coincided with recruitment for the optimization pilot, we were able to develop procedures for completing clinic visits remotely via telehealth or telephone visits, or in-person as initially planned, and carry these procedures forward into the main GluCog study, along with a COVID-19 specific impact and stress questionnaire. Recruitment was slower than initially anticipated owing to the rapidly increasing clinical uptake of real-time CGM in the T1D population. The exclusion of participants using real-time CGM was removed in June 2021 after 50 participants were enrolled to ensure that concurrent real-time CGM use could be analyzed as a covariate. The lower age limit was also expanded to 18 years to maximize recruitment. All the other procedures have remained consistent with those reported above. The main GluCog study began recruitment in October 2020. Enrollment was completed on June 15, 2022. Our primary objective was to describe the research methodology used in this pilot study on glycemic and cognitive variability in adults with T1D, the results of which guided key decisions related to EMA use in the main study protocol. There are limited existing cognitive EMA data on which important study-design decisions can be made. Recent systematic reviews on EMA have pointed out a lack of important methodological information in the scientific literature [6,49-51]. Our report includes all recommendations from the guidelines adapted for EMA studies across disciplines (Checklist for Reporting EMA Studies, CREMA) [6] and provides a way forward for EMA studies until greater methodological consensus has been reached.

General Considerations for Other EMA Studies

The current availability of smartphones with large and high-resolution screens has made rigorous mobile cognitive assessments possible. Critical dilemmas faced by EMA studies involving cognitive assessment include (1) selecting tests that have been linked to the phenomena of interest based on the traditional test literature (ie, impacted cognitive domains); (2) ensuring psychometric properties that are suited to high-frequency administration (ie, avoiding ceiling effects); (3) balancing the need for adequate reliability, while minimizing test length; and (4) formatting a test that is compatible with smartphone screen size and operating system variations. There are very limited empirical data to aid the selection of EMA cognitive tasks that account for all these factors. Thus, there is an advantage in using a large web-based test platform (such as the TestMyBrain [21] platform) to select high-performing EMA length tests with known device impacts.

Although not anticipated when designing the GluCog study, our exclusive use of remote assessment was useful in mitigating logistical challenges related to face-to-face assessments during the COVID-19 pandemic [52,53]. We were able to quickly pivot our initial in-person clinic enrollment visit to a teleconference visit (with CGM supplies mailed to the participants). In addition, remote assessment mitigates logistical challenges related to traditional face-to-face testing administration, such as costs (staff time, clinic and laboratory space, physical assessment materials), difficulties in getting to a study site for people with mobility limitations or who have transportation challenges such as those who live in rural or remote areas, necessary training for the examiner, and training of study personnel in complex test administration (which can be particularly challenging with multisite studies).

Among the most exciting aspects of EMA use is the opportunity to explore biopsychosocial mechanisms underlying human health and disease. Technological advances in physiological detection capability (eg, CGM) and data-driven machine learning techniques for predicting cognitive changes are advancing rapidly. Our understanding of real-world influences on cognitive performance will be exponentially increased by the ability to accurately measure fluctuations as they occur. Repeated measurements allow for the identification of mediators and moderators of cognitive change over time in real-world environments.

Conclusions

The EMA optimization pilot study described here responds to the urgent need for systematic and detailed information on EMA study designs. Recent advances in mobile technologies have resulted in new opportunities for EMA to examine cognition in everyday environments. When applied in a well-planned manner, EMA can be an important tool for research involving biopsychosocial mechanisms. In addition, cognitive EMA can assist in the early diagnosis of cognitive impairment as well as follow-up and intervention and can complement traditional neuropsychological assessments. EMA holds immense promise for understanding everyday conditions, both internal and external, that influence cognitive performance in individuals over time. This can be particularly useful in the assessment of populations with greater vulnerability to dynamic physiological, behavioral, and psychological interactions, such as individuals with T1D. Given the complexity of EMA studies, choosing the right instruments and assessment schedules is an important aspect of study design and subsequent data interpretation. Empirically determining these parameters in the target population will ensure adequate sampling of the phenomena of interest.

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Authors' Contributions

LMF wrote the manuscript and participated in discussion. RWS contributed to the study design, participated in the discussion, and led data analysis. SS edited the manuscript and participated in the discussions. JDB, MC, EG, KJ, LJ, KM, EP, KR, MS, AV, and RSW contributed to study design and edited the manuscript. LG and NSC were responsible for the GluCog study, contributed to the study design, participated in the discussion, and edited the manuscript. All authors have reviewed and approved the final manuscript for publication.

Conflicts of Interest

RSW participates in multicenter clinical trials, through their institution, sponsored by Medtronic, Insulet, Kowa, Eli Lilly, Novo Nordisk, Boehringer Ingelheim, and has received insulin pumps and glucose monitoring devices from Tandem and DexCom for use in clinical research.

Multimedia Appendix 1
Ecological momentary assessment questions and tasks.
[DOCX File , 52 KB - diabetes_v8i1e39750_app1.docx]

Multimedia Appendix 2
Score distribution across tests.
[PNG File , 73 KB - diabetes_v8i1e39750_app2.png]

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Abbreviations

CGM: continuous glucose monitoring
DIA-LINK1: Towards a Better Understanding of Diabetes Distress, Depression and Poor Glycaemic Control
DSM: Digit Symbol Matching
EMA: ecological momentary assessment
FEEL-T1D: The Function and Emotion in Everyday Life with T1D
GluCog: Glycemic Variability and Fluctuations in Cognitive Status in Adults with Type 1 Diabetes
GradCPT: Gradual Onset Continuous Performance Test
Hypo-RESOLVE: Hypoglycaemia – Redefining Solutions for better lives
MOT: Multiple Object Tracking
T1D: type 1 diabetes
TMB: TestMyBrain.org

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Original Paper

Social Support in a Diabetes Online Community: Mixed Methods Content Analysis

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Abstract

Background: Patients with diabetes may experience different needs according to their diabetes stage. These needs may be met via online health communities in which individuals seek health-related information and exchange different types of social support. Understanding the social support categories that may be more important for different diabetes stages may help diabetes online communities (DOCs) provide more tailored support to web-based users.

Objective: This study aimed to explore and quantify the categorical patterns of social support observed in a DOC, taking into consideration users' different diabetes stages, including prediabetes, type 2 diabetes (T2D), T2D with insulin treatment, and T2D remission.

Methods: Data were collected from one of the largest DOCs in Europe: Diabetes.co.uk. Drawing on a mixed methods content analysis, a qualitative content analysis was conducted to explore what social support categories could be identified in users' posts. A total of 1841 posts were coded by 5 human annotators according to a modified version of the Social Support Behavior Code, including 7 different social support categories: achievement, congratulations, network support, seeking emotional support, seeking informational support, providing emotional support, and providing informational support. Subsequently, quantitative content analysis was conducted using chi-square post hoc analysis to compare the most prominent social support categories across different stages of diabetes.

Results: Seeking informational support (605/1841, 32.86%) and providing informational support (597/1841, 32.42%) were the most frequent categories exchanged among users. The overall distribution of social support categories was significantly different across the diabetes stages (χ^2_{18}=287.2; P<.001). Users with prediabetes sought more informational support than those in other stages (P<.001), whereas there were no significant differences in categories posted by users with T2D (P>.001). Users with T2D under insulin treatment provided more informational and emotional support (P<.001), and users with T2D in remission exchanged more achievement (P<.001) and network support (P<.001) than those in other stages.

Conclusions: This is the first study to highlight what, how, and when different types of social support may be beneficial at different stages of diabetes. Multiple stakeholders may benefit from these findings that may provide novel insights into how these categories can be strategically used and leveraged to support diabetes management.

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KEYWORDS

diabetes online community; social support; health communication; mixed methods; content analysis; prediabetes; type 2 diabetes; type 2 diabetes insulin; type 2 diabetes remission

Introduction

Background

Diabetes is a chronic disease that leads to high blood glucose levels owing to defects in insulin secretion from the pancreas, action, or both [1]. Diabetes affected 439 million people globally in 2019 [2], and this is projected to increase to 700 million people by 2045 [2]. This rising prevalence and costs have been associated with an increase in the incidence of type 2 diabetes (T2D), which represents 90% to 95% of all diabetes cases [3].

Individuals with T2D require effective management of blood glucose levels via diabetes-structured education, suitable treatment and management, and healthy lifestyle behaviors focused on weight loss (eg, diet to delay or prevent the onset of health complications) [4]. Adhering to these daily, long-term, and demanding self-care activities can leave patients feeling overwhelmed, frustrated, and discouraged from the stress of managing diabetes and its complications [5,6]. Therefore, individuals with T2D may have a range of informational and emotional needs over time. These needs may be met via social media, where people with diabetes are reported to mainly seek health-related information [7] and exchange social support [8]. Such online peer support can be imperative for successful diabetes outcomes, including improved self-management, self-efficacy, knowledge, and emotional well-being [9,10]. Among the many social media platforms, the main source of social support for diabetes is online health community (OHC) platforms, including discussion forums [11], Facebook groups [12], and dedicated health communities, such as TuDiabetes.org [13].

OHCs and Social Support

OHCs are important sources for patients or caregivers to share experiences, post questions, and predominantly seek and provide social support more readily and regularly from or to peers facing similar health problems [14-16]. Social support refers to the exchange of communication between individuals to reduce uncertainty and promote a recipient's perception and ability to cope with stressful events [17]. The types of social support exchanged in OHCs have been identified using the Social Support Behavior Code (SSBC) scheme [18-21]. This scheme includes five social support categories: (1) emotional support (expressing empathy to reduce emotional distress), (2) esteem support (sharing compliments on others' abilities), (3) informational support (providing advice on problem solving), (4) network support (attempting to promote one's sense of belonging to a community), and (5) tangible support (providing practical help to relieve an individual in a stressful situation).

According to a meta-analysis of 41 studies on OHCs, information and emotional support were the predominant types of social support exchanged, whereas esteem and network support appeared less frequently, with tangible support being exchanged the least [22]. However, the frequencies of their occurrences vary across health conditions. For example, information support was more predominant than emotional support in OHCs dedicated to diabetes [23] and irritable bowel syndrome [24], whereas emotional support was more required in online breast cancer communities [25]. This social support framework seems to be useful for identifying the types of categories that are most relevant in different diseases. However, to date, no research has investigated what and when different types of social support are sought and provided according to the different stages of diabetes, which require different self-management approaches.

The Different Stages of Diabetes

The development and transition of diabetes stages can be viewed as a continuum of increasing insulin resistance and decreasing insulin production if blood glucose levels are not optimal over time [26]. In these situations, patients are subjected to different approaches or treatment regimes, from lifestyle interventions [27,28] to the initiation of oral drugs [29] and, in more severe cases, the need for exogenous insulin treatment [30]. However, if blood glucose levels are below the threshold used for T2D diagnosis for a minimum period of 6 months, patients can discontinue all medications and achieve T2D remission [31]. On the basis these regimens, a longitudinal model containing the stages representing the trajectory of diabetes was applied in this study. The stages were as follows: prediabetes, T2D, T2D with insulin treatment, and T2D remission.

Significance of the Study

It is important to identify and understand the types and amount of social support that patients use during these transitions, because patients experience complex decision-making challenges and questions about lifestyle changes upon diagnosis [32] and experience emotional burden during the initiation of insulin treatment [33]. The different stages of diabetes may therefore create different needs, and therefore, different types of social support may be offered and exchanged. For example, self-management approaches for people with T2D mostly include making decisions about nutritional choices [34], which can be supported by providing information. Conversely, people requiring insulin treatment may typically require more nurturant support owing to feelings of powerlessness in managing diabetes [33], higher emotional distress, and poorer quality of life than during other stages [35]. In addition, people with T2D remission may feel knowledgeable and confident in their remission status and may provide support or even just socialize with members. Understanding what support is required and given at these different stages has important implications for the design of OHCs and for health care organizations to provide more tailored support to the evolving needs of patients at different stages of diabetes.

Objectives

In summary, patients with diabetes experience a wide range of needs at different stages of the condition, and these stages may require different types of social support. Therefore, the objectives of this study were to explore and compare the frequencies of social support that was sought and provided at different stages of diabetes in users' posts within a diabetes online community (DOC). Accordingly, the following research question was investigated in this study: What types of social support categories are expressed across the different stages of diabetes in a DOC?

Methods

Overview

A mixed methods approach, using both quantitative and qualitative content analysis, was applied to gain a better understanding of the types of social support that were provided within the DOC [36]. First, a qualitative content analysis was applied to develop a codebook of categories of social support before the textual data set was coded to identify patterns of social support [37,38]. Quantitative content analysis was then used to analyze the frequencies, and statistical tests were used to test the associations between social support categories and different stages of diabetes [39].

Data Collection

Data were collected from Diabetes.co.uk, one of the largest online diabetes communities in Europe, which has served >1 million users per month since 2007 [40]. This community has 43 different forums, where users living with diabetes, their relatives, and caregivers can ask questions, share their health-related experiences, participate in discussions, and read posts from others about how to manage or cope with the disease [40]. Data were collected from January 2014 to December 2019 to obtain the most recent social support dynamics in the forum. A total of 703,693 forum messages were extracted during this period.

The data set was prepared by first identifying and selecting users who had self-reported that they were in different stages of diabetes, including prediabetes, T2D, T2D with insulin, and T2D remission. Posts that initiated a thread and the first replies to those were then included in the data set to identify instances when forum users were potentially seeking or providing different types of support. Finally, elements that were deemed irrelevant were removed from the data set by removing threads with no responses and selecting messages with a maximum length of 150 words [41,42]. All the texts were written in English. Following these filtering steps, 2280 posts were randomly extracted from the overall data set to develop the coding scheme and obtain clear instances of social support posts as reported by similar studies [43-45]. The data set included 481 users who initiated 1140 threads with 1140 first replies.

Qualitative Content Analysis

A qualitative content analysis approach was used to explore the social support categories that could be identified and how they were expressed in users' posts. This method was used to analyze web-based text from the data set within a naturalistic paradigm, which was considered appropriate because there was an incomplete understanding of social support categories expressed by users at different stages of diabetes, and thus further descriptions would be beneficial [39]. This approach included three phases: (1) developing a coding scheme based on previous literature and other social support exchanges observed in the data, (2) selecting the appropriate annotators for the coding procedure, and (3) conducting the coding procedure.

Development of Code Scheme

The data were managed and analyzed using NVivo 12 (QSR International). In this phase, 200 randomly selected posts were coded following a hybrid approach, using both deductive and inductive approaches [46]. First, using a deductive approach, posts were coded based on the SSBC [18], which includes five categories of social support: (1) emotional support (communicating empathy); (2) esteem support (communicating confidence in one's abilities); (3) informational support (offering advice); (4) network support (communicating with a group of people with similar experiences); (5) tangible assistance (providing goods); and by referring to the literature on categories of social support reported in OHCs [47-49].

The data were coded in units of whole messages rather than individual sentences within posts to enable the assessment of posts that included 1 main category of social support. During the coding process, an inductive approach was then conducted by adding new codes that emerged from the data to generate a better representation of the posted messages in the DOC [20]. New categories were added after reading the messages several times, counting their frequencies, and comparing them collectively with the existing ones to refine the themes. These processes continued until saturation (ie, when the analysis yielded no further categories).

Some messages involved users sharing their positive diabetes health outcomes and other members expressing joy about these achievements. Therefore, 2 new categories were added to the coding scheme: these were *achievement* and *congratulations*. To promote clarity between the esteem support category from SSBC and the new congratulations category, the compliment subcategory under the esteem support category was removed. This was applied because the congratulations category was solely focused on complimenting other users' achievements, whereas esteem support was used to alleviate users' negative feelings by validating the similarity of experiences and reducing their feeling of blame [50].

The esteem support category was therefore merged with the emotional support category, as both communicated concern for a user's emotional state and negative self-evaluation, similar to previous studies using the SSBC [41,49]. There were no instances of tangible assistance in the analyzed posts, so this category was removed. Previous research on OHCs reported that this was restricted by the geographic distance between community members [47,51] and that this exchange and arrangement may happen via private or offline communication channels. Finally, the concepts of seeking and providing network support were not distinguished because the nature of this category involved users seeking and providing support in their posts simultaneously. After these changes, the coding scheme contained 7 categories, including a description and examples for each category (Multimedia Appendix 1: Social support classification guide used for the coding procedure). Textbox 1 lists the categories and their definitions.

Textbox 1. Definition of social support categories.

- Achievement
  - Users share details about their own health achievements.
- Congratulations
  - Users express of joy or acknowledgment for their achievement.
- Network support
  - Enhances the sense of belonging to the community (eg, emphasizes the presence of other users and encourages continued use of the forum) and enhances group members' social network (eg, tag other users in the post or directly seeking to connect with other users). This also consists of users talking about everyday offline events (eg, travel), humor or teasing, and chatting about topics not related to their condition.
- Seeking emotional support
  - Expression of need for emotional support and reassurance from peers to feel less afraid or doubtful about their disease or condition. They normally provide mood descriptions.
- Seeking informational support
  - Expression of specific questions when trying to obtain factual information, advice, recommendations, personal experiences from peers, and knowledge related to their disease, treatment, or symptoms.
- Providing emotional support
  - Users provide affection, relief of blame, validation, caring, concern, empathy, sympathy, or encouragement to the thread initiator.
- Providing informational support
  - Users provide information and guidance to the thread initiator through advice, referrals, feedback on actions, factual input, and personal experiences with treatment or symptoms.

The following approaches were adopted to assess the applicability of the coding scheme. First, 3 researchers independently coded and analyzed a subset of the data, which included 40 messages with initial threads and corresponding first replies. They iteratively discussed and revised the coding scheme until they reached consensus.

Finally, 2 domain experts from Diabetes.co.uk annotated 40 randomly selected messages with what they regarded as the dominant category. They also reviewed the scheme to determine whether changes were required to provide greater specificity in the diabetes context. Interrater reliability (Cohen κ [52]) was used to estimate the consistency of coding the categories among the annotators using the SPSS software package (version 25; IBM Corp). A κ value of 0.812 was achieved among the domain experts, indicating a very good level of agreement (Cohen κ=0.812; $P<.001$). This experience was also useful for developing clear and unambiguous instructions for annotators in the next phase.

Coding Procedure

A sample of 20 randomly selected messages that were agreed to and previously labeled by domain experts was extracted and used as quality control to select suitable annotators for the coding procedure. A total of 4 researchers (referred to as annotators) were selected for the coding procedure based on their consistency with the domain experts. Each annotator agreed to a minimum of 18 posts classified by domain experts. The messages used for developing the coding scheme were excluded from the coding procedure.

For the coding procedure, 2000 randomly selected posts were extracted from the data set to ensure that they had a higher probability of being selected for inclusion and that they were not subjectively selected. Each annotator was assigned to classify 500 posts, including the first posts within each thread and first replies to these posts. The annotators classified each post into a social support category using a web-based form that included the same instructions and information as the selection stage. The form included 8 multiple-choice answers, referring to the different social support categories, as well as a "Could Not Tell" option, when annotators were unsure about which particular category was represented in the text. The annotators were advised to code each message with the dominant category that appeared to best reflect the nature of the post.

Interannotator agreement was calculated to assess the reliability and degree of homogeneity of annotations conducted independently by the researcher against annotations distributed among the 4 annotators. Accordingly, the researcher who had domain expertise and awareness of the dynamics of OHCs annotated all 2000 posts and compared these with the corresponding posts classified by the annotators. A Cohen κ score of 0.94 was achieved, indicating a very high agreement among the annotators.

Quantitative Content Analysis

A quantitative content analysis using the previously coded messages was applied to produce descriptive statistical data to assess the frequencies of the social support categories. In addition, statistical analyses were conducted using chi-square

tests for independence to assess whether there were overall significant differences between the frequencies of social support categories for each diabetes stage. A threshold significance level of $P<.05$ was adopted ($\alpha=.05$). Once statistically significant differences were identified, post hoc analyses with Bonferroni corrections to control for type I errors were adopted [53] to establish where significant differences existed between social support categories ($P<.001$).

Ethics Approval

The study has been approved by the University of Sheffield Research Ethics Committee (application 032675).

Results

Quantitative Content Analysis

A total of 1841 messages (92.05% of the total 2000 messages) were coded according to social support categories. Table 1 presents the frequency counts of each social support category for each stage of diabetes. Overall, most of the messages contained seeking informational support category (605/1841, 32.86%) and providing informational support category (605/1841, 32.86%), followed by network support category (357/1841, 19.39%), seeking emotional support category (57/1841, 3.09%), achievement category (71/1841, 3.85%), congratulations category (69/1841, 3.74%), and providing emotional support category (57/1841, 3.09%). The chi-square analysis showed that the overall distribution of social support categories was significantly different across the diabetes stages ($\chi^2_{18}=287.2$; $P<.001$). To further understand where the significant differences between social support categories and diabetes stages existed, post hoc comparisons were conducted. The significance level (α) was set at.001.

The post hoc comparisons indicated that users in the prediabetes stage sought more informational support (163/243, 67.1%; $P<.001$) and provided less informational support (7/243, 2.8%; $P<.001$) than those in other diabetes stages. There were no significant associations between people in the T2D stage and any of the social support categories ($P>.001$). People in the T2D insulin stage were significantly more likely to provide emotional (33/637, 5.2%; $P<.001$) and informational (261/637, 41%; $P<.001$) support. In addition, there was an association between people in the T2D insulin stage and network support (84/637, 13.2%; $P<.001$). People in the T2D remission stage exchanged more achievement (27/383, 7%; $P<.001$) and network support (122/383, 31.9%; $P<.001$), while seeking significantly less informational support (86/383, 22.5%; $P<.001$) than those in other stages. There were no significant differences between all the diabetes stages and congratulations category ($P>.001$) and seeking emotional support category ($P>.001$).

Table 1. Frequencies of social support categories per diabetes stage (N=1841).

Social support category	Total (N=1841), n (%)	Prediabetes (n=243), n (%)	*P* value	T2D[a] (n=578), n (%)	*P* value	T2D insulin (n=637), n (%)	*P* value	T2D remission (n=383), n (%)	*P* value
Achievement	71 (3.9)	13 (5.3)	.19	16 (2.8)	.11	15 (2.4)	.02	27 (7)	<.001[b]
Congratulations	69 (3.7)	1 (0.4)	.004	26 (4.5)	.27	31 (4.9)	.07	11 (2.9)	.32
Network support	357 (19.4)	38 (15.6)	.11	113 (19.6)	.92	84 (13.2)	<.001[b]	122 (31.9)	<.001[b]
Seeking emotional support	85 (4.6)	19 (7.8)	.009	33 (5.7)	.13	21 (3.3)	.046	12 (3.1)	.11
Seeking informational support	605 (32.9)	163 (67.1)	<.001[b]	164 (28.4)	.005	192 (30.1)	.07	86 (22.5)	<.001[b]
Provide emotional support	57 (3.1)	2 (0.8)	.03	16 (2.8)	.62	33 (5.2)	<.001[b]	6 (1.6)	.06
Provide informational support	597 (32.4)	7 (2.8)	<.001[b]	210 (36.3)	.02	261 (41)	<.001[b]	119 (31.1)	.55

[a]T2D: type 2 diabetes.

[b]Bonferroni *P* value to correct for multiple comparisons; results were considered statistically significant at $P<.001$.

Qualitative Content Analysis

The qualitative content analysis for each social support category is described in the following sections. Any identifying information (eg, date of birth) was removed, and forum posts were paraphrased in such a way that they retained their meaning while ensuring that they could not be tracked through search engines.

Seeking Information Support

Users mostly solicited advice from peers with similar experiences by using statements such as “does anyone else.” These users normally started threads by disclosing personal health information (eg, test results) before asking specific questions. For example:

> *I have been so thirsty! My blood sugars are up to 6 in the morning and 6.4 throughout the day. Does anyone else feel like this?*

Users also sought advice from peers by seeking actionable thoughts and directions about how to cope with their diabetes challenges. For example, 1 user described her issue of self-disclosed information about her blood glucose readings before requesting advice:

...Should I expect these high levels? What are your opinions please?

Other messages involved requests for factual information or clarification of information that health care professionals would typically address. Topics included information regarding diabetes, blood test results, and medications.

Providing Informational Support

Messages in this category mostly offered advice or suggestions for coping with the difficulties of diabetes (eg, illness management). Such messages normally involved using modal verb expressions (eg, "you can") for support seekers to contemplate a course of action to overcome their problems. Other messages referred users to other sources of information, including seeking input from health care professionals, textbooks, and predominantly relevant websites. For example:

You may find useful information in the NHS Choices website http://www.nhs.uk/...

Some messages provided to new users or newly diagnosed individuals had an educational role. These included sharing factual and technical information or teaching users about various aspects of diabetes management. For example:

A low carb diet is good for weight control because when you eat fat, your fat cells don't store fats without insulin being in your body.

Network Support

Messages categorized under "Network support" often involved interactions between new members and users of the forum. For instance, new users who were often recently diagnosed introduced themselves and explicitly expressed the intention to meet and to get to know people. For example:

Hello guys, I am a new member... I look forward to talking with you.

Forum members often responded to new members by welcoming them, and reminding them that they were always there to help and support people:

The forum members are amazing and you are no longer alone... Welcome

These messages also focused on expanding new members' existing social networks by tagging more experienced users in the posts for further support. Furthermore, they encouraged new members to continue using the forum and keep everyone informed of any progress or difficulties. For example:

...come back with any questions you have.

Members also participated in companionship activities by posting off-topic messages (eg, television programs) that promoted social interactions and enjoyment among users. Finally, several users discussed the specific technical features of the forum and how to use them.

Seeking Emotional Support

Most of the messages in this category included users writing about their negative feelings and emotions (eg, sadness) regarding their experiences with the condition without making direct questions:

I am so fed up!!!!...If you have read all this post then you have a lot of patience. I just thought that it would make me feel good to share.

Achievement

These messages normally involved users sharing their health achievements (eg, weight loss) for peers to read. Such achievements even included the improvement of other health-related problems (eg, macular degeneration). By posting messages, users shared self-reflection on their illness journey by providing periodic updates of their progress and blood test results. From these achievements, users recognized and acknowledged the helpfulness and support provided by peers for making progress on their health goals:

I'm very happy with myself and I am grateful to the forum for continued good advice.

Congratulations

Users praised the diabetes-related achievements of others by mostly conveying positive and complimenting expressions such as "*well done*" and "*congratulations*." Other messages also expressed confidence or encouraged peers to believe in their abilities to further achieve positive diabetes health outcomes:

Well done. It may be a small reduction but you are going in the right direction.

Providing Emotional Support

These messages were often provided to users who were struggling to contend with distressing feelings associated with diabetes and required affirmation. Most of these responses involved empathetic messages, expressing understanding and sharing similar situations, thoughts, and feelings: "The same happened to me." In particular, users rephrased the situations that their peers were experiencing and validated that they understood their situations:

I understand how you must feel.

In contrast, when users could not personally relate to peers' experiences, they expressed sympathy and condolences about their situation. These messages included communication of compassion with regret expressions for peers' distress, such as "sorry to hear." They also included expressions of encouragement, such as "good luck," for recipients. Finally, in some messages, emotional support was offered by sending web-based physical affection messages through contact gestures, including hugs, kisses, and use of emojis:

Oh you poor thing. Sending you big hugs.

Discussion

Principal Findings

To the best of our knowledge, this is the first study to assess the types and frequency of social support categories exchanged on a DOC, taking into consideration the different stages of diabetes. The DOC addressed 3 categories from the SSBC model

[18]: informational, emotional, and network support, which have been found to be the main categories in OHCs [47]. In addition, the results enriched this model by adding 2 new unique categories that did not necessarily express direct support but facilitated online social support exchanges, namely, achievement and congratulations. Here, many users announced personal victories associated with diabetes, while their peers typically congratulated them and often encouraged them to go further. These categories have previously been reported to be present in online forums for people recovering from alcohol-related problems [54] and communities for people seeking weight loss [55], where they promoted a sense of belonging and self-confidence among users. This suggests that the platform may be a valuable outlet for users to celebrate their successes and provide positive reinforcement for the challenging behavioral modifications required for diabetes management.

Overall, the content analysis of 1841 posts indicated that this community was mostly used by individuals to seek and provide informational support. These findings are consistent with those of previous studies, suggesting that a significant number of people with diabetes use OHCs to find and provide health-related information [7,23,56,57]. Moreover, these results appeared to support the Optimal Matching Model [50], which proposes that the nature and controllability of a stressor determine the type of social support that will most likely be beneficial for an individual. This indicates that individuals with controllable stressors benefit the most from informational support, which helps them to solve, manage, or eliminate the stressor. In contrast, individuals with uncontrollable stressors should benefit from emotional support, which helps them cope with the stressor without direct efforts to eliminate it, but rather to make them feel cared for [50]. In many cases, the different stages of diabetes investigated in this study can be considered "controllable events," as there are several recommended approaches (eg, diet) that an individual can adopt to either manage diabetes or even put it into remission. Accordingly, informational support was requested and provided more often than emotional support in this DOC. Previous studies investigating social support in OHCs like HIV [20,57], cancer [58-60], eating disorders [61], infertility [62,63], and complex regional pain syndrome [64] have supported the Optimal Matching Theory.

When analyzing the different stages of diabetes, informational support was the most frequently sought social support and was provided less in users with prediabetes than users in other diabetes stages. Although there is scarce evidence regarding the use of OHCs by users with prediabetes, previous studies suggest that these patients have less understanding of the disease than people with T2D [65] and require tailored information about diabetes, nutrition, and exercise [66]. Therefore, these individuals may have unmet informational support needs and thus are likely to seek these via other sources, such as OHCs. The results also showed that users with prediabetes provided less information support than users in other diabetes stages. This may be attributed to the users' web-based engagement as observed in other OHCs [47]. For example, at first, users with prediabetes may be very active in the community asking for informational support, but once their information needs are met, they are more likely to leave the OHC.

Conversely, the distributions of all social support categories in users with T2D were not significantly different when compared with other stages of diabetes. These categories may be equally important for users with T2D to use and establish effective foundations for future interactions and relationship development in the community. Providing informational support may be the first step in this process, whereas by seeking informational support, they may communicate on a more personal level with their peers and engage further in community relationships by exchanging network support.

The provision of support, including informational and emotional support, was posted more frequently by users with T2D under insulin treatment than those in other stages. These users offered factual information aligned with professional knowledge and advice, referred members to external sources of information, shared personal experiences, and also expressed positive and uplifting messages to other members. Interestingly, these users tended to play the role of experienced members with diabetes, whose regimens were settled. Accordingly, as these users had experienced diabetes over a long time, they could potentially feel more comfortable or inclined to share their knowledge and experience more widely to support seekers and feel more sympathy toward the emotional burdens experienced by people with diabetes (eg, anxiety derived from treatment) [67]. They might also feel compelled to reciprocate and give support out of gratitude to the community that helped them [68]. Finally, when discussing topics requiring professional knowledge, these users would often refer peers to seek medical advice from doctors to ensure safety. This highlights the need for further research to consider the quality, accuracy, and trustworthiness of the information and any hyperlinks to other sources provided by users. This may help to determine the extent of misinformation and alleviate the uncertainty that individuals may experience when using OHCs.

Finally, people who were in remission from T2D were more likely to exchange more achievement and network support and were less likely to seek informational support than those in other stages. These users gained knowledge about diabetes over time and shared their successful personal achievements in gratitude for the help that they received from the community. Reciprocating and sharing these achievements may work as a knowledge-sharing process that may motivate others to achieve similar health goals or behaviors [69,70]. Consequently, it may enable others to learn safer and more efficient strategies to manage their diabetes rather than trying and failing, suggesting that sharing achievements could be used as a strategy to motivate participation in health-related interventions. These users also played a central role in welcoming and reinforcing the availability of similar users to new members, offered access to other users for further support, and chatted about off-topic content unrelated to diabetes. Interestingly, regardless of the users' remission status, they continued to engage more in social interactions rather than seeking or offering direct support. This suggests that network support may contribute to high community commitment for these users over time, and they may play an important role in sustaining the longevity of the community.

Such engagement in web-based companionship activities has been found to foster the formation of friendship ties and strong bonds more than informational and emotional support and to further contribute toward users' continued engagement [47].

The findings of this study have important theoretical, research, and practical implications for online social support in OHCs. This is the first study to analyze web-based messages exchanged between users with different stages of diabetes, whereas previous studies have typically examined social support exclusively in people with type 1 diabetes or T2D in offline settings and applied methods such as surveys, focus groups, and interviews [71-73]. The use of a validated theoretical framework and subsequent modifications ensured that the categories were well defined in the online diabetes context and included a comprehensive coding system that yielded a high level of agreement between 2 independent annotators. Therefore, this study provides further evidence for the generalizability of this model to assess online social support exchanges in a diabetes community.

Implications

As the first content analysis on this topic, our research provided empirical evidence on the distribution of social support categories in a DOC and how these are expressed. This finding may serve as a basis for future research. In particular, the data may be used to develop automated machine learning classifiers capable of coding data on a larger scale to support or discover new relationships that could not really be assessed through hand-coding messages.

Our findings also have practical implications for multiple stakeholders. Health care providers might be supported with information about how to maximize the full effectiveness of social support and the stages of the condition that these types of support may be beneficial. The findings can help administrators to create dynamic recommendation services, including information about frequently asked questions that concern members the most and access to more experienced members. Consequently, users may receive targeted support at different stages of diabetes, which may prevent them from posting similar questions, reduce information redundancy, and improve accessibility of useful information.

Limitations and Future Work

This study has potential limitations that may require further research. First, messages posted in a single DOC were analyzed and the extent to which the observed patterns of social support categories are generalizable to other DOCs warrants further research. Further studies assessing recipients' interpretations of whether the messages were perceived as being supportive in the way intended or according to the annotated categories could be useful as an additional source of data. Second, the annotators were advised to select 1 main category per message. These messages could potentially have >1 category present (eg, provide emotional and informational support), and therefore, this could have an effect on the observed low frequencies of emotional support exchanges. Future research may need to incorporate a multilabel scheme that expands the annotation task at the sentence level. Nevertheless, it is worth mentioning that the single-label approach in this study produced a high level of agreement among annotators. Finally, the amount of data analyzed alone does not allow us to ascertain the distribution of social support categories in this community. However, this study provides a good basis for building a more comprehensive evaluation in the future, which will be improved in future research.

Conclusions

Overall, most posts in this DOC involved users seeking and providing informational support. In particular, users with prediabetes were more likely to seek informational support than those in other diabetes stages, whereas there were no significant differences between the social support categories posted by the users with T2D. Users with T2D and under insulin treatment provided more informational and emotional support, and users with T2D remission exchanged more achievement and network support compared with those in other stages. This study supported the idea that different social support categories are more prominent in different types of diabetes. Findings from this study await further insights into these exchanges by using a larger sample size and supervised machine learning approaches.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Social support classification guide.
[DOCX File , 18 KB - diabetes_v8i1e41320_app1.docx]

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Abbreviations

DOC: diabetes online community
OHC: online health community
SSBC: Social Support Behavior Code
T2D: type 2 diabetes

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Original Paper

The Effectiveness of an App (Insulia) in Recommending Basal Insulin Doses for French Patients With Type 2 Diabetes Mellitus: Longitudinal Observational Study

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Abstract

Background: For patients with type 2 diabetes (T2D), calculating the daily dose of basal insulin may be challenging. Insulia is a digital remote monitoring solution that uses clinical algorithms to recommend basal insulin doses. A predecessor device was evaluated in the TeleDiab-2 randomized controlled trial, showing that a higher percentage of patients using the app achieved their target fasting blood glucose (FBG) level compared to the control group, and insulin doses were adjusted to higher levels without hypoglycemia.

Objective: This study aims to analyze how the glycemic control of Insulia users has evolved when using the app in a real-life setting in France.

Methods: A retrospective observational analysis of data collected through the device in adult French patients with T2D treated with basal insulin and oral antihyperglycemic agents using the system for ≥6 months was conducted. Analyses were descriptive and distinguished the results in a subpopulation of regular and compliant users of the app. Glycemic outcomes were estimated considering the percentage of patients who achieved their individualized FBG target between 5.5 and 6 months following the initiation of device use, the frequency of hypoglycemia resulting in a treatment change over the 6-month period of exposure, and the evolution of the average hemoglobin A_{1c} (HbA_{1c}) level over the same period.

Results: Of the 484 users, 373 (77.1%) performed at least one dose calculation. A total of 221 (59.2%) users were men. When app use started, the mean age, BMI, HbA_{1c}, and basal insulin dose were 55.8 (SD 11.9) years, 30.6 (SD 5.9) kg/m^2, 10.1% (SD 2.0%), and 25.5 (SD 15.8) IU/day, respectively. Over a median use duration of 5.0 (95% CI 3.8-5.7) months, patients used the system 5.8 (SD 1.6) times per week on average, and 73.4% of their injected doses were consistent with the app's suggested doses. Among regular and compliant user patients (n=91, ≥5 measurements/week and ≥80% adherence to calculated doses), 60% (55/91) achieved the FBG target (±5%) at 6 months (5.5-6 months) versus 51.5% (145/282) of the other patients (*P*=.15). There was an increase in the proportion of patients achieving their target FBG for regular and compliant users (+1.86% every 2 weeks) without clear improvement in other patients. A logistic model did not identify the variables that were significantly associated with this

outcome among regular and compliant users. In the overall population, the incidence of reported hypoglycemia decreased simultaneously (–0.16%/month). Among 82 patients, the mean HbA_{1c} decreased from 9.9% to 7.2% at 6 months.

Conclusions: An improvement in glycemic control as measured by the percentage of patients reaching their FBG individualized target range without increasing hypoglycemic risk was observed in patients using the Insulia app, especially among regular users following the dose recommendations of the algorithm.

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KEYWORDS

diabetes mellitus; insulin; medical informatics apps; telemedicine; mobile health; mobile health intervention; health app; digital monitoring; remote monitoring; virtual care; clinical algorithm

Introduction

For patients with type 2 diabetes (T2D), achieving recommended glycemic targets remains difficult, especially in people treated with basal insulin. One of the reasons for this difficulty is related to the challenge of titrating insulin doses. Insulia is a digital solution combining a smartphone app for basal insulin dose suggestions and a web portal accessible to professionals to personalize and manage patients' treatments remotely. Beyond remote monitoring of basal insulin therapy, the app uses the data entered by the patients to calculate the recommended basal insulin dose according to the objectives set by the patient's physician. This dose calculation is triggered by the patient's request.

A predecessor device to Insulia called Diabeo-Basal was evaluated in the TeleDiab-2 study [1]. This randomized controlled trial evaluated the efficacy and safety of two remote monitoring systems to optimize basal insulin initiation in patients with poorly controlled T2D (hemoglobin A_{1c} [HbA_{1c}] 7.5%-10%). A total of 191 participants (mean age 58.7 years, mean HbA_{1c} 8.9%) were randomized into three groups: group 1 (standard care, n=63), group 2 (interactive voice response system, n=64), and group 3 (Insulia app software, n=64). After 4 months of follow-up, HbA_{1c} reduction was significantly higher in the remote monitoring groups (group 2: –1.44% and group 3: –1.48% vs group 1: –0.92%; *P*=.002). In addition, twice as many patients in the telemonitoring groups achieved their target fasting blood glucose (FBG) level as in the control group, and insulin doses were adjusted to higher levels. No severe hypoglycemia was observed in the remote monitoring groups, and the frequency of mild hypoglycemia was similar in all groups.

Consequently, Insulia was available by prescription and used in France as part of a nationwide program financing new health remote monitoring systems (Expérimentations de télémédecine pour l'amélioration des parcours en santé [ETAPES] program: National Experiments on Remote Diabetes Monitoring [2]) since the end of 2020. Despite the potential benefits for patients suggested by the TeleDiab-2 study, Insulia, as with other apps offering insulin dose calculation, carries a risk of incorrect dose recommendations, which could lead to suboptimal disease control [3]. In this field, perhaps even more than for other health products, it is necessary to complement experimental results with the analysis of monitoring data on both the clinical efficacy and safety of the apps during their use in real life.

The data entered by the patients and their physicians in the Insulia app are collected on a dedicated computer platform. This study aims to analyze this database to determine how the glycemic control of Insulia users has evolved when using the app in a real-life setting in France.

Methods

Overview

The Insulia app is presented in Multimedia Appendix 1. From the Insulia app's home screen, patients can enter their blood glucose monitoring, hypoglycemia symptoms, and insulin doses. Insulia takes this data into account to recommend personalized doses in real time. Each recommended dose is accompanied by an explanation of how it was calculated. Data is automatically sent to the health care team so that they can monitor the patient's progress and even adjust the treatment. The ETAPES program funds the device for 6 months for patients with T2D diagnosed more than 12 months ago, who are 18 years or older, with an HbA_{1c} ≥9% on two measurements taken within a 6-month interval, and treated with insulin. It also funds the device for a maximum of 3 months in patients with T2D diagnosed for more than 12 months who were 18 years or older at the time of insulin initiation when their HbA_{1c} level was <9% at two measurements taken within a 6-month interval.

A retrospective observational study was conducted using data collected through the Insulia device in adult patients with T2D who were treated with basal insulin and oral antihyperglycemic regimen and who were enrolled as users of the solution for 6 months or more by September 30, 2021.

A subpopulation of regular and compliant users was identified. These are patients who have used the device for at least 6 months without interruption with at least 5 dose calculations per week on average during the study period and for whom more than 80% of their injected insulin doses corresponded to the recommended doses.

Glycemic outcomes were estimated considering the percentage of patients who achieved their individualized glycemic target (average FBG level ±5%) between 5.5 and 6 months following the initiation of the device use.

Other criteria included the frequency of hypoglycemia resulting in a change in treatment over the 6-month period of exposure and the evolution of the average HbA_{1c} level over the same period of time (+/– 1.5 months). HbA_{1c} level was not considered

as the primary glycemic outcome as the collection of this data is not mandatory in the app, which determines the insulin doses to be administered based on FBG levels.

A multivariate regression analysis was finally conducted on the achievement of the FBG objective, including a subgroup analysis considering the patients from the center with the most patients versus other patients to identify a possible center effect.

Ethical Considerations

This study was conducted in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and the free movement of such data. Informed consent of the patients was not requested as the data analyzed were fully anonymized. A full privacy impact assessment was conducted on July 29, 2021.

Results

The Insulia database included 484 patients enrolled as users of the app for 6 months or more. Among them, 111 patients did not conduct any dose calculation with the device or did not indicate any basal insulin dose injected since their registration on the app. Consequently, 373 patients were considered in the main analysis. Among them, 91 (24.4%) patients were identified as regular and compliant users over a 6-month period.

The characteristics of the patients are described in Table 1. On average, they were aged 55.8 (SD 11.9) years, and 59.2% (n=221) were men. At the time of their first use of the Insulia device, 48.6% (n=181) of them had a BMI ≥30 kg/m^2 (average BMI 30.6 kg/m^2). The mean HbA_{1c} level was 10.1% (SD 2%). The individual FBG target ranged from 70-100 to 100-150 mg/dL. The target ranges were 80-130 mg/dL for 33.5% (n=125) of the patients and 80-120 mg/dL for 30% (n=112) of the patients. The first calculated basal insulin dose averaged 25.5 IU with significant variability (between 4 IU and 92 IU according to the patients). Among compliant and regular users (n=91, 24.4% of the patients over the 6 months of observation), the HbA_{1c} level at baseline was slightly lower compared to other patients (9.6% vs 10.3%; *P*=.002), and the FBG target was slightly more stringent, with a higher proportion of patients having an FBG target in the range of 80-120 mg/dL and a lower proportion in the range of 100-150 mg/dL.

The percentage of patients defined as regular and compliant users evolved during the 6-month period of the study with a progressive disaffection of the patients from the second month of use. A similar evolution was observed considering only regular use of the device (at least 5 dose calculations per week; Figure 1).

Figure 2 shows the percentage of Insulia users with an average FBG in their individualized target range over 15-day periods according to whether they are regular and compliant users. The percentages are calculated on the number of patients still using the device over the 15-day period. We observed an increase in the proportion of patients achieving their target FBG for regular and compliant users (+1.86% every 2 weeks). No clear improvement was observed in other patients (irregular or not compliant users of the app).

After 6 months of use (5.5 to 6 months), the FBG target was achieved in 60% (55/91) of the regular and compliant users versus 51.5% (145/282) of the other patients (*P*=.15), although the FBG target was slightly more stringent for the regular and compliant users.

Variables available at baseline (age, gender, BMI, HbA_{1c} level, and insulin dose at Insulia initiation) were tested in a logistic model to explain potential factors associated with achieving the individualized FBG target at 6 months among regular and compliant users (n=91; Figure 3). None of these variables were significantly associated with this outcome.

Figure 4 presents the evolution of the HbA_{1c} level over time for patients having at least 2 measurements regardless of the time elapsed between these two measurements (all patients, n=182, and all regular and compliant users, n=69). In both cases, a slight but significant decrease in HbA_{1c} values of –0.155% and –0.161% per month, respectively, was observed.

Data were available at baseline and 6 months for only 82 patients. The mean HbA_{1c} level decreased from 9.9% to 7.2% after 6 months (±1.5 months) of app use, with no significant difference according to the degree of Insulia use.

Table 2 shows the numbers and proportions of patients who reported in the app that they had at least one change in treatment because of hypoglycemia, defined as a blood glucose measurement <70 mg/dL and whether this hypoglycemia was symptomatic or not. A favorable trend (–0.16% per month) was observed but not statistically significant due to the low number of patients.

Finally, to identify a possible center effect, a subgroup analysis was conducted on the sample of patients enrolled in the principal investigating center (Centre Hospitalier Sud Francilien [CHSF], Corbeil-Essonnes) where 68 (18.3%) patients of the overall population considered in the analysis (N=373) were enrolled. The baseline characteristics of those patients were similar to those of other centers, excluding a higher average HbA_{1c} level at the time of the first basal insulin dose calculation (10.9%, SD 2.3% vs 10.0%, SD 1.9%). Interestingly, individualized FBG targets were also often less strict in this center than in other centers (patients with a target between 100-150 mg/dL: 20/68, 29.4% vs 12/305, 3.9%), and over the first 6 months, patients at the CHSF were less often regular and compliant users than at the other centers (9/68, 13.2% vs 82/305, 26.9%; *P*=.02). Despite these discrepancies, the percentage of Insulia app users achieving their FBG target after 6 months was not different considering the overall population (*P*=.77) or only regular and compliant users (*P*=.75), excluding a center effect on the results.

Table 1. Patients' characteristics (at the time of the first basal insulin dose calculation).

	Regular and compliant users (n=91)	Other patients (n=282)	Total (N=373)	*P* value
Gender (male), n (%)	52 (57.1)	169 (59.9)	221 (59.2)	.64
Age (years), mean (SD)	58.0 (9.4)	55.3 (12.2)	55.8 (11.9)	.06
Age (years), n (%)				.10
<40	1 (1.1)	29 (10.3)	30 (8.3)	
40-50	17 (18.7)	54 (19.2)	71 (19.0)	
50-60	35 (38.5)	90 (31.9)	125 (33.4)	
60-70	28 (30.8)	77 (27.3)	105 (28.1)	
70-80	8 (8.8)	29 (10.3)	37 (10.0)	
≥80	2 (2.2)	3 (1.1)	5 (1.3)	
Clinical characteristics				
BMI (kg/m^2), mean (SD)	31.0 (5.0)	30.4 (6.1)	30.6 (5.9)	.49
BMI (kg/m^2), n (%)				.06
<26.5	15 (16.5)	77 (27.3)	92 (24.7)	
26.5-30	33 (36.6)	67 (23.8)	100 (26.8)	
30-35	25 (27.5)	80 (28.4)	105 (28.2)	
≥35	18 (19.8)	58 (20.6)	76 (20.4)	
HbA_{1c}[a] level (%)				.002
Mean (SD)	9.6 (1.4)	10.3 (2.1)	10.1 (2.0)	
Median (min, max)	9.5 (6.8, 13.0)	9.8 (6.0, 18.8)	9.7 (6.0, 18.8)	
Quartile 1, quartile 3	8.7, 10.3	9.0, 11.5	8.8, 11.2	
FBG[b] target as defined by the practitioner (mg/dL)				.02
80-130	30 (33.0)	95 (33.7)	125 (33.5)	
80-120	36 (39.6)	76 (27.0)	112 (30.0)	
100-150	2 (2.2)	30 (10.6)	32 (8.6)	
Other	23 (25.3)	81 (28.7)	104 (27.9)	
Treatment				
First calculated insulin dose (UI)				.58
Mean (SD)	26.3 (17.1)	25.2 (15.4)	25.5 (15.8)	
Median (min, max)	22.0 (4.0, 74.0)	20.0 (4.0, 92.0)	20.0 (4.0, 92.0)	
Quartile 1, quartile 3	14.0, 32.0	14.0, 32.0	14.0, 32.0	

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

[b]FBG: fasting blood glucose.

Figure 1. Percentage of patients who were regular and compliant Insulia users over time.

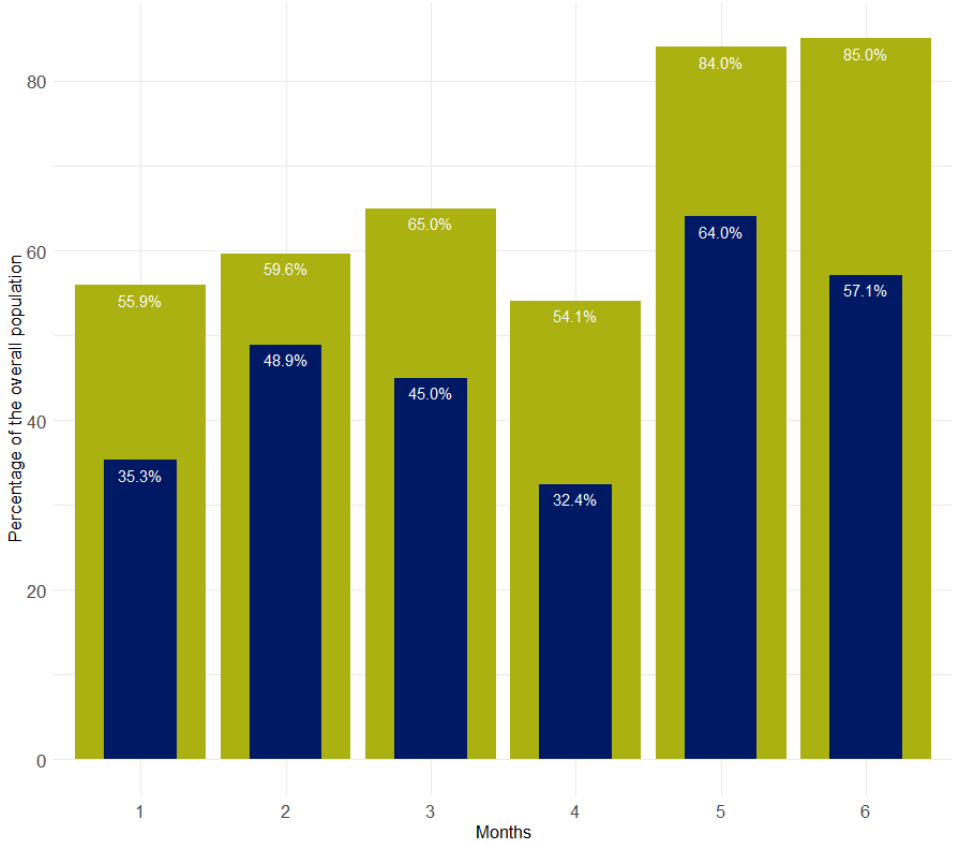

Figure 2. Percentage of Insulia users achieving their individualized fasting blood glucose target over time.

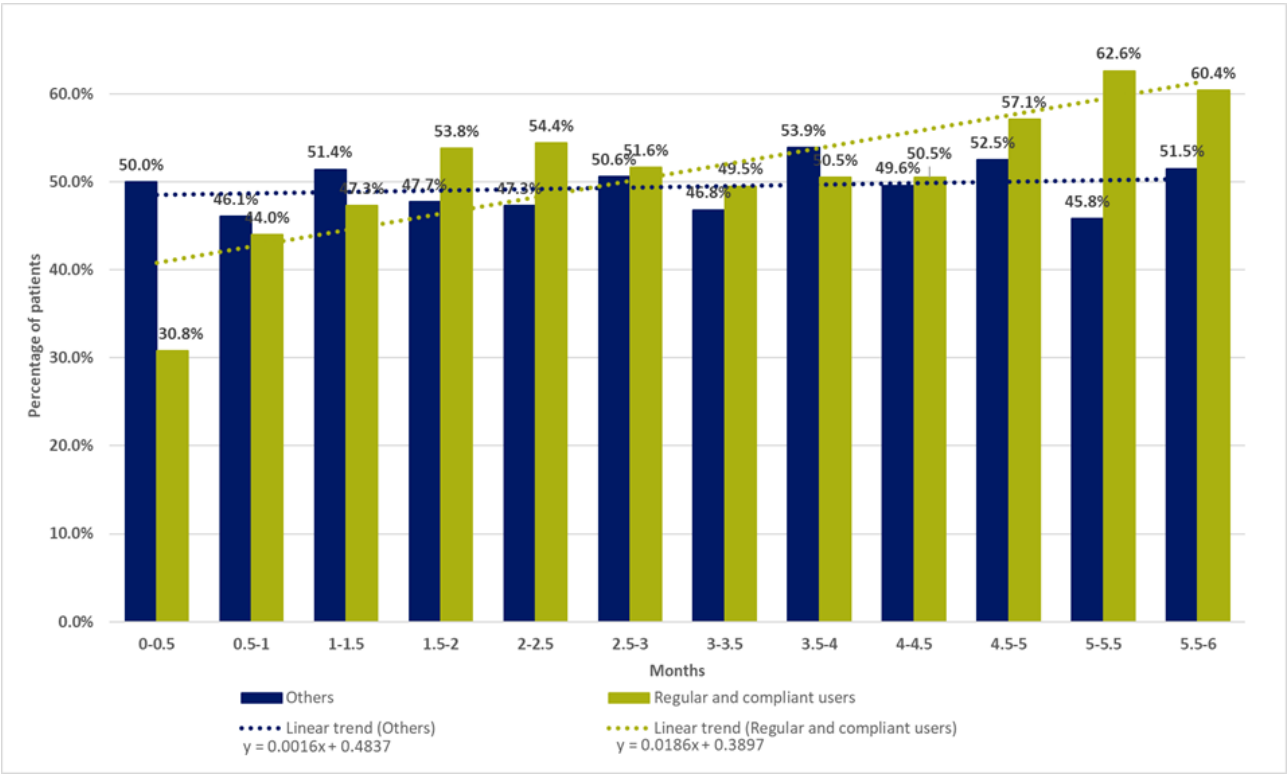

Figure 3. Explanatory logistic model for achieving the individualized fasting blood glucose target after 6 months among regular and compliant users (n=91). HbA_{1c}: hemoglobin A_{1c}; OR: odds ratio.

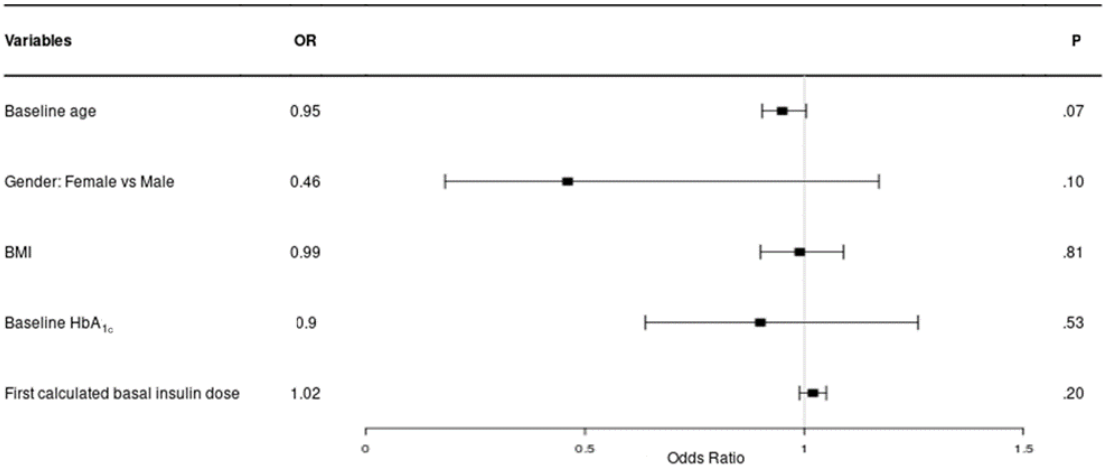

Figure 4. Trends in HbA_{1c} level evolution over 6 months of Insulia app use. HbA_{1c}: hemoglobin A_{1c}.

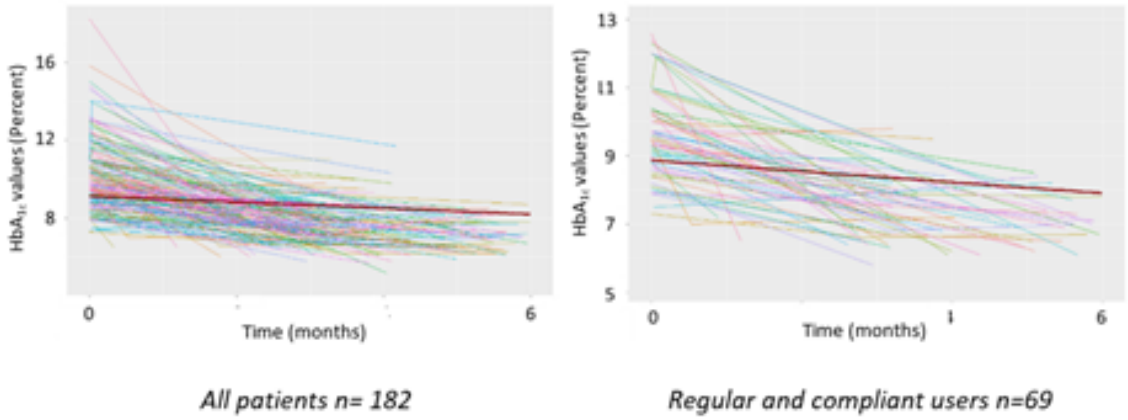

Table 2. Percentage of patients reporting a hypoglycemic episode over a 6-month period using the Insulia app.

Month of use	Patients with at least one BG[a] measure <70 mg/dL, n (%)	Patients with at least one BG measure <70 mg/dL with symptomatic hypoglycemia, n (%)	Patients with at least one BG measure <70 mg/dL with asymptomatic hypoglycemia, n (%)
0-1	17 (17.7)	14 (15.4)	5 (5.5)
1-2	15 (16.5)	12 (13.2)	3 (3.3)
2-3	18 (19.8)	16 (17.6)	2 (2.2)
3-4	12 (13.2)	9 (9.9)	5 (5.5)
4-5	12 (13.2)	11 (12.1)	1 (1.1)
5-6	9 (9.9)	9 (9.9)	1 (1.1)

[a]BG: blood glucose.

Discussion

Principal Findings

More technologies are being developed to assist in outpatient insulin dosing [4], but few of them are intended to adjust long-acting insulins for patients with T2D. After reviewing patients' data, medical history, comorbidities, and current treatment, providers formulate initial insulin dose and titration plans. A target blood glucose range is defined individually as other criteria including adjustment period, low blood glucose threshold, and maximum total daily doses. Patients are supposed to log their FBG readings and episodes of hypoglycemia events or administered insulin doses. Based on these inputs, the system recalculates the next appropriate dose of basal insulin. Franc et al [1] reported on the TeleDiab-2 trial that, at month 4, twice as many patients using such a device compared to the control group achieved an HbA_{1c} level <7% (29.8% vs 12.5%). Other similar devices have also shown positive results [5,6]. However, the translation of clinical trial results into real life often raises a series of questions that lead to an interest in conducting postmarketing observational studies of products. This is especially the case when the assessed technology is strongly

dependent on the involvement of the patients who use it as well as on the nature of the support implemented by the professionals around the technology.

Following the marketing of the Insulia device in France, we aimed to examine the results obtained in real life by the users of such a solution. This study was conducted based on data collected through the system itself, which constitutes a methodological limitation due to the relatively large number of missing data on some outcomes (ie, HbA_{1c} level evolution). Nevertheless, some results were of interest. First, the device cannot be expected to have a positive effect if it is not used by the patient. About one-fifth of the patients did not use it after the first inscription on the device, and among users, only 37% (138/373) were still regular users, and 24.4% (91/373) were regular and compliant users after 6 months. We noted a progressive disaffection of the patients with time; even in the first 3 months, only half of the patients were regular users and slightly more than one-third of the patients were both regular and compliant users.

As anticipated, the impact on glycemic control was significantly better among regular and compliant users, with an individualized FBG target achieved in 60% (55/91) of patients after 6 months versus 51.5% (145/282) in other patients using Insulia less frequently. The trend in the proportion of patients achieving their target FBG (+1.86% every 2 weeks for regular and compliant users) and the HbA_{1c} level decrease (from 9.9% to 7.2%) after 6 months (±1.5 months) of app use are in the same direction as the results obtained in clinical trials but were clearly less favorable. The patient selection and close monitoring generally implemented in clinical trials is one possible explanation for this situation. Another explanation probably lies in the fact that, in the TeleDiab-2 study as well as the Bergenstal et al [7] study, the included patients benefited from sustained human support, which was not necessarily the case in our real-life observational study. This probably reflects the importance of the support that must be provided to patients when a tool such as Insulia is offered to them. It also highlighted the necessity to conduct as often as possible pragmatic trials to estimate the added value of such devices.

Conclusion

In real life, an improvement in glycemic control as measured by the percentage of patients reaching their FBG individualized target range without increasing the incidence of hypoglycemia was observed in patients regularly using the Insulia app and following the dose recommendations of the algorithm. However, these results should be confirmed on a larger population as no significant difference according to the degree of Insulia use was observed considering HbA_{1c} level results.

Acknowledgments

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Authors' Contributions

CN contributed to the methodology and formal analysis. NG, B Delemer, and SB contributed to the investigation and reviewing and editing. B Detournay contributed to the conceptualization, methodology supervision, and writing of the original draft. A Benkhelil contributed to the funding acquisition, project administration, and reviewing and editing. A Bahloul contributed to the conceptualization and reviewing and editing. GdO contributed the resources. AP contributed to the conceptualization, supervision, investigation, and reviewing and editing.

Conflicts of Interest

B Detournay and CN are employed by Cemka, a consulting team specializing in health economics, epidemiology, and outcomes research. B Detournay also received personal compensation for board participation and speaking fees from Merck Sharp & Dohme, Novo-Nordisk, Sanofi, Eli Lilly, Janssen, and Pfizer. B Delemer received personal compensation for board participation and speaking fees from Abbott, Astra Zeneca, Eli Lilly, Insulet, Medtronic, Novo Nordisk, Pfizer, Recordati, Sanofi, and Timkl. NG received personal compensation for board participation and speaking fees over the last 5 years from Asdia, Astra-Zeneca, Boehringer Ingelheim, Eli Lilly France, LifeScan, Medtronic, Merck Serono, Novo Nordisk, Sanofi Aventis, and Vitalaire. SB received personal compensation for board participation and speaking fees over the last 5 years from Amgen, Arair Assistance, Asdia, Astra-Zeneca, Asten Santé Est, Axis Santé, Bastide Le Confort Médical, Dinno santé, Eli Lilly France, Insulet, LifeScan, Medtronic, Merck Sharp & Dohme, Nestle Homecare, Novo Nordisk, Roche Diabetes Care, Sanofi Aventis, and Vitalaire. A Benkhelil and A Bahloul are employed by Sanofi, France. GdO is employed by Voluntis, France. AP received personal compensation for board participation and speaking fees from Abbott, Ascencia, Astra-Zeneca, Eli Lilly, Medtronic, Merck Sharp & Dohme, Novartis, Novo Nordisk, and Sanofi Aventis.

Multimedia Appendix 1
Insulia app description.
[DOCX File , 196 KB - diabetes_v8i1e44277_app1.docx]

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Abbreviations

CHSF: Centre Hospitalier Sud Francilien
ETAPES: Expérimentations de télémédecine pour l'amélioration des parcours en santé
FBG: fasting blood glucose
HbA_{1c}: hemoglobin A_{1c}
T2D: type 2 diabetes

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Original Paper

Adaptation of an Adult Web Application for Type 1 Diabetes Self-management to Youth Using the Behavior Change Wheel to Tailor the Needs of Health Care Transition: Qualitative Interview Study

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Abstract

Background: Youth (aged 14-24 years) living with type 1 diabetes (T1D) encounter increased challenges in their diabetes self-management (DSM), especially during the transition to adult care. Although DSM education and support are imperative, there is insufficient information on how web-based digital tools tailored to their demands can be developed.

Objective: On the basis of the Behavior Change Wheel, this study aims to identify, among youth living with T1D, the needs and factors influencing their DSM in the context of health care transition and to inform the adaptation (content and features) of an adult self-guided web application (*Support*).

Methods: Internet-based semistructured individual interviews based on a phenomenological study design were conducted with 21 youths, and transcripts were analyzed using an inductive approach with concept mapping.

Results: Factors influencing T1D self-management were categorized into barriers and facilitators and then as external or internal. Features influencing the accessibility to information, increasing the sense of support, and use of the tool were positively accepted. Features unrelated to their expectations of digital tool use or difficulty navigating were viewed negatively. Participants expressed an interest in reliable, practical, and novel educational content. Although youth considered the information provided by medical professionals to be important, peer exchange was deemed necessary to obtain a practical perspective and real-life examples.

Conclusions: Compared with the adult population, in addition to tailored content and a simplified information search process, when building a DSM education and support digital tool for youth, features should be selected to encourage supervised peer exchange.

(JMIR Diabetes 2023;8:e42564) doi:10.2196/42564

KEYWORDS

type 1 diabetes; youth; eHealth; self-management; mobile phone; peer support

Introduction

Background

In Canada, the estimated prevalence of people living with type 1 diabetes (T1D) was 276,284 in 2021, including 31,601 people aged <19 years [1]. T1D is an autoimmune disease that requires external insulin injection and sustainable diabetes self-management (DSM) behaviors to maintain optimal glucose levels [2]. On the basis of an American survey of certified diabetes educators, a child diagnosed with T1D needs 78-305 minutes daily to complete all the recommended components of DSM [3]. Given this intensity and lifelong efforts, adherence to medical treatment is difficult to achieve, especially for adolescents and young adults with T1D (aged 14-24 years) [4]. The adolescent period is characterized by physiological changes (eg, an increase in insulin resistance), navigating social constructs, peer influence, a shift in family dynamics, and the transfer of responsibilities from parent to child [5]. For instance, in the province of Quebec, Canada, adolescents aged ≥14 years can consent to care alone if there is no serious risk to health [6] and make their own decisions in their diabetes management. Despite the varied T1D management priorities across early adolescence (eg, aged 14 years) and young adulthood (eg, aged 24 years) [7], both groups are challenged with the transition in care. Although parents might still play a central role and participate in the transition process [8], youth, as they age, are searching for more diabetes autonomy and emancipation from their family [9,10]. This health care transition period can thus be viewed as an opportunity to equip youth with the necessary education. Furthermore, pairing them with peers who recently experienced the transition (eg, those aged ≥18 years) can support them in acquiring DSM behaviors and addressing these additional responsibilities [11].

One approach to increasing the acquisition of DSM behaviors among youth living with T1D is the use of self-guided (ie, absence of individual contact with health care professionals [HCPs]) digital tools. Web-based approaches can be interesting given the lower development cost compared with a mobile-based tool [12] and the possibility of designing web apps to be mobile responsive. Studies have shown that youth are active users of digital health technologies, and they appreciate using web-based information as an opportunity to improve their health and use social media as an emotional support [13]. However, there is a gap in resources specially developed for this population [13] and limited information on how their needs can be linked to behavior change theories and translated into DSM education and support (DSME/S) interventions. For instance, Diabetes Youth Empowerment and Support is a 12-week self-guided web-based program developed for young adults (aged 18-35 years) in Australia [14]. Regardless of its acceptability among the target population and inclusion of topics related to transition, the intervention only addressed people who were at the end of the health care transition (eg, those aged ≥18 years) and did not prepare adolescents for the transition. In addition, the development of this intervention was not guided by behavior change theories or frameworks. Another study focused on a younger population aged 12-16 years living with T1D, but the designed mobile app was related mainly to the tracking of blood glucose values, and the challenges of health care transition were not addressed [15].

The integration of behavior change theories or frameworks such as the Behavior Change Wheel (BCW) guides the understanding of behavior mechanisms and can increase the applicability of an intervention in the real-world setting [16,17]. The BCW starts with the Capability-Opportunity-Motivation-Behavior model at its core to understand a behavior and is then encircled by 9 intervention functions needed to change behaviors; such interventions are supported by 7 policy categories [18]. The BCW also links these interventions to behavior change techniques (BCTs), which are the backbone of each behavior change intervention [19]. The integration of BCTs within interventions can potentially increase their replicability and the positive outcomes of behavioral changes. To convey these behavioral changes from a technological perspective, BCTs can guide the choice of characteristics and features [19,20]. An example of the application of BCTs for T1D is *Support* [21], a self-guided web app for people living with T1D that has an evidence-based design [22]. It offers multidimensional education and support to adults living with T1D to improve their DSM. Developed by HCPs in the field, in collaboration with patient partners, it is personalized based on the user's treatment regimen to offer tailored content. This web app also includes a discussion forum mediated by HCPs and features requiring active participation (eg, quizzes and calculators) [21]. However, as youth living with T1D encounter specific challenges of health care transition, DSME/S for this population should address this specific issue.

Objectives

Considering the lack of accessible self-guided web apps based on youths' interests and needs [23,24], as an early exploratory developmental study based on the BCW, this study aimed to identify, among youth living with T1D, the needs and factors influencing their DSM in the context of health care transition and to inform the adaptation (content and features) of an adult self-guided web app (*Support)* to those needs.

Methods

Study Design and Recruitment

We conducted a phenomenological qualitative study (ie, a study focusing on the experience of the participants related to their DSM in the context of health care transition and their interest in using digital health tools for DSM) with semistructured individual interviews. The method section follows the Consolidated Criteria for Reporting Qualitative Research checklist [25].

We recruited participants from 2 age categories (14-18 years to understand the needs of people who are preparing for health care transition and 19-24 years to understand the experience of people who have recently transitioned to adult care from pediatric care). The inclusion criteria were being aged between 14 and 24 years; living in the province of Quebec, Canada; diagnosed with T1D; and being able to communicate in English or French. The recruitment followed three main convenience and purposive sampling methods: (1) word of mouth; (2) email

invitation via the BETTER (Behaviors, Therapies, Technologies and Hypoglycemic Risk in Type 1 Diabetes) registry (a registry of people living with T1D in Quebec; ClinicalTrials.gov identifier: NCT03720197 [26]); and (3) advertisement on social media (eg, private T1D Facebook groups) and on the study website. Potential participants were screened for eligibility via phone by a research assistant. Written informed consent was obtained by email before the interview, which was conducted using Microsoft Teams.

Ethics Approval

The study was approved by the McGill University Research Ethics Board (20-08-036).

Semistructured Interview

The interviews were planned to last 60 minutes and were conducted in French or English. The participants had the option to turn on their cameras or proceed with voice only. All interviews were recorded and then transcribed. The interviews followed a guide developed by a multidisciplinary team (dietitians, nurses, endocrinologists, and pediatricians) and were reviewed and tested by patient partners (Multimedia Appendix 1). The interview guide was adapted (eg, modifying the wording and converting a few closed-ended questions to open-ended questions) after 4 interviews. All interviews were led by a female research assistant (CL, a registered dietitian with experience in clinical diabetes care). The participants did not know their interviewer before the study.

The interviews were based on an existing self-guided web app designed for adults with T1D (ie, *Support* [21]) as an example of a web-based DSME/S resource. The information on *Support* is divided into 6 learning categories with 3 levels of complexity. The web app integrates various features to facilitate the learning and navigation experience (eg, a discussion forum facilitated by an HCP, quizzes, and videos). This web app is completely self-guided, and users can learn at their own pace. Before each interview, participants received a PowerPoint presentation of the adult *Support* and a 3-minute explanatory video of the web app. At the beginning of each interview, the research assistant confirmed that the participants had the opportunity to review the material and asked if they had any related questions. If the participant did not review the material, the interviewer presented it at the beginning of the interview.

The interview consisted of 4 sections with a total of 20 questions (including open- and closed-ended questions). Interviews started with a self-introduction of the participants, followed by their current diabetes management practices (eg, their treatment plan [eg, type of insulin use and method of blood glucose monitoring], where they find information related to health and diabetes, and their confidence in managing diabetes) and their general use of web-based education tools. The interviewer then probed for feedback regarding *Support* (eg, most preferred features and adaptations that should be made for youth) and the potential for creating new content (eg, by providing examples of barriers in daily life and other topics that they would like to discuss), and the interviewer then concluded the interview. Some of these questions included probes that facilitated the discussion if participants initially had no answers.

Upon completion of the interview, each participant received a CAD $40 electronic gift card (US $31) to compensate for their time. Each participant was interviewed once and was also invited to send their comments or suggestions by email following their interview, if applicable. However, no comments were received after the interviews.

Transcript and Analysis

The interviews were first transcribed by 1 of the researchers (LFX or AH) and then reviewed by the other researcher to confirm the accuracy of the information. Two researchers (LFX and AH) performed the coding independently using NVivo software (QSR International) and discussed the agreement on the coding attributed to each transcript section. The researchers reached mutual agreement for all codes included. The percentage of agreement was calculated based on the total number of included codes divided by the largest number of codes independently found by the 2 researchers. The interviews were analyzed using an iterative inductive approach. The initial codes were determined based on 2 randomly selected interviews and then adapted throughout the analyses. Inductively, codes with similar topics related to their DSM or feedback regarding *Support* were then merged into categories and further into themes using concept mapping. All analyses were performed in French. Codes and quotes were translated into English using a forward-backward translation process by 3 bilingual researchers (LFX, AH, and RC) for the purpose of publication. Results were discussed with research patient partners but were not returned to the participants.

Results

Overview

Among the 32 invitation emails sent, 27 potential participants contacted the research assistant and were screened for eligibility. Among the eligible participants, 22 agreed to participate, but 1 participant was excluded during the interview because of difficulty in understanding the questions and responding to them. The final sample size included 21 participants: 8 participants in the 14-18 years category (5 women and 3 men) and 13 participants in the 19-24 years category (7 women and 6 men). The mean diabetes duration was 9.4 (SD 4.5) years, ranging from 1 to 16 (median 10, IQR 5.1) years; 86% (18/21) of the participants were White. Most participants were using an insulin pump (16/21, 76%) and continuous or flash glucose monitoring systems (15/21, 71%). One participant (Participant 5, man, aged 23 years, 17 years since diagnosis) used *Support* for 6 months before the interview. The interviews were conducted between October 2020 and January 2021. The mean length of the interviews was 44 (range 27-62) minutes.

Data saturation (ie, no new codes were determined during the analysis) was reached after analyzing 17 transcripts, and the average agreement score was 72%. Codes related to DSM were categorized into themes using a concept mapping approach (Figure 1), and feedback regarding the features was analyzed (Tables 1and 2).

Figure 1. Barriers and facilitators of diabetes self-management (DSM). HCP: Healthcare professional; T1D: Type 1 diabetes.

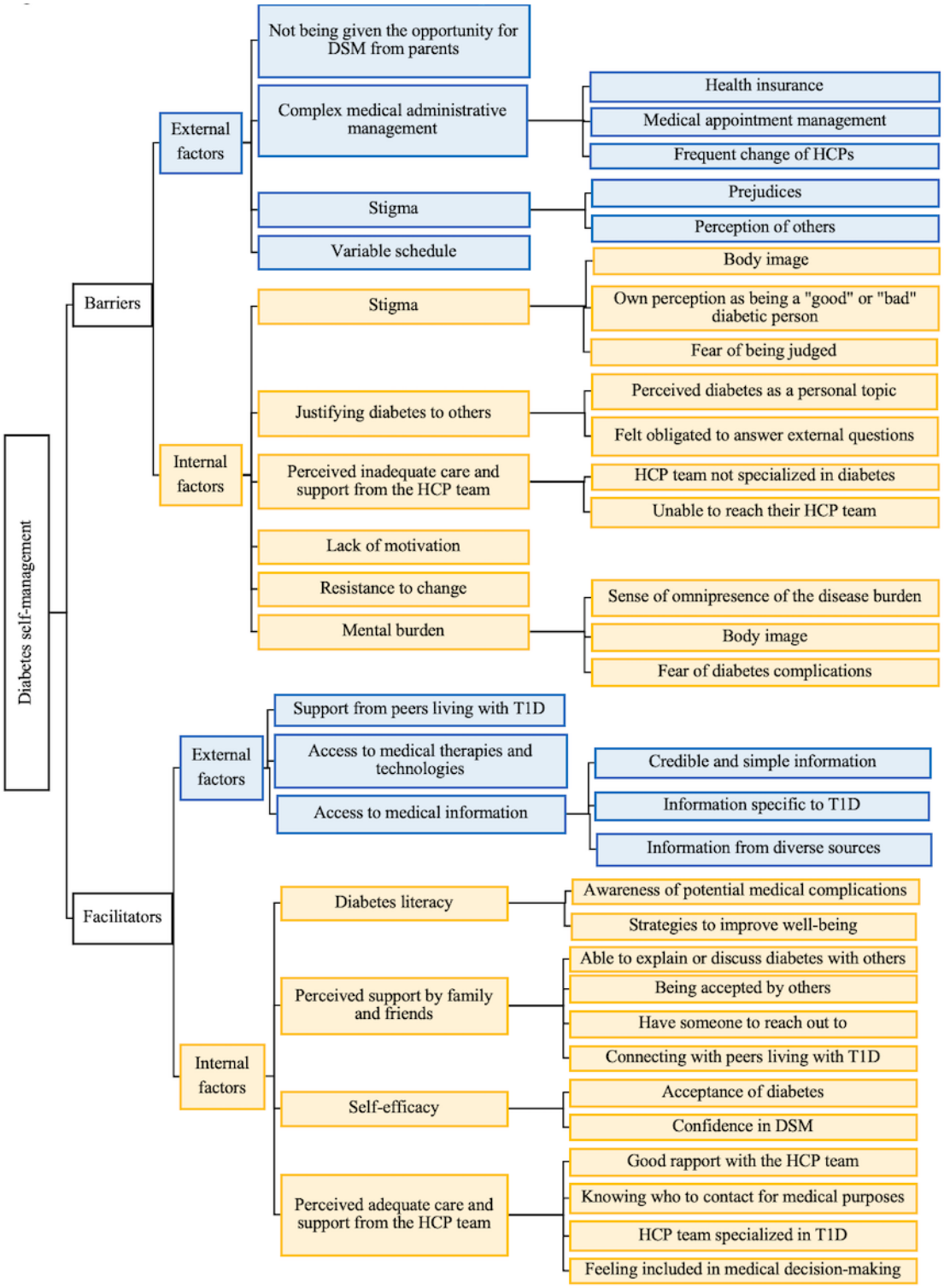

Table 1. Examples of quotes and discussed features starting with A-P.

Characteristics or features	Related behavior change techniques	Description	Feedback[a]	Examples of quotes
Anonymity	• Avoid aversive stimulus[b]	Ability to use the tool without being known by others	(+) • Access to information • Sense of support	• "They [youth with T1D] are afraid to confess to others [peers or health care professionals]. It might be important for them to use these platforms. Like knowing the information without others knowing about it" (Participant 12, male, aged 14 years, 6 years since diagnosis).
Carbohydrate calculator	• Avoid aversive stimulus • Problem-solving	Calculator to estimate the food's carbohydrate content	(+) • Access to information	• "I was wondering if it would be possible if you have an app that when taking a photo, it would be able to estimate your carbs" (Participant 15, male, aged 21 years, 6 years since diagnosis).
Cartoon illustrations	• Avoid aversive stimulus	General visual design of *Support* (eg, pictures, colors, and word font)	(+) • Access to information • Sense of support (−) • Dislike owing to personal preference • Not perceived relevant for DSM[c]	• "Then the site is also visually beautiful, I have the impression that since I find that it is interesting, it can motivate me to go on it" (Participant 10, female, aged 19 years, 3 years since diagnosis). • "[...] I found that it [the profile avatars] was a little bit childish. Maybe I would have put it a little more suited because it is a clientele over 18 years old" (Participant 15, male, aged 21 years, 6 years since diagnosis).
Categories	• Avoid aversive stimulus	Learning modules classified in categories	(+) • Access to information	• "The ease of finding information, with it clearly divided into sections. If the first time I had difficulty finding the answer to my question, for example, in relation to food, I would be less inclined to go to this site" (Participant 16, female, aged 19 years, 9 years since diagnosis).
Chat room	• Social support	One-on-one message with a health care professional or another participant	(+) • Access to information • Sense of support	• "I would say drugs and alcohol are not the most comfortable topic. [...] I think it's more comfortable to talk about it anonymously, or in a chatroom, than it is face-to-face with your doctor, especially as a 15, 16, 17-year-old. [...]" (Participant 19, male, aged 16 years, 9 years since diagnosis). • "I don't know if that would be possible, but sometimes, on sites, there are little chats, something where if you have a question [...] you sometimes contact someone who is there directly" (Participant 5, male, aged 23 years, 17 years since diagnosis)
Discussion forum	• Social support	A health care professional–moderated forum where users can ask questions or post comments	(+) • Access to information • Engagement with the tool • Sense of support (−) • Difficulty using the feature • Dislike owing to personal preference • Not perceived relevant for DSM	• "Also, the exchange blog, because sometimes yes there are professionals, but they can't really feel 100% what it is like as a diabetic. So sometimes having support from other people who aim for the same things as you, [...] it's more reassuring I would say" (Participant 18, female, aged 16 years, 15 years since diagnosis). • "[I liked] the discussion forums, […] I could find them everywhere else; the only difference is that they are not like moderated by a health professional, but you know a lot of social networks have people sharing their experience, there is even a social network that was created just for diabetics" (Participant 13, female, aged 16 years, 5 years since diagnosis).
Downloadable summary documents	• Credible source • Avoid aversive stimulus	Summary documents that are ready to be downloaded and printed	(+) • Access to information	• "I also like when there are, let's say, cheat-sheets, or whatever, that you can print out and keep with you, not necessarily to have to look for them on the site, that also helps a lot" (Participant 18, female, aged 16 years, 15 years since diagnosis).

Characteristics or features	Related behavior change techniques	Description	Feedback[a]	Examples of quotes
Gamification	• Nonspecific reward	Accumulation of points, trophies, and certificates; provide possibilities of having competitions among participants	(+) • Access to information • Engagement with the tool • Sense of support (−) • Dislike owing to personal preference • Not perceived relevant for DSM	• "We accumulate them [points] on the different categories. It's fun. [...] I find it must be like a kind of self-fulfillment feeling, you say to yourself, I'm a good person" (Participant 14, female, aged 16 years, 5 years since diagnosis). • "Maybe if I had been younger, that I just got diagnosed with diabetes, that would motivate me more, but now it's been 10 years that I have it, so I learned to manage well. So, whether I have a trophy or not, it won't influence me to change my control" (Participant 17, female, aged 23 years, 10 years since diagnosis).
Internal search engine	• Avoid aversive stimulus	Search engine by keywords	(+) • Access to information	• "You forget something, you want to remember, you are going to look for the specific information, but this is found in lesson 3, you have to do all the lessons before" (Participant 3, male, aged 22 years, 6 years since diagnosis).
Links to external resources	• Social support	External resources provided (eg, from governmental and health institutions) within the digital tool	(+) • Access to information	• "[It would be useful to have information] which is not necessarily on the platform, but links to other external links or phone numbers" (Participant 18, female, aged 16 years, 15 years since diagnosis).
Module duration display	• Avoid aversive stimulus	Estimated time needed for completion	(+) • Access to information • Engagement with the tool	• "When you see that it's 10 minutes, it motivates you a little to finish the class" (Participant 21, male, aged 24 years, 10 years since diagnosis).
Notifications	• Avoid aversive stimulus	Update notifications of the app, news, or DSM	(+) • Access to information • Engagement with the tool	• "Maybe there should be a notification to say that there is some news that came out. But I'm not sure people have, let's say, the habit to log in once a week just to go and see if there is any news" (Participant 15, male, aged 21 years, 6 years since diagnosis).
Personal objectives	• Commitment • Goal setting • Review behavior goal	Self-given or provided personal objectives for DSM	(+) • Engagement with the tool	• "Maybe weekly goals to achieve. Like maybe 'Have you managed to measure your blood sugar a certain number of times?', goals to achieve which really makes you want to do it" (Participant 21, male, aged 24 years, 10 years since diagnosis).
Placement quiz	• Graded tasks	Diabetes-related questions to adjust the learning at beginning of the program	(+) • Access to information	• "Maybe it could be [helpful] to take a little test to establish the level and know […] at what course we should be placed at" (Participant 13, female, aged 16 years, 5 years since diagnosis).
Progress visualization	• Self-monitoring of behavior	Timeline within the platform to see the learning progress and option to exit the learning modules at any time with the progress saved	(+) • Access to information • Engagement with the tool	• "There are little points that show our progress in the program, I find that relevant because […] it's a visual cue. It tells us we're about halfway" (Participant 16, female, aged 19 years, 9 years since diagnosis). • "I also found it fun that you could see your progress so that you don't have to do [the course] all at once. You can do part of it, and come back, you know where you've been, […] it's visual" (Participant 20, male, aged 19 years, 11 years since diagnosis).

[a]The (+) sign refers to positive feedback regarding the presence of features or characteristics on the platform for the diabetes self-management of the participants, and the (−) sign refers to negative feedback. A feature or characteristic can have a mix of positive and negative feedback.

[b]"Avoid aversive stimulus" is adapted from the "remove aversive stimulus" of the behavior change techniques taxonomy.

[c]DSM: diabetes self-management.

Table 2. Examples of quotes and discussed features starting with Q-Z.

Characteristics or features	Related behavior change techniques	Description	Feedback[a]	Examples of quotes
Quiz	• Feedback on outcomes of behavior	Questions for participants throughout the learning modules; correct answers are provided right after their answer	(+) • Access to information • Engagement with the tool (−) • Dislike owing to personal preference	• "I think the quizzes are good, I think they're important just to make sure you know what you're doing so that you don't get in trouble when you're actually dealing with stuff. Like, just basic stuff in the quizzes" (Participant 19, male, aged 16 years, 9 years since diagnosis). • "Personally, the quizzes appeal to me a little less, but at the same time, I tell myself that there may be people for whom it is easier to know that they have understood the material" (Participant 18, female, aged 16 years, 15 years since diagnosis).
Sharable link	• Credible source • Social support	Automatically generated sharable link	(+) • Sense of support	• "Maybe articles they can be shared on social media [...]., Like if there is a way to share an article that discusses a particular topic on Facebook [...] with everyone and say: Take 2 seconds of your day to read this" (Participant 5, male, aged 23 years, 17 years since diagnosis).
Smartphone compatibility	• Avoid aversive stimulus	Ability to navigate using a smartphone	(+) • Access to information	• "In the format of an application, [...] it appeals to me a lot more in my cellphone, since I already have my sensor, everything is in there" (Participant 17, female, aged 23 years, 10 years since diagnosis).
Tangible rewards	• Material incentive	Rewards (eg, pen and booklets) given based on the points	(+) • Engagement with the tool	• "Maybe a way to attract teenagers more, [...], but also like having small prizes, but physical ones, then it could be a Dex4 package [...] or pencils. [...] I think that it might motivate" (Participant 13, female, aged 16 years, 5 years since diagnosis).
Testimonials	• Credible source • Identification of self as a role model • Social support	Stories from people living with type 1 diabetes	(+) • Engagement with the tool • Sense of support	• "People giving their experiences, and showing, demonstrating to people that we are all different, and that each body reacts differently, [...] it's really just learning to know how the body reacts in relation to it all" (Participant 14, female, aged 16 years, 5 years since diagnosis).
Unrestricted access to all the modules	• Avoid aversive stimulus	All the learning modules are unblocked initially and free of access	(+) • Access to information	• "Another suggestion would be keeping the order of the modules but leave them unblocked, [...] if you don't have a lot of knowledge in diabetes, it can be useful to start with the basics" (Participant 3, male, aged 22 years, 6 years since diagnosis).
Videos	• Credible source • Avoid aversive stimulus	Information given in a video format	(+) • Access to information	• "I think videos are more relevant for learning purposes away from an academic context. I think it's easier for people to learn by video than by written stuff, the concentration is different I find" (Participant 1, female, aged 22 years, 19 years since diagnosis).

[a]The (+) sign refers to positive feedback regarding the presence of features or characteristics on the platform for the diabetes self-management of the participants, and the (−) sign refers to negative feedback. A feature or characteristic can have a mix of positive and negative feedback.

Understanding Needs for DSM

Overview

Participants expressed their experiences and needs with DSM in the context of health care transition. The information was grouped into barriers and facilitators to DSM and further categorized into external (ie, factors that participants could not alter on their own) and internal factors (ie, factors that participants could alter on their own; Figure 1). Except for the factor "not being given the opportunity for DSM from parents," which was only mentioned in the 14- to 18-years groups, all the other factors were covered in both age groups. Examples of the quotes considered for each code are provided in Multimedia Appendix 2.

External Barriers

Four external barriers were identified (Figure 1). With adolescents gradually acquiring more autonomy, 1 external barrier they faced was not being given the opportunity from their parents to self-manage their diabetes. One youth described

it as feeling "handicapped" (Participant 10, female, aged 19 years, 3 years since diagnosis). This prevented them from managing their diabetes autonomously, given the involvement of their parents in their diabetes care. Autonomy also brings more responsibility, such that youth slowly take over the administrative aspects of their diabetes, such as making medical appointments and dealing with health insurance. Participants also cited the transition process as a barrier, including transfer to a new health care team and setting. Administrative factors were described as complex and as barriers to adequately managing T1D. A variable schedule was also stated as adding difficulty to DSM at this age. This affected their sleep, exercise, and meal patterns, which had a magnified impact on diabetes management. One participant said the following:

> *Basically everything can affect your blood sugar is how I see it. Like stress, eating, sleep [...] anything can, which is really hard.* [Participant 19, male, aged 16 years, 9 years since diagnosis]

Stigma was also a barrier and was expressed to be both external and internal. The prejudices and perceptions of others were external stigmas experienced by participants. It ranged from the misconception that sugar intake was alone responsible for diabetes development, wrongful associations between insulin injection and drug use, and discrimination in their capability to perform actions to stereotyping the body weight of "a diabetic [person]." One participant shared the following:

> *I have often been told: "I do not understand why you are diabetic, you seem to eat well and you don't seem to be very overweight." No, but it's not that.* [Participant 18, female, aged 16 years, 15 years since diagnosis]

Internal Barriers

Stigma can also be an internal barrier. In fact, participants expressed concerns about their body image and internalized behavior labeling such as considering themselves as a "good" or "bad diabetic [person]." (Participant 21, male, aged 24 years, 10 years since diagnosis). In addition, youth's fear of being judged by others prevents them from properly managing their diabetes if they perceive it to be a "burden" for others. For example, one of the participants said the following:

> *I will wait until the end of the class to eat something. Otherwise, people will look at me as if I were sick [...]. So, it happened to me to wait for class to end to treat hypos.* [Participant 3, male, aged 22 years, 6 years since diagnosis]

In addition, the difficulty of navigating the high expectations from their health care team was expressed by a participant and can prevent suitable health care support:

> *To understand that […] we are not perfect patients, who take their blood sugar on time, and then they eat a certain number of grams of carbohydrates.* [Participant 21, male, aged 24 years, 10 years since diagnosis]

Participants also expressed their observations related to the lack of specialization in T1D care transition from pediatric to adulthood and their apprehensions of being left alone. One youth shared the following:

> *It was like a shock to me, because [my new health care team] was supposed to be medical specialists; but they had no expertise in diabetes technology at all. Then he didn't even look at my blood sugar.* [Participant 3, male, aged 22 years, 6 years since diagnosis]

Another internal barrier was feeling the need to justify diabetes to others and to answer continuous inquiries from others. In fact, some participants perceived diabetes as a personal topic and preferred not to spend more time discussing it with others. In contrast, it was important for them to feel heard of and supported by the people around them.

The lack of motivation was expressed by some participants as a lack of interest and a lower priority placed on their DSM. This was mainly related to the difficulty of dealing with and accepting their diabetes. One participant said the following:

> *I wanted to hear […] the stuff that might help people with diabetes acceptance and take responsibility [...]. Talk about it a little more when I was young, to have cues to deal with diabetes […] to be able to explain it without living in too much discomfort.* [Participant 17, female, aged 23 years, 10 years since diagnosis]

This becomes an even greater challenge when coupled with the mental burden. Concerns were expressed regarding body image and difficulty with weight, a sense of omnipresence of the diabetes burden, and the fear of consequences related to T1D that adds to the burden of this condition.

The final mentioned internal barrier was the resistance to change. The difficulty of breaking behavior and acquiring a new way of managing their diabetes encompassed the struggles of maintaining a habit. In fact, in addition to understanding and knowing how to deal with certain aspects of diabetes, consistency in performing these actions is an issue. One participant said the following:

> *I know how to calculate my carbohydrates, I know everything to do, but sometimes it's to take the initiative, calculate […] it's more doing it than knowing it.* [Participant 18, female, aged 16 years, 15 years since diagnosis]

External Facilitators

Several facilitators were voiced by the participants as opportunities to strengthen their DSM, such as connecting with peers living with T1D to share their daily lives and routine. Their peers are also a source of practical information, a participant shared the following:

> *[The doctor] doesn't live the same reality as me, [and I would be more interested] to see how people can apply it, sometimes it helps me when I meet a diabetic person.* [Participant 17, female, aged 23 years, 10 years since diagnosis]

Other external facilitators included the use of medical technologies and therapies and access to medical information.

One participant shared that consulting a resource such as *Support* was interesting because it was "a way to acquire information more easily, more quickly, because an appointment with an endocrinologist is long" (Participant 12, male, aged 14 years, 6 years since diagnosis).

Internal Facilitators

Participants' knowledge of technology use contributed to their diabetes literacy and facilitated DSM. One participant expressed her enthusiasm saying the following:

> *I am very excited! I can know how long it has been since I injected my last dose [using an insulin pump therapy].* [Participant 4, female, aged 24 years, 10 years since diagnosis]

Although acquiring strategies to improve well-being was deemed important for youth's DSM, being aware and understanding complications and their breadth of impact on their health and lives were central to facilitating DSM, as a youth inquired:

> *If I didn't inject, what would it do? At 10 months of diabetes, I still don't even know what it [the consequences of not injecting diabetes] does [...].* [Participant 11, female, aged 16 years, 1 year since diagnosis]

According to the participants, adequate DSM is closely linked to perceived support (from their families, friends, and HCPs), as this can facilitate their communication with others about diabetes, being accepted by others beyond their health condition, and having someone to reach out to if they ever feel the need to.

Factors Impacting the Acceptability of a Self-management App's Features

Overview

Participants individually proposed a list of potential features or characteristics included in the self-guided DSM digital tools based on preexisting features in *Support* (Tables 1 and 2). According to the participants, a feature or a characteristic tends to be positively accepted if it (1) provides access to the information, (2) increases a sense of support, and (3) increases engagement with the web app. They were viewed negatively mainly because of (1) personal preferences, (2) difficulty using the feature, and (3) perceived irrelevance to DSM. A feature may be associated with one or more of these factors.

Accessibility to the Information

A feature increases the accessibility to the information when it facilitates autonomous web app navigation by the participants, organizes the content in a logical and simple way, or adds flexibility to their learning process. Features such as an internal search engine, downloadable PDF documents, and specific module categories were all considered as methods to organize information in a simplistic manner and facilitate navigation on the web app. The participant who used *Support* for 6 months found it difficult to navigate without an internal search engine. He stated the following:

> *there was one [module] I wanted to go see and then I was like oh my God where is it. I had to scroll, look a bit through the pages [...] I think [a search engine] can be handy.* [Participant 5, male, aged 23 years, 17 years since diagnosis]

Therefore, implementing features to help users save time should be considered as one of the main priorities during the design of the platform.

To add flexibility to the learning experience, participants suggested that features such as smartphone compatibility should be considered, as viewing the platform on a phone (web page or app-based) is more convenient than opening a browser on a computer.

Sense of Support

Sense of support refers to the need for youth to not feel alone in their diabetes management. This idea includes being able to communicate diabetes-related information with people who do and who do not have this condition. This can be realized through a discussion forum, chat rooms, or the incorporation of testimonials. One participant mentioned the following:

> *For young adults, we are more and more focused on the connection with others, the discussion, the socializing on networks.* [Participant 2, female, aged 23 years, 14 years since diagnosis]

Communication with others helps them understand that others are in the same situation and that there is not only one solution to issues:

> *[Having] people giving their experiences, then showing or demonstrating to people that we are all different, that each body reacts differently […], it's really just learning to know how the body reacts with regards to it.* [Participant 14, female, aged 16 years, 4 years since diagnosis]

Use of the Web App

Participants discussed how the choice of features could impact their use of the web app. For instance, a visually appealing platform can increase their motivation and curiosity to learn and encourage them to return. Displaying the progress of the module completion was also seen to make users feel accomplished, and setting personal objectives may increase their desire for knowledge application, further reinforcing their learnings. Notifications can help increase the use of the digital tools by reminding people of their existence and informing users about new content.

Other features that have a potential impact on engagement include rewards, but the opinions were divided. The integrated gamification (eg, trophies, certificates, and quizzes) may benefit some participants by keeping them using the tool:

> *I think that can be a motivator and make me feel proud. Like I got my new trophy […], basically, it can be a personal pride.* [Participant 12, male, aged 14 years, 6 years since diagnosis]

However, for others, it would have no impact on their use:

> *I think that [trophies] don't matter to me, [...] I would like it for the younger people.* [Participant 5, male, aged 23 years, 17 years since diagnosis]

Characteristics Leading to Negative Acceptability

In addition to not perceiving a feature as being useful for its intended goal, the difficulty of using a feature can also be a barrier. For instance, the discussion forum received mixed feedback owing to its current format (ie, under a specific tab and participants needed to click on each topic to investigate the posts):

> *Well maybe a different format, [...] because I have the impression that a forum is good for asking your own questions, but you lose some of the information because you don't tend to look at [the answer of other posts].* [Participant 10, female, aged 19 years, 3 years since diagnosis]

Therefore, it was suggested to display all the posts in a chronological order and have them automatically shown on their dashboard. The discussion forum could also be directly integrated into a social media platform (eg, Facebook), as many youths are already using it.

Personal preferences were the third explanation given by the participants regarding the negative acceptability of the features. This is reflected in comments on the design of the web app (eg, considering cartoon illustrations as childish) or related to their experience (eg, associating quizzes with academic performance). Participants specifically highlighted that they do not feel "like reading huge paragraphs and then answering quizzes again [...] after a day of school" (Participant 16, female, aged 19 years, 9 years since diagnosis). One of the proposed solutions is to increase the use of videos as they "are lighter, as it is more like listening to a show" (Participant 22, male, aged 22 years, 13 years since diagnosis).

Suggestions for Diabetes Education Content

On the basis of the existing educational content provided to participants, a list of additional topics was discussed and is provided in Multimedia Appendix 3. The results highlighted the characteristics of the learning content that will be the most appreciated by the participants: (1) reliable, (2) practical, and (3) novel.

Reliability of the Educational Information Provided

The source of reliability of information differs for medical (eg, understanding the impact of alcohol on glycemic control) and experience-related topics (eg, how to limit alcohol consumption at a party). For medical information, a high level of reliability would be the ones sourced from governmental or organizational websites, magazines, or journals:

> *I'm really looking for [...] something reliable. Either by the government or anything, such as a project or a foundation that is relatively reliable.* [Participant 7, female, aged 17 years, 14 years since diagnosis]

Participants questioned the reliability of the information from discussion forums and social media group pages. Their reliability, or potential lack thereof, is a barrier for participants seeking information using these tools. However, this issue of credibility could be resolved with the supervision of an HCP who would address invalid recommendations:

> *It's true that having a forum with specialized [health care professionals] would be a real bonus because on the Internet we really get advice that we think we can follow [but they are] not given by professionals.* [Participant 21, male, aged 24 years, 10 years since diagnosis]

Although the role of HCPs and information coming from credited references were essential for medical advice, this appeared to be lessened when referring to personal experience–related information. One participant mentioned the following:

> *Testimonials [...] [are] still pleasant, [...] we see that we are not all alone. In the same boat, there are also others who have the same problem.* [Participant 4, female, aged 24 years, 10 years since diagnosis]

To increase this sense of belonging, the information should also be from people who are in the same age group and living the same reality as them:

> *Me versus someone who is 18 years old, who tells me that it has happened to them before […], versus someone who tells me that as a 45-year-old, they did that. [...] Maybe it's not the same reality, maybe it's not the same management [...]. So I'm gonna trust more people of my age.* [Participant 7, female, aged 17 years, 14 years since diagnosis]

Practicality of the Information

Information is considered practical when it is directly related to a real-life situation that participants can identify with and goes beyond theoretical knowledge. Participants are looking for a resource that will "help [them] more with the practical aspect of everything than with the theory" and "that would [...] support them in a follow-up, because of course the lessons are very good, but in the end, [...] the practical aspect [...] is most important [...]" (Participant 21, male, aged 24 years, 10 years since diagnosis).

Information related to blood glucose management and the choice of medical technologies, devices, and suppliers were of high interest. Participants expressed that they should live with a situation to find a use of the information. The use of an insulin pump was given as an example by 1 participant:

> *I don't have a pump. Anything that is linked to the pump? No. [...] I'll just tell you [that] what didn't happen to me, it looks like I'm not interested [in].* [Participant 17, female, aged 23 years, 10 years since diagnosis]

Novelty of the Information

The novelty of the information refers to the idea that the educational content should provide information that was not known to the participants previously or that the information cannot be found in other places (eg, HCPs, family and friends, and pharmaceutical companies). According to many participants, the amount of unknown information seems to be inversely related to the duration of T1D. For the same reason, participants inquired about having the function of finding specific information in a convenient way (eg, using a search bar or with

a hashtag of the keywords) to avoid losing interest in the digital tool, especially for people with a longer diabetes duration. In addition, it was suggested that the tool does not only include "basic topics that can be found on the internet, but that pushes the questions a little further" (Participant 7, female, aged 17 years, 14 years since diagnosis).

Discussion

Principal Findings

This study explored the barriers and facilitators encountered in DSM in the context of health care transition by youth living with T1D and adaptation (feature and content) to an adult self-guided DSME/S web app by connecting needs expressed by youth in their DSM with the BCW [18] and its related BCTs [19]. The user-oriented approach used in this study aligned with the recommendations from *the Lancet and Financial Times Commission on governing health futures 2030: growing up in a digital world*, where youth should voice their needs and be placed at the center of the digital health tool development [27]. Having the end user as the primary expert can also increase its usability [28]. In our study, participants highlighted that the features and characteristics included in the self-guided digital tool should facilitate access to information and increase social support and engagement with the tool. The content provided should be reliable, practical (adapted to reality), and novel.

Simplicity in Finding Information

Barriers encountered by youth in their physical and social environments can often be perceived as uncontrollable and decrease their physical and mental opportunities for performing DSM behaviors. For instance, the "enablement" intervention function of the BCT should be a primary consideration when designing a web-based DSME/S tool, as participants in this study needed easy access to information owing to their variable schedules. Information categorization, short videos, progress saving, and smartphone compatibility are all potential features and characteristics to decrease this barrier and make both the tool and its content available at the convenience of the participants.

Importance of Receiving Support

The social environment also includes interaction with others, which can imply barriers such as stigma and a perceived lack of social support. Due to these factors, participants reported that they might experience a decrease in their level of confidence in managing their diabetes, make decisions based on the attitude of others, or have fewer opportunities to access DSM-related information. To address these concerns, the BCT "social support" can be used and translated into features such as discussion forums, chat rooms, and shareable links of information from the digital tool. These exchanges provide opportunities to bridge the gap of understanding between youth living with T1D and their family and friends who do not live with this condition, raising awareness of the realities of living with T1D and decreasing stigma and the fear of being judged by others.

In addition, the BCT "feedbacks" could be another integration to decrease external stigma and increase social support while increasing access to information. This technique can be combined with features relating to "social support" (eg, providing feedback for a discussion forum post") or be used alone (eg, answers given after quiz completion); it can be given in a text format (eg, "Congratulation for your good answers!"), rewards (eg, points provided with the number of quizzes completed), communication with the health care team (eg, providing a medical certificate for program completion), or individualized communication (eg, follow-up phone calls). However, although this method may be effective in achieving self-management outcomes, it may not be feasible owing to financial constraints to produce the feedback algorithm in all circumstances [21]. In addition, feedback must be provided by a qualified person, which further increases the cost of human resources. When comparing feedback via phone calls versus a discussion forum, scheduled calls may not provide the spontaneity that a discussion forum can allow, thus increasing the risk of forgetting the inquiry or losing interest in the matter. The acceptability of this technique varies according to the context. For instance, providing results after a quiz can be psychologically associated with academic performance and becomes a barrier to the use of the related feature. Therefore, it is important to further investigate the use of feedback as a BCT in different groups and its most suitable format.

Enabling Self-identification

The presence of a role model (intervention function: "modeling") can increase self-regulation in early adolescence [29] and impact motivation [30]. Associated techniques include "identification of self as a role model" and "social support" and can be brought about by the feature "testimonials." Participants could have the opportunity to become a mentor for others or be able to identify themselves in the stories of others. Other formats of providing social support in this population demonstrated by the literature include creating teams on the platform using a participant messaging system and the option to share content on social media [31]. However, despite the spontaneity provided by these social groups [23], it is essential to consider the confidentiality of users, especially for the discussion of stigmatizing topics [24]. Therefore, an option of posting information in an anonymous manner should be provided.

Adapted Content From Credible Sources

Although some DSM factors can be modified by the general design of the digital tool, others such as self-efficacy, diabetes literacy, and access to medical information are directly related to the learning content [32] and the intervention function "education." The BCT "credible sources" should be integrated to increase the quality of information. In this study, participants distinguished "credible medical source" versus "credible practical source." The first one often refers to information from HCPs and governmental and diabetes-related organizations, whereas the second refers to information related to daily issues coming from peers living in a similar situation. Therefore, the digital tool should be adapted with the help of different stakeholders to ensure the diversity and credibility of the information. In addition, the BCT "instruction on how to perform a behavior" can be referred to when the information is related to a behavior change; the format of the demonstration

(eg, with a real person, in a cartoon, or in a video) can vary depending on the topic.

Consider Tangible Rewards

Learning content targeting the needs of the population alone might not be sufficient to ensure adherence to the digital tool and to maintain user motivation. As reported by our participants, the lack of motivation for DSM and in using digital tools can be addressed with the use of the BCT "goal setting" [11] associated with the intervention function "persuasion." This can be translated into a "goal setting" feature within the tool development. The goal can come from the participants or be provided by their health care team. In both cases, the goal must be realistic and attainable objectives. Similarly, a few studies investigated the use of feature "rewards" and "gamification" on the lack of motivation for disease management and digital tool use, this feature was expressed as healthy-living challenges [33,34] team competitions, a points system with monetary rewards [31], and trivia questions [34]. Controversial results were found [35,36]. These differences might be related to the type of reward given and the age of the population. For instance, the participants expressed that the rewards might be a motivator for children but not for teenagers and suggested a preference for tangible rather than virtual rewards. As incorporating features related to gamification (eg, virtual rewards) and a greater level of interactivity are associated with a higher financial cost at the design phase of the digital tool [21] and tangible rewards imply long-term financial investment, we suggest investigating the preferences of the users on these features during its planification.

Limitations

A few limitations were present in the interpretation of the results. Not all questions were open ended during the interviews. Closed-ended questions were used to validate some concepts and might have biased participants' answers. To reduce the risk of bias by the researcher when conducting the interviews, the same interviewer was present for all interviews and was asked to follow an interview guide. Translation of the interviews can increase bias in the reporting of the information; therefore, 3 bilingual researchers (LFX, AH, and RC) reviewed the translation independently to ensure translation accuracy. Most participants were White, which could limit the generalizability of the results. The geographical locations of the participants were not recorded during the interviews. Owing to the early exploratory nature of this study, participants provided an overview of their opinion on the included features within the limited time of the interview. Further investigation into how youth would access and use these features is needed.

In conclusion, our analysis demonstrated that youth have an interest in a self-guided digital resource for their DSM where they can encounter peers living in similar situations and who can share their experiences. To increase the sense of support from their family, participants also suggested including sharable links for the information contained in such tools. Given the interest in youth for a self-guided digital tool for DSM, as a future direction, a prototype will be developed and exploration of youth opinion via think-aloud and focus groups will be conducted.

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Authors' Contributions

All authors have read and approved the final manuscript. LFX participated in the design of the study; transcribed the interviews; analyzed the data; and wrote, reviewed, and corrected the manuscript. AH transcribed the interviews; analyzed the data; and wrote, reviewed, and corrected the manuscript. RC translated all the quotes from French to English, contributed to the initial draft of the manuscript, and reviewed the manuscript. CL participated in the design of the study, performed the interviews, and reviewed the manuscript. MN, who is the coinvestigator of the study, participated in the design of the study, provided feedback on the analysis of the data, and reviewed the manuscript. DDC provided feedback on the analysis of the data and reviewed the manuscript. ASB, who is the principal investigator of the study, participated in the design of the study, supervised the process, provided feedback on the analysis of the data, and reviewed the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 17 KB - diabetes_v8i1e42564_app1.docx]

Multimedia Appendix 2

Example of quotes for diabetes self-management.
[DOCX File , 23 KB - diabetes_v8i1e42564_app2.docx]

Multimedia Appendix 3
Topics proposed by participants.
[DOCX File , 16 KB - diabetes_v8i1e42564_app3.docx]

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Abbreviations

BCT: behavior change technique

BCW: Behavior Change Wheel
BETTER: Behaviors, Therapies, Technologies and Hypoglycemic Risk in Type 1 Diabetes
DSM: diabetes self-management
DSME/S: diabetes self-management education and support
HCP: health care professional
T1D: type 1 diabetes

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Original Paper

The Influence of Age, Sex, and Socioeconomic Status on Glycemic Control Among People With Type 1 and Type 2 Diabetes in Canada: Patient-Led Longitudinal Retrospective Cross-sectional Study With Multiple Time Points of Measurement

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Abstract

Background: Clinical guidelines for most adults with diabetes recommend maintaining hemoglobin A_{1c} (HbA_{1c}) levels ≤7% (≤53 mmol/mol) to avoid microvascular and macrovascular complications. People with diabetes of different ages, sexes, and socioeconomic statuses may differ in their ease of attaining this goal.

Objective: As a team of people with diabetes, researchers, and health professionals, we aimed to explore patterns in HbA_{1c} results among people with type 1 or type 2 diabetes in Canada. Our research question was identified by people living with diabetes.

Methods: In this patient-led retrospective cross-sectional study with multiple time points of measurement, we used generalized estimating equations to analyze the associations of age, sex, and socioeconomic status with 947,543 HbA_{1c} results collected from 2010 to 2019 among 90,770 people living with type 1 or type 2 diabetes in Canada and housed in the Canadian National Diabetes Repository. People living with diabetes reviewed and interpreted the results.

Results: HbA_{1c} results ≤7.0% represented 30.5% (male people living with type 1 diabetes), 21% (female people living with type 1 diabetes), 55% (male people living with type 2 diabetes) and 59% (female people living with type 2 diabetes) of results in each subcategory. We observed higher HbA_{1c} values during adolescence, and for people living with type 2 diabetes, among people living in lower income areas. Among those with type 1 diabetes, female people tended to have lower HbA_{1c} levels than male people during childbearing years but higher HbA_{1c} levels than male people during menopausal years. Team members living with diabetes confirmed that the patterns we observed reflected their own life courses and suggested that these results be communicated to health professionals and other stakeholders to improve the treatment for people living with diabetes.

Conclusions: A substantial proportion of people with diabetes in Canada may need additional support to reach or maintain the guideline-recommended glycemic control goals. Blood sugar management goals may be particularly challenging for people going through adolescence or menopause or those living with fewer financial resources. Health professionals should be aware of the challenging nature of glycemic management, and policy makers in Canada should provide more support for people with diabetes to live healthy lives.

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KEYWORDS

adolescent; adult; cohort studies; co-design; diabetes mellitus; diabetes mellitus type 1; diabetes mellitus type 2; glycated hemoglobin; menopause; participatory medicine; patient engagement; postmenopause; premenopause; public and patient involvement; sex factors; socioeconomic disparities in health; user design; patient engagement; public and patient involvement

Introduction

Background

Diabetes is a chronic condition with 2 common types: type 1 and type 2 [1]. Both types of diabetes are marked by elevated blood glucose levels, but their causes of onset and treatments are generally different [2], and type 1 is less common than type 2 [3]. A standard laboratory test for people with all types of diabetes is the hemoglobin A_{1c} (HbA_{1c}) test. Unlike a single blood glucose measure, HbA_{1c} is a measure of approximate mean blood glucose over 2-3 months [4] that can be measured at any time of day [5] and is often used as a marker of overall glycemic control. Higher HbA_{1c} levels are associated with an increased prevalence of complications of diabetes, affecting the eyes, kidneys, heart, and nerves [1]. Clinical guidelines in Canada recommend maintaining HbA_{1c} levels ≤7% (≤53 mmol/mol) for most adults with diabetes and ≤7.5% (≤59 mmol/mol) for most children with diabetes [6].

Among people with diabetes, differences in HbA_{1c} levels are associated with sociodemographic characteristics, including age [7-10], socioeconomic status [11,12], and sex [9,13-23]. Specifically, HbA_{1c} levels tend to be higher among adolescents compared with other age groups [7-10] and lower among people with higher socioeconomic status (measured using postal codes) compared with those with lower socioeconomic status [11,12]. Studies comparing HbA_{1c} levels by sex have shown mixed results across countries, sometimes showing higher HbA_{1c} levels among those who are male [9], sometimes showing higher HbA_{1c} levels among those who are female [13-20], and sometimes showing no difference [21-23].

The relationships between HbA_{1c} levels and individual and social characteristics are not only apparent in the literature [24]; they are also tangible in the lives of people with diabetes. As noted by team members living with diabetes reflecting on their own lives and on comparisons with peers, HbA_{1c} goals may be easier to attain in some situations than others. Such expertise and perspective gleaned from the lived experience of diabetes can add insight and nuances to diabetes research. Including this expertise in health research is a central tenet of patient partnership. Patient-partnered research involves people living with conditions as full members of the research team. In addition to ethical reasons that people living with conditions should be included in research decisions that affect them, such inclusion can also improve the relevance and quality of the studies [25-27].

Objective

This study's research question was developed by people living with type 1 or type 2 diabetes who were involved in a larger

project in which people living with diabetes developed and prioritized research questions about diabetes. This study aimed to answer one of the identified and prioritized questions*: Accounting for socioeconomic status, what patterns exist in HbA_{1c} results among people in Canada with type 1 or type 2 diabetes of different sexes at different ages?* Although some data already exist regarding HbA_{1c} results in Canada [24,28], there has not yet been a national analysis like this stratified by the type of diabetes and including variables of sex, age, and socioeconomic status. Furthermore, few or no studies have included people living with diabetes as members of the research team.

Methods

Study Design

This study used a longitudinal retrospective cross-sectional study design with multiple time points of measurement.

Study Data and Inclusion Criteria

To answer our research question, we used data from the Canadian National Diabetes Repository. As of July 1, 2021, this repository consisted of electronic medical records of 123,543 people with type 1 and type 2 diabetes living in Canada. The repository continues to grow, and as of April 23, 2022, it included records of 147,459 such people. Records describe patients treated in family medicine practices in 5 Canadian provinces: Ontario (57% of HbA_{1c} results), Alberta (25% of HbA_{1c} results), Manitoba (15% of HbA_{1c} results), Quebec (3% of HbA_{1c} results), and Newfoundland and Labrador (0.4% of HbA_{1c} results) [29,30]. These data originate from a larger data repository, the Canadian Primary Care Sentinel Surveillance Network. Previous analyses of the representativeness of the Canadian Primary Care Sentinel Surveillance Network have noted that, compared with the Canadian population, the data describe more people who are older and more people who are female, which may reflect patterns of greater health care seeking among these groups. It is therefore recommended to include age and sex in analytical models when analyzing these data [31].

In the National Diabetes Repository, people are identified as having diabetes if their record includes an HbA_{1c} result of ≥6.5% or at least 2 fasting blood glucose results >7 mmol/L recorded on different dates ≤1 year apart. However, medical records in Canada do not currently specify the type of diabetes. Therefore, we distinguished between people with type 1 and type 2 diabetes using an algorithm recently developed and validated using Canadian data. The machine learning algorithm analyzed 21 variables (eg, insulin use, nonmetformin antihyperglycemic agent use, and insulin pump use) and demonstrated a sensitivity (ie, ability to correctly identify that someone with type 1 diabetes has type 1 diabetes) of 80.6% and a specificity (ie, ability to correctly identify that someone without type 1 diabetes does not have type 1 diabetes) of 99.8% [32].

For this study, we included all HbA_{1c} results from the Canadian National Diabetes Repository from individuals with diabetes who had at least one HbA_{1c} measurement between 2010 and 2019 and for whom our other variables of interest (age, sex, and socioeconomic status) were available. In other words, we excluded records that lacked one or more of these data elements. We also excluded records with HbA_{1c} results <3.5% (15 mmol/mol) or >20% (195 mmol/mol), as clinical experts on our team deemed these to be likely laboratory errors, data entry errors, or rare outliers. We derived individuals' ages by subtracting each person's date of birth from the date when each HbA_{1c} measurement was performed. We excluded data from individuals aged <10 years, as they contributed such a small proportion of the data in the repository (0.04%) that we would be unable to conduct robust analyses for this subpopulation. As a proxy measure of socioeconomic status, the Canadian National Diabetes Repository applies an established index developed by the Canadian Institute for Health Information [33] to derive neighborhood before-tax income quintiles using the first 3 digits of individuals' most recent residential postal codes. Quintile 1 denotes people living in lower-income neighborhoods, quintiles 2 to 4 denote middle-income neighborhoods, and quintile 5 is assigned to the highest-income neighborhoods [34].

Statistical Analysis

Our unit of analysis was each HbA_{1c} result. We graphically inspected HbA_{1c} results across age groups using locally estimated scatterplot smoothing curves for type 1 diabetes. We used generalized additive model curves for type 2 diabetes to account for the large amount of data in this category. We then analyzed HbA_{1c} results using generalized estimating equations to account for dependency structure at the between-subject and within-subject levels. As the correlations between HbA_{1c} measurements in different years were similar, we used an exchangeable correlation structure to account for correlations between HbA_{1c} measurements of each individual [35]. As the distribution of HbA_{1c} levels was highly skewed, we used log transformation to reduce the skewness and stabilize the variance [36]. Owing to nonlinearity, we categorized age, dividing it into ordinal categories at 10- or 20-year intervals. The age range of 10 to 19 years included puberty and menarche for a large proportion of people who experience puberty and menarche [37,38]. The age range of 20 to 39 years included childbearing years for a large proportion of people who experience pregnancy [39-41]. The age range of 40 to 59 years included perimenopause and menopause for a large proportion of people who experience perimenopause and menopause [42-45]. The age range of 60 to 79 years included postmenopause for a large proportion of people who experience postmenopause [46]. The age range of ≥80 years included advanced adulthood.

We performed 2-way ANOVA to determine the relationship between HbA_{1c} levels and independent variables. We then analyzed potential interactions between age and sex for type 1 and type 2 diabetes, reporting pairwise interaction contrasts. We set our threshold for statistical significance at $P<.05$. We conducted 2 sets of sensitivity analyses. First, to explore whether practice and guideline changes over time might have influenced HbA_{1c} results and our findings, we conducted sensitivity analyses by rerunning all plots and models on 3 subsets of data: 2010 to 2012, 2013 to 2016, and 2017 to 2019. Second, we

wished to check for potential biases in our results associated with unstable blood glucose levels shortly after diabetes diagnosis. In other words, if diagnostic HbA_{1c} values were present in the data set, higher HbA_{1c} values may not have anything to do with diabetes care or self-management but rather, may simply be reflections of a new condition. We did not have dates of diagnoses in the data set; therefore, to explore this issue, we removed the earliest HbA_{1c} result from the data set for each person and reran our analytical models. The details of these sensitivity analyses are provided in Multimedia Appendix 1.

We performed all analyses using R 3.6.1 (R Foundation for Statistical Computing) and associated packages, including ggplot2 for graphics, GEE for generalized estimating equations, and estimated marginal means for contrasts [47-57].

Interpreting Results With Team Members With Diabetes

Following our analyses, we organized meetings with members of the research team living with type 1 and type 2 diabetes. These team members had already been involved throughout the yearlong larger project, including a series of early meetings to orient all team members to epidemiological cohort studies and subcommittee meetings led and attended only by patient partners to generate research questions.

To present and discuss the results of this study, our bilingual team held 1 meeting in English and 1 meeting in French. We invited all team members living with diabetes to attend, presented the results for approximately 15 minutes, and then held an open discussion for the remaining 45 minutes. We recorded the meetings to ensure that we accurately noted team members' comments, and we invited all team members to review the manuscript to ensure that we conveyed meaning correctly. We invited all team members to fulfill the authorship criteria as defined by the International Committee of Medical Journal Editors and, accordingly, be coauthors of the manuscript. A total of 9 patient partner team members accepted the invitation to serve as coauthors of the manuscript.

Because team members were identified as such; that is, they were members of the research team, not study participants, neither our research team nor the research ethics committee that approved the study wished to treat these team members any differently than the team members who were professors, scientists, health professionals, students, and research staff. For this reason, we did not treat discussions among patient partners as research data with study participants, but rather, used the same approaches that one might use with any group of research team members. Specifically, we recorded meetings to ensure accurate note-taking, wrote summaries of discussions, and invited meeting attendees to review and comment on the summaries as we collaboratively drafted this manuscript. Although scientific papers do not typically report the identity characteristics of authors and it is rare to read concerns about whether a group of scientist authors can adequately represent the perspectives of the scientific community as a whole, we will also note that Diabetes Action Canada's methods for recruitment of patient partners explicitly focuses on making extra efforts to ensure broad representation [27]. For this project, as in other projects [58], we deliberately constructed a team of people across all project roles who had a wide variety of backgrounds, with a particular focus on ensuring diversity in type of diabetes and in ethnocultural and socioeconomic backgrounds.

Ethics Approval

Our study received ethics approval from the Laval University Research Ethics Committee, 2020-373/20-01-2021. The original data collection was also conducted with ethics approval. This study was approved by the National Diabetes Repository governance committee. The governance committee comprises a minimum of 50% of people living with diabetes.

Results

Population

The resulting data set consisted of 2 groups of data: one for people identified by the algorithm as having type 1 diabetes and one for people identified by the algorithm as having type 2 diabetes. Table 1 summarizes the HbA_{1c} results from people with type 1 and type 2 diabetes according to age, sex, and socioeconomic status. Because HbA_{1c} continues to be reported as a percentage in Canada, we use percentages to facilitate understanding by people living with diabetes in Canada. Of the 1950 and 946,931 available records, we excluded 1 record from the data available for people with type 1 diabetes and 1337 records from the data available for people with type 2 diabetes owing to HbA_{1c} values <3.5% (15 mmol/mol) or >20% (195 mmol/mol). Among people living with type 1 diabetes, individuals contributed data for a median of 3 (Q1-Q3 2-6) years. Most (244/296, 82.4%) participants contributed data to only 1 of the age groups used in our analyses. The others (52/296, 17.6%) contributed data to 2 age groups. Among people living with type 2 diabetes, individuals contributed data for a median of 5 (Q1-Q3 3-7) years. Most (68,437/90,417, 75.7%) participants contributed data to only 1 of the age groups used in our analyses. The others (21,980/90,417, 24.3%) contributed data to 2 age groups.

Mean HbA_{1c} was 8.3% (SD 1.7%) for female people with type 1 diabetes, 8.0% (SD 1.7%) for male people with type 1 diabetes, 7.1% (SD 1.3%) for female people with type 2 diabetes, and 7.2% (SD 1.3%) for male people with type 2 diabetes. In both types of diabetes, people who are female more often lived in geographic areas with lower socioeconomic status compared with people who are male.

Table 1. Characteristics of hemoglobin A_{1c} results[a] among people with type 1 and type 2 diabetes.

Variable	Type 1 diabetes (1949 HbA_{1c}[b] results from 296 people)		Type 2 diabetes (945,262 HbA_{1c} results from 90,417 people)	
	Male (n=155)	Female (n=141)	Male (n=47,286)	Female (n=43,131)
Population				
People with HbA_{1c} results in 2 age groups, n (%)	22 (14.2)	30 (21.3)	11,630 (24.6)	10,350 (24)
HbA_{1c} results[a]				
Mean (SD), %	8 (1.7)	8.3 (1.7)	7.2 (1.3)	7.1 (1.3)
Mean (SD), mmol/mol	64 (16)	67 (16)	55 (12)	54 (12)
Median (Q1-Q3[c]; range[d]), %	7.6 (6.9-8.5; 4.8-16.3)	8 (7.2-9.1; 5-16)	6.9 (6.3-7.8; 3.5-19.6)	6.8 (6.3-7.6; 3.5-19.5)
Median (Q1-Q3[c]; range[d]), mmol/mol	60 (52-69; 29-155)	64 (55-76; 31-151)	52 (45-62; 15-191)	51 (45-60; 15-190)
Results per person, median (Q1-Q3[c]; range[d])	4 (2-9; 1-42)	5 (2-9; 1-48)	8 (4-15; 1-112)	8 (4-15; 1-115)
HbA_{1c} results ≤7%, %	30.5	21	55	59
Total, n (%)	970 (49.7)	979 (50.2)	505,364 (53.4)	439,898 (46.5)
Age (years), n (%)[a]				
10-19	44 (4.5)	37 (3.7)	1020 (0.2)	1097 (0.2)
20-39	454 (46.8)	559 (57)	13,744 (2.7)	18,675 (4.2)
40-59	305 (31.4)	277 (28.2)	145,393 (28.7)	123,621 (28.1)
60-79	167 (17.2)	106 (10.8)	287,045 (56.7)	235,044 (53.4)
≥80	0 (0)	0 (0)	58,162 (11.5)	61,461 (13.9)
Socioeconomic status, n (%)[a]				
1 (lowest income)	199 (20.5)	336 (34.3)	115,565 (22.8)	116,715 (26.5)
2	141 (14.5)	151 (15.4)	108,374 (21.4)	98,284 (22.3)
3	223 (22.9)	196 (20)	94,672 (18.7)	80,026 (18.1)
4	222 (22.8)	182 (18.5)	93,043 (18.4)	74,537 (16.9)
5 (highest income)	185 (19)	114 (11.6)	93,710 (18.5)	70,336 (15.9)

[a]As noted in the *Methods* section, our unit of analysis is each HbA_{1c} result. These summary statistics are therefore calculated across HbA_{1c} results in the data set, meaning that each HbA_{1c} result within a given category contributes 1 data point.

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

[c]Q1-Q3: quartile 1-quartile 3.

[d]Range=minimum value-maximum value.

As shown in Figure 1, we observed a relationship between age and HbA_{1c} levels among people with type 1 or type 2 diabetes. We also observed that these relationships may differ between people who are male and people who are female. As shown in Figure 2, socioeconomic status may also be associated with HbA_{1c} levels during much of adulthood, with somewhat higher HbA_{1c} values among adults aged 30 or 40 years through 70 years and living in geographic areas with lower mean income.

Table 2 shows the results of ANOVA fitted by generalized estimating equations for both types of diabetes.

According to our analyses of 296 people in the Canadian National Diabetes Repository with type 1 diabetes, there was a statistically significant relationship between age and HbA_{1c} levels, with overall lower HbA_{1c} levels among older people with type 1 diabetes. We observed no statistically significant relationships between sex and HbA_{1c}, socioeconomic status and HbA_{1c}, and the interaction term showed no statistically significant differences between people who are male and female at different ages. For 90,417 people in the Canadian National Diabetes Repository with type 2 diabetes, all variables demonstrated statistically significant relationships with HbA_{1c} levels. HbA_{1c} results are lower among people who are older, higher among people who are male, and higher among people living in geographic areas with lower mean income. There was a significant interaction between age and sex, suggesting that

the pattern of lower HbA_{1c} values among older people with type 2 diabetes was somewhat different between those who are male and female. Specifically, those who are male appear to reach lower HbA_{1c} values later in their life span compared with those who are female. Multimedia Appendix 1 shows pairwise interaction contrasts for this interaction.

Sensitivity analyses (Multimedia Appendix 1) demonstrated that the results were similar for data from 2010 to 2012, 2013 to 2016, and 2017 to 2019, suggesting that practice and guideline changes during the data collection period did not substantially influence our findings. Sensitivity analyses also suggested no changes in our findings when the first HbA_{1c} value for each person was removed from the data set, suggesting that patterns observed are not a reflection of new diagnoses.

Figure 1. Mean HbA_{1c} levels by sex (male, female) across all ages of people with type 1 and type 2 diabetes in Canada. gam: generalized additive model; HbA_{1c}: hemoglobin A_{1c}; loess: locally estimated scatterplot smoothing.

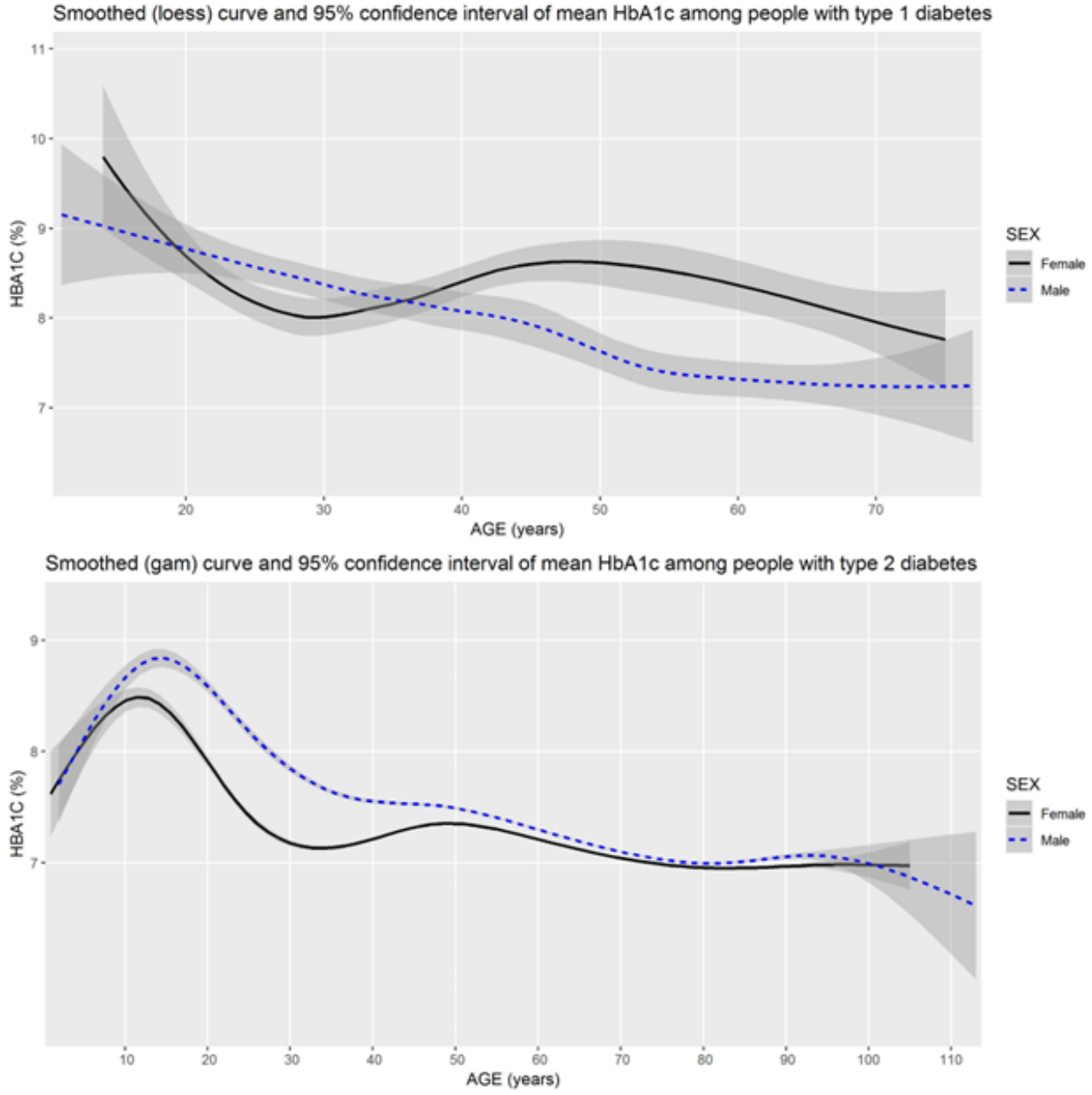

Figure 2. Mean HbA_{1c} levels of people with type 1 and type 2 diabetes in Canada across all ages by socioeconomic status. gam: generalized additive model; HbA_{1c}: hemoglobin A_{1c}; loess: locally estimated scatterplot smoothing.

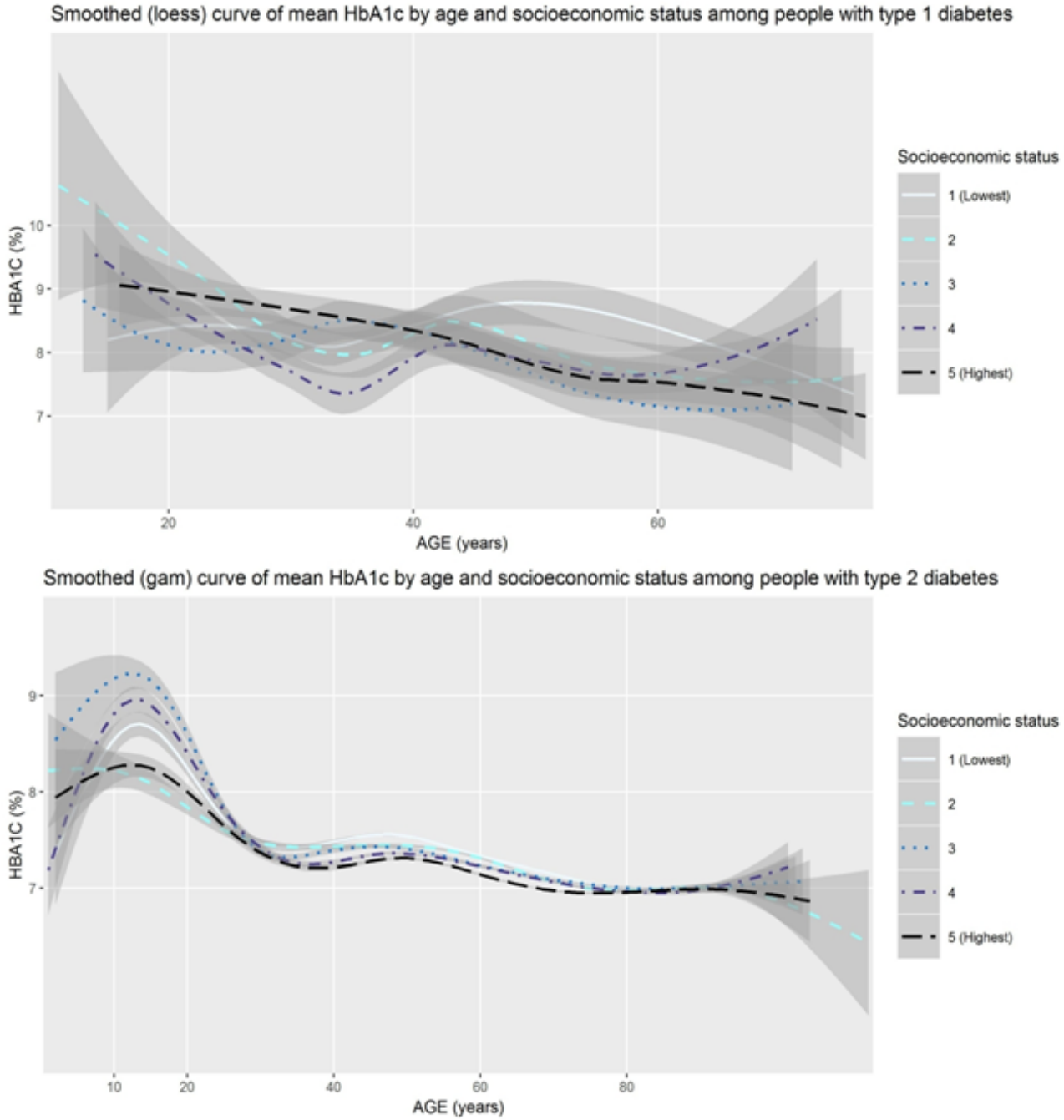

Table 2. Relationship between age, sex, socioeconomic status, and hemoglobin A_{1c} (HbA_{1c}) among people with type 1 and type 2 diabetes in Canada.

	Type 1 diabetes (1949 HbA_{1c} results from 296 people)		Type 2 diabetes (945,262 HbA_{1c} results from 90,417 people)	
	F statistic	*P* value	*F* statistic	*P* value
Age	3.74	.01	635.70	<.001
Sex	2.26	.13	186.85	<.001
Socioeconomic status	0.77	.54	218.78	<.001
Age:sex interaction	1.48	.21	113.165	<.001

Interpretation of Results by Team Members With Diabetes

Approximately equal numbers of team members living with type 1 and type 2 diabetes attended the meetings to discuss and interpret results. In these meetings, people living with diabetes raised potential post hoc explanations for the findings, asked technical questions about the analyses, raised potential study limitations, and discussed implications for policy and future research.

Specifically, with respect to explanations of findings, women living with type 1 diabetes suggested that the potential pattern among female people with type 1 diabetes mimicked their own life courses and may reflect lower HbA_{1c} levels during potential childbearing years and higher HbA_{1c} levels during potential menopausal years. People with diabetes also noted the differing sex-based differences between type 1 diabetes and type 2 diabetes. In both types of diabetes, HbA_{1c} results for people who are female dipped around the age of 30 years and peaked just before the age of 50 years, whereas HbA_{1c} values for people who are male decreased more smoothly with age. However, in the case of type 1 diabetes, curves met and intersected at multiple ages, whereas there were no similar meetings and intersections in the case of type 2 diabetes. Finally, people with diabetes questioned whether differences in the HbA_{1c} levels at different ages might reflect differences in the effort that people are able to put into diabetes management at different stages of their life course, depending on when they were diagnosed.

With respect to technical questions, people living with diabetes noted that accurate HbA_{1c} measurement was not possible for some individuals [59], queried how hypoglycemia unawareness might influence HbA_{1c} results, and raised the issue that HbA_{1c} is a highly imperfect measure. HbA_{1c} is essentially analogous to average blood glucose, and averages can mask substantial variation. Nonetheless, it remains a standard measure, as other methods of measurement (eg, time-in-range measured by flash or continuous glucose monitoring) are not universally available across Canada.

People living with diabetes also raised study limitations including the relatively small amount of data available for people with type 1 diabetes in these primary care electronic medical records, the need to use an algorithm to estimate diabetes type because of the lack of specificity about this in the Canadian electronic medical records, the lack of data on education level to better identify the contribution of income and education to glycemic control, and the lack of data on race and ethnicity, which strongly impact outcomes for people with diabetes in Canada and elsewhere. Team members with diabetes also questioned whether HbA_{1c} results might have differed during the 10-year span of the study given the introduction of new technologies in Canada between 2010 and 2019 that allow greater glycemic control.

With respect to implications for policy and future research, people living with diabetes noted that an HbA_{1c} level of ≤7% appeared to be very difficult to reach and maintain for many people living with diabetes in Canada. They suggested that these results be communicated to health professionals to help set realistic expectations and that people living with diabetes should consider being "insistent" with their health professionals to explore options for treatment and appropriate goals. Although guidelines suggest that HbA_{1c} targets should be set between a health professional and an individual living with diabetes while taking into account all relevant aspects of the individual's life, in practice, many people with diabetes do not receive this level of individualized care [24].

Indigenous patient partners expressed interest in data specifically for Indigenous peoples in Canada. The National Diabetes Repository does not currently contain data from health centers specifically serving Indigenous communities, although there may be data from urban Indigenous people within the data set that cannot be identified separately from the larger data set. Our goal with this project was to establish a means for people living with diabetes to determine research questions and drive epidemiological cohort studies. Although we knew our data source would not allow us to answer research questions specific to Indigenous peoples, we specifically included Indigenous patient partners, researchers, and non-Indigenous researchers who work with Indigenous communities in the project to help us collectively ensure that our approaches would not harm potential future Indigenous-led projects conducted under relevant ethical frameworks such as the First Nations' Principles of Ownership, Control, Access, and Possession [60].

Discussion

Principal Findings

In this study co-designed with people living with diabetes, we aimed to explore differences in HbA_{1c} levels between people with type 1 or type 2 diabetes of different sexes at different ages and with different levels of socioeconomic status, using a large database of primary care electronic medical records for people with diabetes in Canada. We report 6 main observations from our study.

First, the differences in statistical significance between the smaller sample of people with type 1 diabetes and the much larger sample of people with type 2 diabetes are reflective of broader patterns in research. These patterns have policy implications that can affect the lives of people living with more or less common conditions, including more or less common types of diabetes. Larger sample sizes allow identification of smaller associations or effects [61]. In the case of diabetes, this means that it is easier to identify statistically significant effects in the much larger populations of people with type 2 diabetes than in the smaller populations of people with type 1 diabetes or the even smaller populations of people with other types. This can have negative policy impacts on people with diabetes, for different reasons. For people with type 2 diabetes, as health research enters the era of big data and personalized medicine, large data sets analyzed by research teams with little clinical, epidemiological, or personal expertise may allow identification of associations or effects that may not be clinically or personally meaningful. For people with type 1 diabetes, who represent an estimated 5% to 10% of cases of diabetes, minority status within the larger disease community has led to policy issues such as

type 2 diabetes being identified as a risk factor for severe COVID-19 outcomes, whereas type 1 diabetes, which demonstrated higher odds ratios or hazard ratios for severe COVID-19 outcomes in multiple studies but had wider CIs owing to smaller populations [62-64], was identified only as a "potential risk factor" [65]. As with other less common conditions, it is important that policy decisions that affect people with diabetes account for differences in type of diabetes and avoid applying the same statistical standards to differently sized populations without accounting for the influence of sample size.

Second, age is an important consideration for HbA_{1c} targets for people with both types of diabetes. Similar to studies in other countries [7-10,66,67], our study demonstrated overall higher HbA_{1c} values among adolescents with diabetes compared with people with diabetes in other age groups. This may reflect the ways in which adolescents differ from people in other age groups due to biology (eg, puberty, menarche), diabetes management (eg, time since diagnosis to develop useful habits and patterns, lack of full control over management options due to family preferences and finances), and life stage (eg, externally imposed structures of school, work, family; internally-directed focus on social development). Although providing high-quality health care to children and adolescents with diabetes has long been an area of focus in Canada [68], our results suggested that adolescents may still need more support both within and outside of clinical encounters.

Third, there is a tendency toward different patterns across the life course between people of different sexes with type 1 diabetes. Our relatively small sample of people with type 1 diabetes in this data set did not allow us to draw definitive conclusions. However, women living with type 1 diabetes in our team noted that the potential pattern we observed mimicked their own HbA_{1c} patterns during childbearing, perimenopausal, and menopausal years. Hermann et al [69] similarly observed significantly higher HbA_{1c} among female people with type 1 diabetes compared with male people with type 1 diabetes before the age of 30 years and after the age of 50 years. People with type 1 diabetes who plan to bear children may be particularly motivated to maintain a lower HbA_{1c} level during their childbearing years because of more stringent recommendations regarding glycemic control during pregnancy [70,71] and societal, medical, and self-directed expectations regarding how pregnant people, especially those at increased risk, should prioritize the health of their offspring [72-75].

Following childbearing, the hormonal shifts of perimenopause and menopause combined with common life stressors of middle age and gendered parenting roles may explain the somewhat higher HbA_{1c} values among many middle-aged female people. As noted by the lead patient partner in this project (DG), the evidence available about menopause and type 1 diabetes is scarce. There are a small number of studies addressing age of menopause among people with type 1 diabetes [76-79] and associated health risks [80]. However, there is little evidence about how to manage one's diabetes and other health concerns post menopause [81]. This evidence gap negatively impacts the lives of people with type 1 diabetes who progress through menopause.

Fourth, the direction of the overall sex-based differences we observed among people with type 2 diabetes differed from some previous studies in other countries. In our study using data from people in Canada, male people with type 2 diabetes had overall higher HbA_{1c} values, indicating a potentially higher risk of diabetes-related complications compared with female people. Other studies using data from people in Portugal [13], Brazil and Venezuela [15], Korea [19], and Spain [82] reported the opposite, with overall higher HbA_{1c} values among those who are female compared with those who are male. Studies in the United States [22] and the Netherlands [23] reported no sex-based differences in HbA_{1c} values, and a study in Sweden reported higher HbA_{1c} values in male people compared with female people [9]. All of these other studies either focused on type 2 diabetes or did not distinguish between types of diabetes, meaning that the data were necessarily drawn from people with type 2 diabetes, who constitute 95% of people living with diabetes globally according to the World Health Organization [1]. The lack of agreement among different studies regarding sex-based differences might occur because overall differences may be a product of both biology and gender equality as seen via social roles. The World Economic Forum's Global Gender Gap Report offers data in support of the suggestion that gender roles may explain the different results regarding sex-based differences across countries. As measured by this index, the countries in which male people have lower HbA_{1c} values than female people (Spain, Korea, Portugal, Brazil, Venezuela) have lower mean gender equality (mean 0.723, SD 0.043) than the countries in which there was no difference (the United States and the Netherlands: mean 0.763, SD 0.001), which in turn had lower mean gender equality than countries in which male people had higher HbA_{1c} values (Canada, Sweden: mean 0.798, SD 0.036) [83]. In other words, in countries with better overall gender equality, female people may have better diabetes-relevant health outcomes relative to male people, while in countries with worse gender equality, female people with type 2 diabetes may have worse diabetes-relevant health outcomes relative to male people.

Fifth, people with type 2 diabetes living in less affluent areas in Canada had higher HbA_{1c} levels than those living in more affluent areas. This is unfortunately unsurprising, as type 2 diabetes is a progressive disease and is more prevalent in Canada among people with lower incomes than among those with higher incomes [84-86]. There may also be a similar pattern among people with type 1 diabetes that is not detectable in our relatively small sample. People with type 1 diabetes with higher incomes have less variability in their HbA_{1c} results [12]. Lower income has been shown to be associated with higher HbA_{1c} among children with type 1 diabetes in Canada [87], and complications are more prevalent among people living with type 1 diabetes in Canada with lower incomes [88]. Owing to the uneven coverage of diabetes medications and devices across Canada, unequal access to high-quality health care, and large differences in levels of food security, people with both types of diabetes who live on lower incomes may face additional challenges in diabetes management compared with those with higher incomes [89-92]. Without efforts to address these inequities, such patterns may

worsen in the coming years with the advent of new technologies and medications.

Finally, a substantial proportion of people with diabetes in Canada have not yet demonstrated guideline-recommended HbA_{1c} values. This shows the difficulty in reaching and maintaining this goal [93]. Similarly, Aronson and colleagues [94] showed, within a larger sample of 3600 adults living with type 1 diabetes and receiving care from endocrinologists in Canada, that less than a quarter of people demonstrated HbA_{1c} values ≤7%. Health professionals and policy makers should be aware of this gap to better support people living with diabetes in Canada. As noted by the people on our team who live with diabetes, health professionals' acknowledgment of the difficulty of attaining this target would help them feel less like they are failing and more like they are part of a large group living with a difficult condition and potentially struggling to achieve targets set by academic researchers and health professionals. Policy makers can improve this situation by better funding health care, education, medications (eg, insulin and other medications), supplies (eg, test strips, flash or continuous glucose monitors, and closed-loop artificial pancreas systems) [95], food security initiatives (eg, access to affordable healthy foods) [96], healthy environment initiatives (eg, walking trails, bicycle paths, and community gardens) [97], broader antipoverty initiatives [98], and research aimed at supporting people living with diabetes in Canada to achieve self-directed health goals [99].

This study had 3 main limitations. First, although the data set was large and of overall high quality, the lack of relevant data (eg, electronic medical records in Canada do not include relevant data such as ethnicity), the use of proxy variables (eg, socioeconomic status as an unvarying quintile derived from the most recent postal codes), and the necessity of using an algorithm to predict the type of diabetes may have limited our results. We cannot be certain that all people predicted by the algorithm to have type 1 diabetes were correctly identified, and even then, the small number of people identified by the algorithm as having type 1 diabetes meant that our findings with respect to type 1 diabetes were less conclusive than those for type 2 diabetes. Other rarer types of diabetes such as latent autoimmune diabetes in adults were not represented at all. Second, we did not include comorbid medical conditions in this preliminary study, as these were not part of the research question identified by people living with diabetes. Although people who live with other conditions in addition to diabetes may have higher or lower HbA_{1c} values than those who live only with diabetes; for this preliminary analysis, we sought only to determine broad patterns in this large national data set. Third, our analyses had some threats to external validity (ie, generalizability). All medical records from the National Diabetes Repository were collected from the primary care records of 5 provinces in Canada. Approximately 15% of people in Canada lack access to a primary health care provider, and lack of access is not distributed evenly [100,101], meaning that our study may have had some selection bias.

This study had 3 main strengths. First, the entire study, from the initial idea and development of the research question to the interpretation of results and drafting of this manuscript, was conducted in full partnership with people living with the condition studied. This allowed us to identify a research question that is relevant to people living with diabetes in Canada, enrich our interpretation of results, and avoid framing our results in ways that are heedless of the humanity of people whose medical data were analyzed. Second, this study offered insight into glycemic control for people living with diabetes across Canada, included key variables of sex and age, and accounted for the potential influence of socioeconomic status. It is important to avoid a one-size-fits-all approach when discussing diabetes management. Identifying patterns according to common variables is a step toward more individualized care. Third, data from the Canadian National Diabetes Repository represent high-quality big data across multiple provinces, allowing national-level analyses that were previously difficult to perform in Canada.

Conclusions

This study demonstrated the value and potential of patient-led research and of a national data repository for diabetes. People who live with a condition should have the power to set health research agendas so that research serves their needs. Responding to a research question developed by people living with diabetes, we mapped nearly a million HbA_{1c} results over 10 years from people with type 1 and type 2 diabetes in Canada and showed how HbA_{1c} results may differ by age, sex, and socioeconomic status. These factors are important to consider when setting HbA_{1c} targets and when studying the relationship between HbA_{1c} levels and complications of diabetes. Further research and support are needed to help people manage diabetes across life stages, with notable challenges during adolescence for people of both sexes and during menopause for people of female sex. As noted by members of our research team living with diabetes, people living with diabetes may not consistently receive adequate support from their health care team, family, employer, and regulatory and funding systems that determine the availability of medications and technologies. Health professionals should be aware of the difficulty in maintaining an HbA_{1c} value below the guideline-recommended targets without access to additional support, medications, and technologies. Policy makers should set policies that enable people with diabetes in Canada to live healthy lives.

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Data Availability

National Diabetes Repository data are available for analysis [102].

Authors' Contributions

SMM and HOW contributed to the study design. SMM, MG, and HOW contributed to data collection. SMM and HOW conducted data analysis and interpretation. SMM and HOW drafted the first version of the manuscript. SMM, DG, RN, MG, OD, SCD, DB, JMC, SD, RF, MG, JMG, AN, MR, TW, DJW, AD, and HOW critically revised the manuscript and approved the final version for publication. SMM had full access to all the data in the study. SMM and HOW had the final responsibility for the decision to submit for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Pairwise contrasts and sensitivity analyses.
[PDF File (Adobe PDF File), 960 KB - diabetes_v8i1e35682_app1.pdf]

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Abbreviations

HbA_{1c}: hemoglobin A_{1c}

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Understanding Patient Beliefs in Using Technology to Manage Diabetes: Path Analysis Model From a National Web-Based Sample

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Abstract

Background: With 425 million individuals globally living with diabetes, it is critical to support the self-management of this life-threatening condition. However, adherence and engagement with existing technologies are inadequate and need further research.

Objective: The objective of our study was to develop an integrated belief model that helps identify the significant constructs in predicting intention to use a diabetes self-management device for the detection of hypoglycemia.

Methods: Adults with type 1 diabetes living in the United States were recruited through Qualtrics to take a web-based questionnaire that assessed their preferences for a device that monitors their tremors and alerts them of the onset of hypoglycemia. As part of this questionnaire, a section focused on eliciting their response to behavioral constructs from the Health Belief Model, Technology Acceptance Model, and others.

Results: A total of 212 eligible participants responded to the Qualtrics survey. Intention to use a device for the self-management of diabetes was well predicted (R^2=0.65; $F_{12,199}$=27.19; P<.001) by 4 main constructs. The most significant constructs were *perceived usefulness* (β=.33; P<.001) and *perceived health threat* (β=.55; P<.001) followed by *cues to action* (β=.17; P<.001) and a negative effect from *resistance to change* (β=−.19; P<.001). Older age (β=.025; P<.001) led to an increase in their *perceived health threat*.

Conclusions: For individuals to use such a device, they need to perceive it as useful, perceive diabetes as life-threatening, regularly remember to perform actions to manage their condition, and exhibit less *resistance to change*. The model predicted the intention to use a diabetes self-management device as well, with several constructs found to be significant. This mental modeling approach can be complemented in future work by field-testing with physical prototype devices and assessing their interaction with the device longitudinally.

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KEYWORDS

type 1 diabetes mellitus; self-management; intention; psychological models; tremor; hypoglycemia; mobile app; health technology

Introduction

Overview

Diabetes is a prevalent condition affecting more than 400 million adults worldwide [1]. To limit serious complications, patients with diabetes need careful adherence to a self-management regimen, which includes monitoring of critical values such as intake of carbohydrates, blood sugar levels, and medication or insulin adherence [2-4] and help patients form healthy habits [5-7]. Several technologies exist to support diabetes self-management, such as blood glucose monitors and continuous glucose monitors. However, despite the promise shown by these technologies, user engagement and satisfaction are relatively low [8]. For example, while the recommended number of blood sugar measurement using blood glucose monitors is 4 to 10 times per day for patients with type 1 diabetes [9], studies show that the majority of patients measure their blood sugar an average of 2-3.5 times a day [10,11].

Several factors may contribute to poor adherence to continuous glucose monitoring use, including discomfort, costs, lack of technological savviness, and overall low interest from the users to sustain engagement with the technology [12,13]. Several behavioral models have emerged to understand contributing factors to such health-related behaviors. One such model, which is commonly used in the literature, is the Health Belief Model (HBM), which provides a framework to explain how an individual's perceptions (eg, barriers and self-efficacy) influence intention to perform health-related behaviors [14]. Recent work has attempted to integrate constructs from HBM with the Technology Acceptance Model (TAM) [15] to improve the prediction of intention to use patient-facing technologies for hypertension with promising results [16,17].

However, to our knowledge, such models have not been used to understand the intention to use diabetes self-management technologies. In addition, the application of beliefs and acceptance models has mostly focused on an existing technology. Investigating the efficacy of such models during the early phases of design remains a research gap. With the widespread use of mobile health and home telemonitoring technologies [18], understanding the potential impact of beliefs and acceptance on intentions could potentially inform proactive methods to identify variables that form the perception of a particular technology. Since participants' beliefs regarding their health and acceptance of technology may influence intention and actual usage, knowing the key belief constructs that must be targeted is of particular importance [19]. By identifying which beliefs limit the adoption of a technology, specific design elements (eg, behavior change techniques, motivational messages) may be integrated into the design of this technology to ensure higher chances of sustained usage [20].

Objectives

The objective of this study was to develop an integrated belief model that helps identify the significant constructs in predicting intention to use a diabetes self-management device for the detection of hypoglycemia. In this paper, we document a survey of a large national sample of patients with type 1 diabetes mellitus to investigate how health beliefs and acceptance constructs influence potential usage of diabetes self-management technologies. This study is part of a larger effort to design a tool to predict the onset of hypoglycemia by monitoring hand tremors. Inspired by Dou et al [17], we developed an integrated model to identify significant constructs by predicting an individual's intention to use a diabetes self-management technology that helps detect hypoglycemia.

Background

Our research used a combination of HBM and TAM constructs but did not investigate intentions to use a specific device or technology. Rather, we used a device-agnostic approach where participants were primed to think about how they manage their hypoglycemia and then asked to think about their preferences for a medical device that would help detect the onset of hypoglycemia and manage their diabetes. Accordingly, the following hypotheses were posited.

Perceived usefulness, one of the constructs included in TAM, has been shown to influence the use of technology [15]. *Perceived usefulness* refers to how useful and beneficial a system is perceived in achieving a specific purpose. Participants' prior experiences with or knowledge of diabetes self-management technologies have informed their mental model of such devices [21]. Such mental models include a notion of *perceived usefulness* that may influence adoption. Therefore, we hypothesize that:

- H1: *Perceived usefulness* is positively associated with intention.

The HBM helps identify how certain health beliefs affect an individual's intention to perform a health-related behavior [14]. *Perceived health threat*, one of the constructs included in HBM, is the extent to which an individual perceives their condition as threatening. Previous literature has suggested that *perceived health threat* has a significant positive effect on perceived usefulness and intention to use [14,17]. Therefore, we hypothesize that:

- H2a: *Perceived health threat* is positively associated with intention.
- H2b: *Perceived health threat* is positively associated with perceived usefulness.

According to HBM, *perceived severity* is one's opinion of the seriousness and potential impact of their condition on themselves and those around them. While the effects of perceived severity on adherence to new health regimens have shown inconclusive results in 1 study [22], their efficacy in the context of diabetes is worth investigating. Therefore, we hypothesize that:

- H3: *Perceived severity* is positively associated with intention.

Cues to action, another construct from HBM, is the stimulus that motivates the adaption of a new behavior. In this study, we refer to *cues to action* as the internal cues and motivations to perform more activity. For example, it has been shown that reminders are effective in improving technology usage [23]. While *cues to action* has not been assessed in relation to intention [24,25], we hypothesize that:

- H4: Cues to action is positively associated with intention.

According to HBM, *perceived barriers* is the perception that challenges exist to performing a healthy behavior [14]. Several barriers have been documented and shown to prevent individuals from adopting new technology as seen in previous literature [15]. Therefore, we hypothesize:

- H5: *Perceived barriers* is negatively associated with intention.

A few behavioral constructs not included in HBM or TAM were also explored. *Past experience* pertains to whether the user has used technology to manage their diabetes. Lack of experience or even a negative experience can reflect a major obstacle for individuals to adopt technology [12]. We hypothesize that:

- H6: Previous positive experience using technology is positively associated with intention.

Resistance to change, which is adapted from the dual factor model [26], refers to certain inhibiting beliefs that prevent the undertaking of a new behavior. *Resistance to change* has been found to negatively influence intention to use and perceived usefulness [17]. Therefore, the stronger individuals perceive themselves to be *resistance to change*, the lower their intention to use and perceived usefulness of a device may be [27,28]. We hypothesize that:

- H7a: *Resistance to change* is negatively associated with intention.
- H7b: *Resistance to change* is negatively associated with perceived usefulness.

Finally, the individual's relationship with their doctor influences how patients manage their conditions. This relationship has been found to significantly predict perceived usefulness of a device [17,29]. Therefore, we hypothesize that:

- H8: Relationship with doctor is positively associated with perceived usefulness.

Methods

Participants

A cross-sectional, internet panel survey of 212 adults with type 1 diabetes mellitus residing in the United States was conducted using the Qualtrics platform (Qualtrics) between May and April 2019. The study followed the guidelines of STROBE (Strengthening the Reporting of Observational studies in Epidemiology). The Texas A&M University institutional review board reviewed and approved the study protocol (IRB #2017-0914D) in May 2019 before the survey was launched. Recruitment was arranged by Qualtrics, which has a pool of individuals that can be recruited based on the inclusion criteria provided by our research team. First, a pilot data set consisting of the first 10% (n=20) of responses was shared with the research team to evaluate the inclusion criteria and assess the quality of the response. Individuals who qualified for the survey based on self-reported demographic data (18 years of age and older and diagnosed with type 1 diabetes mellitus) were invited via email to join the panel, with a link to follow if they were interested to participate. Those who participated in the survey were incentivized by points awarded through Qualtrics, which they can later redeem for a reward. Specific logic was added to the instrument to automatically remove unreasonable responses and participants who attempted to answer the questions quicker than a reasonable threshold set by Qualtrics. No identifiable information was recorded, but latitude and longitude were stored by Qualtrics for each respondent and used to confirm that all participants were located within the United States.

Survey Design

The survey questions were composed such that participants were primed to reflect on how they manage hypoglycemic events and their diabetic condition. As such, the survey targeted three main themes in addition to the demographic information: (1) user perception of hypoglycemia occurrence, (2) diabetes management experience, and (3) the beliefs of users regarding managing diabetes. The focus of this article is on the third theme of the survey, whereas details regarding the other 2 themes of the study are reported elsewhere [11]. The questions (Table 1) were published on Qualtrics and were rated by the participants on a 10-point Likert scale where 1=strongly disagree, 5=neutral, and 10=strongly agree.

Table 1. Questions and constructs asked in the survey.

Construct	Question	Reference
Perceived usefulness		[19,22]
PU1	Logging or sending my blood glucose values would help me manage diabetes better	
PU2	Overall, a diabetes management technology would be useful	
PU3	I don't think any device can help me in managing my condition	
Intention to use		[19,22]
ITU1	Given the opportunity, I would like to use a technology that helps me manage my diabetes	
ITU2	I would consider continuously using such a device	
ITU3	I am very determined to manage my diabetes	
Perceived health threat		[19,21]
PHT1	I am very knowledgeable of the severity of my diabetes condition	
PHT2	I am concerned about my diabetes	
PHT3	I put in effort to manage my diabetes	
PHT4	I feel keeping track of my glucose levels is very important	
Perceived severity		[14]
PS1	Having diabetes limits my overall quality of life	
PS2	Having diabetes negatively impacts my job performance	
Self-efficacy		[19,30]
SE1	I am confident in my ability to manage diabetes	
SE2	If I try enough, I know I can have proper control over my condition	
Social influence		[19,30]
SI1	People important to me think that I should use technology to help manage my diabetes	
SI2	People who are important to me use a diabetes management tool	
User experience		Newly developed
UE1	I use smartphones to help me manage my condition	
UE2	My past experience with Diabetes management tools has been positive	
UE3	I think of myself as a tech savvy person (someone comfortable learning and using technology)	
Resistance to change		[19,31]
RTC1	I do not want the technology to change the way I deal with diabetes	
RTC2	I do not want the technology to change the way I interact with other people	
RTC3	I am comfortable with using a diabetes management technology to help me with my condition	
Relationship with doctor		[19,32]
RWD1	Doctors are my most trusted source of health information	
RWD2	When I have a health concern, my first step is to contact a doctor	
RWD3	I trust the health care system	
Cues to action		[14]
CTA1	I have heard good things about diabetes management technology	
CTA2	I know where to go to get my blood sugar history monitored	
CTA3	I know that I should use technology to help me manage my condition	
Perceived barriers		[14]
PB1	There are barriers to me managing my condition	
PB2	I am aware of why I am unable to properly manage my condition	

Analysis

Partial least square path modeling [33] was used to assess the magnitude and significance of the causal relationships between the various constructs similar to the approach in [17]. It was performed to evaluate the hypothesized relationships between intention to use and behavioral constructs.

Results

Demographics

All 212 respondents were located within the United States, with 40 out of the 50 states represented in the sample; 129 out of 212 participants (61%) were females, and about half (n=117, 55%) were between the ages of 30 and 50 years, which comprised half the sample size. The data underrepresent older adults who might not be inclined to take a web-based survey and overrepresent the middle age groups. As shown in Table 2, other demographic factors align with the national data available. Most participants (n=182, 82%) were White non-Hispanic, and 92 (57%) participants had a household income greater than US $50,000. When asked if they used technology to manage their diabetes, most respondents (n=150, 71%) indicated that they currently use or have used at least one in the past. While these categories are not mutually exclusive, 41 out of 150 participants (27%) have used a continuous glucose monitor, 49 out of 150 (33%) have used an insulin pump, 107 out of 150 (71%) have used a blood glucose meter, and 57 out of 150 (38%) have used a smartphone app to aid in the self-management of diabetes. Further details on demographic information can be found in [11].

Table 2. Demographics.

Characteristic	Web-based data sample Participants, n (%)	National data Population (%)	References
Gender			[34]
Female	129 (60.9)	51	
Male	83 (39.1)	49	
Age (years)			[35]
18-29[a]	34 (16.0)	18.4	
30-39	64 (30.2)	17.8	
40-49	53 (25.0)	16.6	
50-59	33 (15.6)	17.4	
≥60	28 (13.2)	29.8	
Race			[36]
White	182 (85.9)	76.5	
Native Hawaiian or Pacific Islander	2 (0.9)	0.2	
Black or African American	13 (6.1)	13.4	
Asian	6 (2.8)	5.9	
Two or more races	6 (2.8)	2.7	
Other	3 (1.4)	—[b]	
White non-Hispanic	174 (82.1)	60.4	
Hispanic or Latino	17 (8.0)	18.3	
Smartphone			[37]
None	15 (7.1)	19	
Yes	197 (92.9)	81	
Android	103 (52.2)	51.1	
iOS	93 (47.2)	48.1	
Other	1 (0.5)	0.8	
Income level (US $)			[36]
<$20,000[c]	24 (11.3)	19.1	
$20,000-$29,999[d]	20 (9.4)	8.8	
$30,000-$39,999[e]	23 (10.9)	12	
$40,000-$49,999	17 (8.0)	N/A[f]	
$50,000-$59,999[g]	29 (13.7)	17.2	
>$60,000[h]	92 (43.4)	42.9	
Did not answer	7 (33)	—	
Educational level			[30]
None	—	1.4	
Less than high school	2 (0.9)	4.2	
High school	36 (17.0)	34.9	
Some college, no degree	43 (20.3)	21	
Bachelor's	61 (28.8)	18.8	
Associate degree or trade school	20 (9.4)	8.2	

Characteristic	Web-based data sample Participants, n (%)	National data Population (%)	References
Graduate or professional	50 (236)	11.5	
Years of living with diabetes		N/A	N/A
≤1	69 (32.5)		
>1 and ≤10	46 (21.7)		
>10 and ≤25	39 (18.4)		
>25	58 (27.4)		
Daily blood glucose measurements[i]		N/A	N/A
0	12 (5.9)		
1-3	85 (41.7)		
4-10	107 (52.5)		

[a]National data represents those aged 20-29 years.

[b]Data not available.

[c]National data represents income levels <US $25,000.

[d]National data represents income levels from US $25,000 to US $35,000.

[e]National data represents income levels from US $35,000 to US $50,000.

[f]N/A: not applicable.

[g]National data represents income levels from US $50,000 to US $75,000.

[h]National data represents income levels >US $75,000.

[i]Eight entries were removed due to invalid numbers or text.

Survey Reliability

The average responses for each question are listed in Table 3, along with the reliability metrics. For constructs having 3 or more questions, Cronbach alpha (α>.7) showed good reliability for *intention*, *perceived health threat*, *past experience*, *relationship with doctor*, and *cues to action*. However, Cronbach alpha was lower (α>.5) for *perceived usefulness* and *resistance to change*. Among the constructs that had 2 questions, we witnessed a strong Spearman's correlation (ρ>0.7) for *perceived severity* and *self-efficacy* which was significant at P<.001. A medium correlation (ρ>0.5) was found for both *social influence* and *perceived barriers*, also significant at P<.001.

Table 3. Response to the belief questions.

Construct	Question	Mean (SD)	Correlation (α)
Perceived usefulness			.5
PU1	Logging or sending my blood glucose values would help me manage diabetes better	6.79 (2.67)	
PU2	Overall, a diabetes management technology would be useful	7.62 (2.24)	
PU3	I don't think any device can help me in managing my condition	4.27 (2.92)	
Intention to use			.83
ITU1	Given the opportunity, I would like to use a technology that helps me manage my diabetes	7.56 (2.49)	
ITU2	I would consider continuously using such a device	7.57 (2.37)	
ITU3	I am very determined to manage my diabetes	8.07 (2.02)	
Perceived health threat			.71
PHT1	I am very knowledgeable of the severity of my diabetes condition	8.18 (1.97)	
PHT2	I am concerned about my diabetes	7.25 (2.46)	
PHT3	I put in effort to manage my diabetes	7.96 (1.97)	
PHT4	I feel keeping track of my glucose levels is very important	8.01 (1.98)	
Perceived severity			
PS1	Having diabetes limits my overall quality of life	6.35 (2.91)	
PS2	Having diabetes negatively impacts my job performance	5.43 (3.12)	
Self-efficacy			.70
SE1	I am confident in my ability to manage diabetes	7.32 (2.21)	
SE2	If I try enough, I know I can have proper control over my condition	7.65 (2.10)	
Social influence			.53
SI1	People important to me think that I should use technology to help manage my diabetes	6.56 (2.89)	
SI2	People who are important to me use a diabetes management tool	5.26 (3.30)	
User experience			.73
UE1	I use smartphones to help me manage my condition	5.20 (3.37)	
UE2	My past experience with Diabetes management tools has been positive	6.53 (2.65)	
UE3	I think of myself as a tech savvy person (comfortable learning and using technology)	7.02 (2.77)	
Resistance to change			.53
RTC1	I do not want the technology to change the way I deal with diabetes	4.78 (2.93)	
RTC2	I do not want the technology to change the way I interact with other people	6.52 (3.02)	
RTC3	I am comfortable with using a diabetes management technology to help me with my condition	7.59 (2.32)	
Relationship with doctor			.84
RWD1	Doctors are my most trusted source of health information	7.35 (2.36)	
RWD2	When I have a health concern, my first step is to contact a doctor	7.25 (2.39)	
RWD3	I trust the health care system	6.83 (2.41)	
Cues to action			.83
CTA1	I have heard good things about diabetes management technology	7.08 (2.52)	
CTA2	I know where to go to get my blood sugar history monitored	7.26 (2.64)	
CTA3	I know that I should use technology to help me manage my condition	7.02 (2.70)	
Perceived barriers			.57

Construct	Question	Mean (SD)	Correlation (α)
PB1	There are barriers to me managing my condition	5.70 (2.86)	
PB2	I am aware of why I am unable to properly manage my condition	6.32 (2.86)	

Path Analysis

The model was assessed by checking the significance of path coefficients (β) among the independent variables and the latent variables. The results of the path modeling are shown in Figure 1. Each construct was regressed against the other constructs to confirm existing relationships hypothesized above and uncover any relationships that were not accounted for. The model shows that intention to use is significantly influenced (R^2=0.627; $F_{12,199}$=27.19; *P*<.001) by *perceived usefulness*, *perceived health threat*, *cues to action*, and *resistance to change*.

Overall, the more useful participants perceived a diabetes self-management technology would be, the more likely they were to use it (β=.33; t_{199}=4.69; *P*<.001), which supports H1. Male participants were more likely to have a positive perception of usefulness (β=.12; t_{199}=2.24; *P*=.03). Also, the more threatening participants perceived their condition to be, the more likely they were to intend to use a device (β=.55; t_{199}=7.02; *P*<.001), which supports H2a. However, *perceived usefulness* was not found to be significantly predicted by a higher *perceived health threat*, so H2b was not supported. Rather, *perceived usefulness* was influenced by *perceived severity* of the condition (β=.15; t_{199}=2.19; *P*=.03), which is related to *perceived health threat*. Male participants were less likely to perceive their condition as threatening (β=−.65; t_{199}=−3.81; *P*<.001) and older individuals had higher *perceived health threat* (β=.025, t_{199}=4.29, *P*<.001). *Perceived severity* did not have a direct effect on intention; thus, H3 was not supported. In addition, a stronger *relationship with their doctor* and stronger *self-efficacy* reflected an increase in *perceived health threat* (β=.14; t_{199}=2.09; *P*=.03 and β=.27; t_{199}=5.12; *P*<.001, respectively) so they indirectly influenced intention.

Cues to action positively influenced intention to use (β=.17; t_{199}=2.73; *P*=.007), thereby supporting H4. Meanwhile, *perceived barriers* did not have any significant direct or indirect effect on *intention*, so H5 was not supported. *Past experience* had a significant effect on *self-efficacy* (β=.54; t_{199}=6.72; *P*<.01); however, it did not have a direct influence on intention to use, so H6 was partially supported. Also, *resistance to change* had a negative effect on intention to use (β=−.19; t_{199}=−3.61; *P*<.001), which supports 7a and having high *self-efficacy* made individuals more *resistant to change* (β=.19; t_{199}=2.25; *P*=.03). However, no significant relationship was found between *resistance to change* and *perceived usefulness*, so H7b was not supported. Finally, participants' *relationship with their doctor* did not have a significant relationship with *perceived usefulness*, so H8 was not supported. A summary of the hypotheses and their status is provided in Table 4.

Figure 1. Path analysis model. *P<.05, **P<.01, ***P<.001.

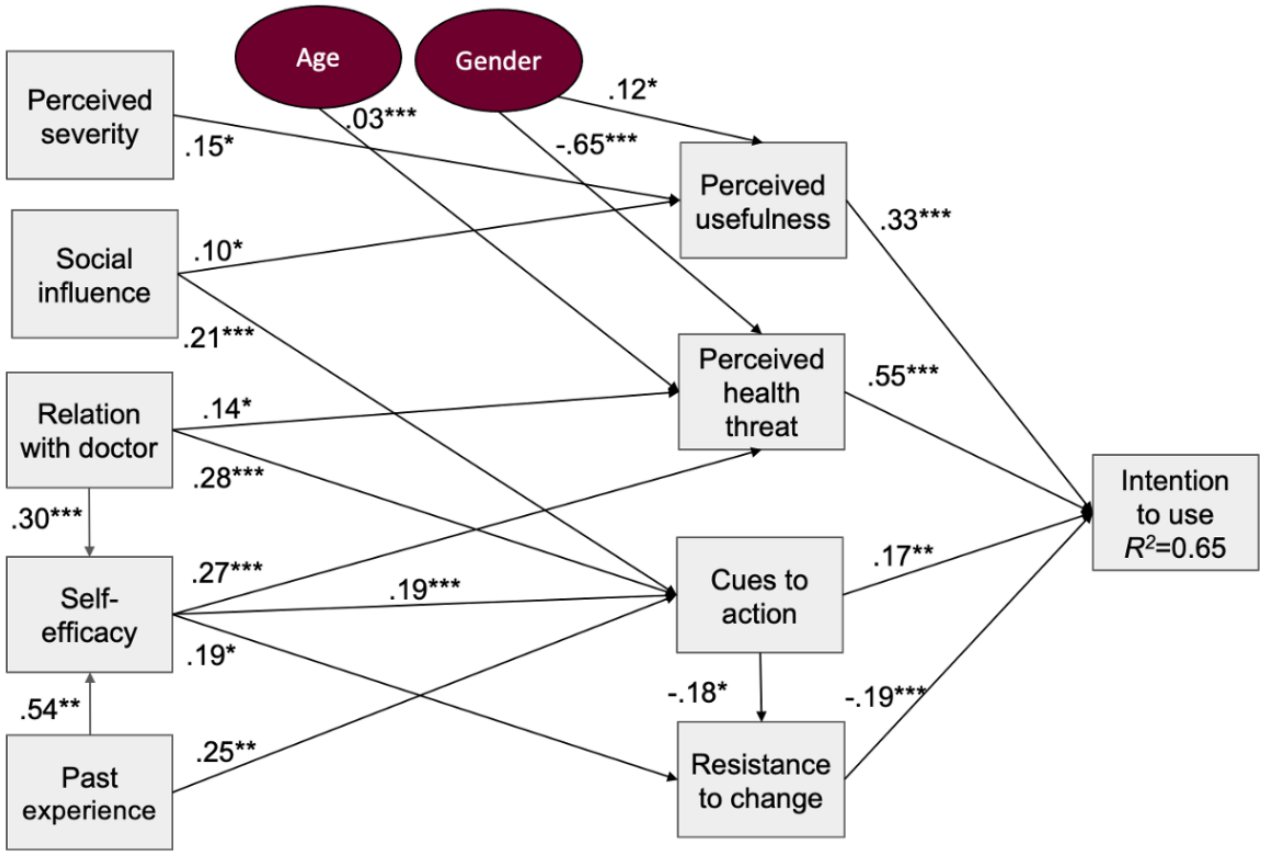

Table 4. Summary of the hypotheses and whether they were supported.

Hypothesis	Result
H1: Perceived usefulness is positively associated with intention	Supported
H2a: Perceived health threat is positively associated with intention	Supported
H2b: Perceived health threat is positively associated with perceived usefulness	Not supported
H3: Perceived severity is positively associated with intention	Not supported
H4: Cues to action is positively associated with intention	Supported
H5: Perceived barriers is negatively associated with intention	Not supported
H6: Positive past experience is positively associated with intention	Partially supported
H7a: Resistance to change is negatively associated with intention	Supported
H7b: Resistance to change is negatively associated with perceived usefulness	Not supported
H8: Relationship with doctor is positively associated with perceived usefulness	Not supported

Discussion

Principal Findings

In this study, we integrated HBM with the TAM and incorporated additional constructs (in line with [17]) to predict the intention of patients with type 1 diabetes to use technology to manage their condition. To our knowledge, this is the first attempt to use behavioral constructs to investigate patient intentions to use diabetes self-management technologies. The findings presented here highlight several significant relationships that may inform future proactive approaches in understanding the adoption and sustained usage of diabetes technologies. In particular, constructs with significant effects on intention may be subject to further investigation to assess their use in behavior change efforts.

The results show that the strongest relationship was between an individual's *intention* to use technology and the *perceived usefulness* of such technology. This finding supports the premise of TAM [15] and a large body of literature that have used it. The evidence documented here may suggest that adoption and sustained usage of diabetes technologies may depend on patients' buy-in and conviction about the benefits provided by the technology. For participants to find benefit in such a technology, it must integrate high information quality, personalization, and usable core functions such as notifications, goal setting, and feedback into its design [31]. For example, high-quality content from authoritative sources (eg, American Diabetes Association) may be used to gain users' trust in the credibility of the content [32]. Personalization may be achieved by including the name of the user while interacting with them and forming a user profile and accounting for their personality [38]. Users must also be educated on the benefits of the technology and provided some form of social proof from other individuals who have used it and benefitted from it [39]. Training users on the technology may help users feel confident they are able to use the device [40]. Ultimately, participants also need to witness an improvement in their health outcomes to perceive it as useful.

Next, *intention* was significantly influenced by *perceived health threat*. In other words, the more serious the condition was perceived to be, the more likely the higher the intention to use a technology to manage it. This finding is in line with other studies investigating eHealth services [41] or hypertension management technologies [17]. Given the importance of this construct for potential impacting behaviors related to adoption and sustained usage of diabetes technologies, future efforts may focus on educational content, reminders and alerts, and information visualization techniques that make the risks that diabetes poses to a patient's health as well as the consequence of unhealthy behaviors more tangible. For example, descriptive statistics from authoritative and credible sources could be used to make the health threat more salient by highlighting the risks for the patients' respective demographic (eg, age, race, and location) and long-term complications of not managing their condition [42]. Special care must be given to elderly populations as older age was shown to increase an individual's *perceivedhealth threat*; however, despite high intentions to use, low tech savviness or literacy have been shown to be a major barrier to sustained usage in other studies [43,44].

In addition, *resistance to change* had a significant negative effect on intention to use. Understanding why users are resistant to changing their behavior is important but challenging and due to contentment with their current habit or because there is a certain level of anxiety from trying out a new behavior or technology [45]. Progressive persuasion has been posited as an approach to work around participants' *resistance to change* their behavior and use a new technology. This method may be implemented by assuring resistant individuals that little change is required, stressing the ease of use, then introducing them slowly to more features over time [45]. Addressing *perceived barriers* may also aid participants to be less resistant to change, which could be a key to help individuals become more willing to engage in behaviors that manage their health [46].

Finally, *cues to action* had a significant impact on intentions. Individuals who often recall performing behaviors related to their regimen, also known as internal *cues to action*, are more likely to use the technology. Individuals who form good prospective memory have more strongly internalized cues and are more likely to remember to perform certain behaviors (eg, measure blood sugar) [47]. Regular reminders and making patients more aware of the need to manage their diabetes could

contribute to users forming the intention to use a device for that purpose and, ultimately, establish a habit from this behavior [48]. In fact, reminders have been reported to be among the core functions that an app must have in order to achieve adequate functionality [31]. *Cues to action* is an important factor but has not been assessed for how it is influenced by a longitudinal intervention. Studies may benefit from using automated reminders in an app and testing the change in *cues to action* for those who receive automated reminders versus those who do not.

Limitations

This study had several noteworthy limitations that may affect the generalizability of the findings. First, our participants self-reported to have type 1 diabetes, and while the sample was drawn from a panel defined by this condition, the research team had no way of validating this claim. Second, the sample's average age was biased toward young to middle-aged participants, and more work is needed to assess such relationships for older populations. Third, this work elicited at one point in time similar to other studies focusing on beliefs [19,20,27]. Future work should assess longitudinal changes in beliefs and potentially compare intentions with actual usage.

Conclusion

Proactive and predictive approaches in understanding technology adoption and usage remain a research gap. Behavioral constructs such as health beliefs and technology acceptance show promise in providing potentially useful insight on behaviors. This research showed that *perceived health threat*, *perceived usefulness*, *cues to action*, and *resistance to change* might possess such predictive efficacy in the context of diabetes technology usage. The findings presented here suggest that future work can benefit from the assessment of belief constructs early in the technology design and development cycle to inform areas of opportunity to address bottlenecks and to identify personalized behavior change interventions [49]. For example, a patient scoring low on *perceived health threat* can receive educational messages to increase their knowledge of chronic diseases and their risks, whereas those with high scores on *resistance to change* can receive persuasive and motivational messages. However, work is needed to validate these findings under varied health contexts and with specific technologies.

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Conflicts of Interest

None declared.

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Abbreviations

HBM: Health Belief Model
TAM: Technology Acceptance Model

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Original Paper

Improving the Well-being of Adolescents With Type 1 Diabetes During the COVID-19 Pandemic: Qualitative Study Exploring Acceptability and Clinical Usability of a Self-compassion Chatbot

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Abstract

Background: Before the COVID-19 pandemic, adolescents with type 1 diabetes (T1D) had already experienced far greater rates of psychological distress than their peers. With the pandemic further challenging mental health and increasing the barriers to maintaining optimal diabetes self-management, it is vital that this population has access to remotely deliverable, evidence-based interventions to improve psychological and diabetes outcomes. Chatbots, defined as digital conversational agents, offer these unique advantages, as well as the ability to engage in empathetic and personalized conversations 24-7. Building on previous work developing a self-compassion program for adolescents with T1D, a self-compassion chatbot (COMPASS) was developed for adolescents with T1D to address these concerns. However, the acceptability and potential clinical usability of a chatbot to deliver self-compassion coping tools to adolescents with T1D remained unknown.

Objective: This qualitative study was designed to evaluate the acceptability and potential clinical utility of COMPASS among adolescents aged 12 to 16 years with T1D and diabetes health care professionals.

Methods: Potential adolescent participants were recruited from previous participant lists, and on the web and in-clinic study flyers, whereas health care professionals were recruited via clinic emails and from diabetes research special interest groups. Qualitative Zoom (Zoom Video Communications, Inc) interviews exploring views on COMPASS were conducted with 19 adolescents (in 4 focus groups) and 11 diabetes health care professionals (in 2 focus groups and 6 individual interviews) from March 2022 to April 2022. Transcripts were analyzed using directed content analysis to examine the features and content of greatest importance to both groups.

Results: Adolescents were broadly representative of the youth population living with T1D in Aotearoa (11/19, 58% female; 13/19, 68% Aotearoa New Zealand European; and 2/19, 11% Māori). Health care professionals represented a range of disciplines, including diabetes nurse specialists (3/11, 27%), health psychologists (3/11, 27%), dieticians (3/11, 27%), and endocrinologists (2/11, 18%). The findings offer insight into what adolescents with T1D and their health care professionals see as the shared advantages of COMPASS and desired future additions, such as personalization (mentioned by all 19 adolescents), self-management support (mentioned by 13/19, 68% of adolescents), clinical utility (mentioned by all 11 health care professionals), and breadth and flexibility of tools (mentioned by 10/11, 91% of health care professionals).

Conclusions: Early data suggest that COMPASS is acceptable, is relevant to common difficulties, and has clinical utility during the COVID-19 pandemic. However, shared desired features among both groups, including problem-solving and integration with diabetes technology to support self-management; creating a safe peer-to-peer sense of community; and broadening the representation of cultures, lived experience stories, and diabetes challenges, could further improve the potential of the chatbot. On the basis of these findings, COMPASS is currently being improved to be tested in a feasibility study.

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KEYWORDS

self-compassion; chatbot; conversational agent; artificial intelligence; adolescence; type 1 diabetes; mental health; digital health; psychosocial interventions; COVID-19; mobile phone

Introduction

Background

Before the COVID-19 pandemic, adolescents with type 1 diabetes (T1D) had already experienced high rates of psychological distress and self-management challenges [1]. T1D is an autoimmune disorder that requires lifelong insulin therapy. Maintaining optimal self-management of T1D involves adherence to a complicated routine of daily self-administration of insulin and monitoring diet, energy expenditure, and blood glucose levels, with an estimated average of 180 daily self-management decisions [2]. In addition, adolescents must learn how to make these complex routines flexible enough to integrate into their daily lives, including school, hobbies, and other activities [3], while concurrently navigating developmental changes and demands. As a result, diabetes self-management tends to deteriorate during adolescence [4], and the prevalence of psychological disorders among adolescents with T1D is estimated to be 2 to 4 times greater than that of their general peers [1]. In Aotearoa, New Zealand, recent studies have estimated the rates of diabetes distress and disordered eating behaviors to be as high as 24% and 31%, respectively [5], with rates of psychological distress and self-management difficulties disproportionately affecting Indigenous Māori youth and those with socioeconomic deprivation [5-7].

Understandably, the COVID-19 pandemic has added further barriers to maintaining optimal glycemic targets and challenges to mental health in this population. As T1D is a condition that depends on multiple daily tasks, the COVID-19 pandemic has caused extensive disruption to daily routines and standard care. Commonly reported disruptions include restricted access to face-to-face health care; periods of home isolation; reduced physical activity owing to confinement; fear of more considerable COVID-19–related health risks; lack of social support from family, friends, and their diabetes care teams; and changes in eating behaviors and routines [8,9]. Although research has not specifically quantified the impacts of the COVID-19 pandemic on adolescents with T1D, the effects of the pandemic among people with T1D are becoming increasingly clear. For example, a high prevalence of eating and sleep disorders has been reported in people with diabetes [10,11]. In addition, although the reported impacts of the pandemic on diabetes management vary by country and insulin treatment technology, multiple countries have reported an increase in diabetic ketoacidosis frequency [12,13] and suboptimal glycemic variability [14,15]. Although a number of novel digital well-being initiatives became available during the COVID-19 pandemic [16-19], none addressed the unique challenges that adolescents with T1D face.

However, although the COVID-19 pandemic has compounded this problem, standard diabetes care was already struggling to provide adequate psychosocial support in this population [20,21]. Furthermore, despite the existence of evidence-based psychosocial interventions, they are rarely integrated within standard care because of ongoing funding constraints and clinician availability [20,22]. With the COVID-19 pandemic disrupting access to face-to-face health services and placing additional demands on systems, the existing constraints and lack of therapist availability are compounded. With worsening mental and physical health outcomes, digital interventions potentially offer this population a more accessible and clinically usable approach. However, a recent systematic review of digital interventions for youth with diabetes revealed an urgent need for evidence-based digital interventions to target psychological well-being [23]. To address the need for clinically usable psychological interventions for this sample and ongoing challenges related to COVID-19, we have recently developed a digital intervention based on self-compassion for adolescents with T1D.

Self-compassion Chatbot

Self-compassion, which focuses on being kind and understanding toward our failures and hardships instead of being harsh and self-critical [24], is a promising treatment approach that appears to be highly relevant to the self-criticism that often accompanies attempts to adhere to complex self-management regimens, such as those in T1D. Face-to-face self-compassion interventions have demonstrated improvements in psychological health in adults [25] and adolescents [26] as well as in glycemic stability in adults with diabetes [27]. Our previous research found self-compassion to be an acceptable approach to improving mental and physical health in adolescents with T1D; however, face-to-face delivery demonstrated serious feasibility issues [28]. Our follow-up qualitative research, exploring perceptions regarding a possible digital adaption, demonstrated that a chatbot adaption was the preferred digital platform among adolescents with T1D [29].

A chatbot is defined as an automated computer program designed to simulate and process natural human conversation, allowing humans to interact with content as if they were communicating with a real person [30]. As a delivery modality, chatbots offer unique advantages over face-to-face therapy and

other digital tools, including 24-hour availability, accessibility, remote delivery, scalability, and the capability to respond with personalized and empathetic responses in real time when they are needed. The evidence for their utility in supplementing standard care is growing. A recent review of mental health chatbots found improvements in symptoms of depression, anxiety, and general coping skills [30]. Chatbots have also been used for youth with health conditions, with a positive psychology skills chatbot showing reductions in anxiety for young adult cancer survivors [31]. In addition, chatbots have also shown acceptability and efficacy for improving self-management in a variety of health care settings, such as pediatric asthma self-management [32], chronic pain [33], and irritable bowel disease [34]. Although the efficacy of chatbots for youth with T1D remains unknown, the existing literature demonstrates that chatbots offer unique modality advantages and the potential to be feasibly embedded into existing diabetes technology to minimize patient burden.

Considering the ongoing impact of the COVID-19 pandemic on the preexisting high prevalence of psychological distress and self-management difficulties in this population and the unique utility of chatbots as a treatment modality, our research team developed a chatbot app intervention (called "COMPASS") for adolescents aged 12 to 16 years with T1D in Aotearoa, New Zealand. The COMPASS chatbot is designed to deliver daily content in 14 conversational lessons daily across 2 weeks, aimed at facilitating self-compassion coping skills for adolescents with T1D. Accordingly, we first conducted focus groups to examine the user acceptability and potential clinical utility of the COMPASS chatbot app. As health care professionals commonly introduce and recommend mobile health apps to their patients [35], their perspective on a potential intervention for their patients was examined alongside the views of adolescents with T1D themselves.

Methods

Study Design

This qualitative study used focus groups and one-on-one interviews to examine the acceptability and the potential clinical utility of the COMPASS chatbot app in adolescents (aged 12-16 years) with T1D and their diabetes health care professionals. Focus groups were chosen for adolescents to encourage interactive, free-flowing conversations, whereas the choice of focus groups or one-on-one interview formats were offered to health care professionals to accommodate schedules during the COVID-19 Omicron surge in Aotearoa, New Zealand, with most health care professionals experiencing redeployment and increased clinical demands. As the prototype is still in the development phase and our focus is on the acceptability and the potential clinical utility of the included content and features, participants were shown screen recordings of the chatbot and were not given access to test it on their own devices.

Ethics Approval

The study received ethics approval from the Health and Disability Ethics Committee, New Zealand (Ref: A+9284), and all participants provided informed consent or assent. Recruitment started on February 23, 2022, and was completed on April 4, 2022. Focus groups and interviews were conducted between March 4, 2022, and April 4, 2022. The methods were reported following the COREQ (Consolidated Criteria for Reporting Qualitative Studies) [36].

Self-compassion Chatbot

Overview

The COMPASS chatbot delivers content designed to facilitate self-compassion coping skills for adolescents with T1D in 14 conversational lessons provided daily for 2 weeks. The preliminary conversational content and decision tree for COMPASS were developed by the first author (AB), with feedback from the coauthor SH and the University of Auckland's Health Advances Through Behavior Intervention Technologies team [37].

Content

The lesson content for the COMPASS chatbot was adapted from the evidence-based standardized 8-week adolescent self-compassion program [13] and our research teams' brief 2-week adaption of the 8-week program for the specific challenges experienced by adolescents with T1D [28,38]. Most lessons are structured around the three components of self-compassion: (1) mindfulness (defined as having a balanced awareness of thoughts and feelings and grouped together in the chatbot as the "be mindful" activities), (2) common humanity (defined as acknowledging that challenges and imperfectness are part of being human and grouped together in the chatbot as the "meet teens like" activities), and (3) self-kindness (defined as being caring and understanding toward oneself and grouped together in the chatbot as "be self-compassionate") [24]. Figure 1 shows an overview of the chatbot's content. The chatbot also contains a psychoeducational activity (called "learn about my brain") and distraction activities, which include rugby, netball, soccer, and basketball swipe sports games. Table 1 presents an outline of each activity included and a brief description.

Figure 1. An overview of the types of activities included in the self-compassion chatbot.

Table 1. The 14 daily activities currently included in the first self-compassion chatbot prototype, presented in the order they are suggested to the user under each subheading of activities.

Activity category	Activity name and a brief description
Compulsory introductory activities	
Be self-compassionate	• "Self-compassion 101," an introductory activity using the "how I treat a friend versus how I treat a friend" exercise to explain the concept of the inner critic and what self-compassion is • "The three steps to self-compassion," an introduction activity practicing using the 3 components of self-compassion for a current stressor (mindfulness, common humanity, and self-kindness)
Psychoeducation	
Learn about my brain	• "Learn about my brain," a psychoeducation activity explaining adolescent brain development and emotion regulation systems [39] to establish why self-compassion can help with managing difficult emotions
Mindfulness	
Be mindful	• "Grounding exercise," a mindfulness activity focusing on paying attention to our different senses • "Check-in meditation," a mindfulness activity focusing on checking in on our emotions and giving self-compassion toward those feelings • "Music meditation," a mindfulness activity focusing attention on the different instruments, tones, and sounds in music • "Compassionate body scan," a mindfulness activity focusing attention on the different areas of our bodies and giving gratitude to what our body does for us instead of what it looks like
Common humanity	
Meet teens like me	• "Meet teens like me," an activity using videos from older teenagers, young adults, and famous New Zealand figures with T1D talking about common struggles to create a sense of common humanity • "Using self-compassion for diabetes struggles," an activity using the 3 steps of self-compassion for diabetes burnout
Self-compassion	
Be self-compassionate	• "Motivating ourselves with self-compassion," an activity on setting goals with self-compassion instead of self-criticism • "Self-compassion myth busters," an activity outlining common struggles to being self-compassionate and metaphors and activities to help overcome common misconceptions or challenges • "Compassionate friend meditation," an activity aimed at giving ourselves the same compassion and understanding a close friend or pet does • "Re-writing inner critic statements," an activity practicing using self-compassionate statements instead of critical ones • "Comforting gestures," an activity aimed at finding a gesture (ie, putting your hands over your heart) that feels comforting (also called "soothing touch")

Format and Functionality

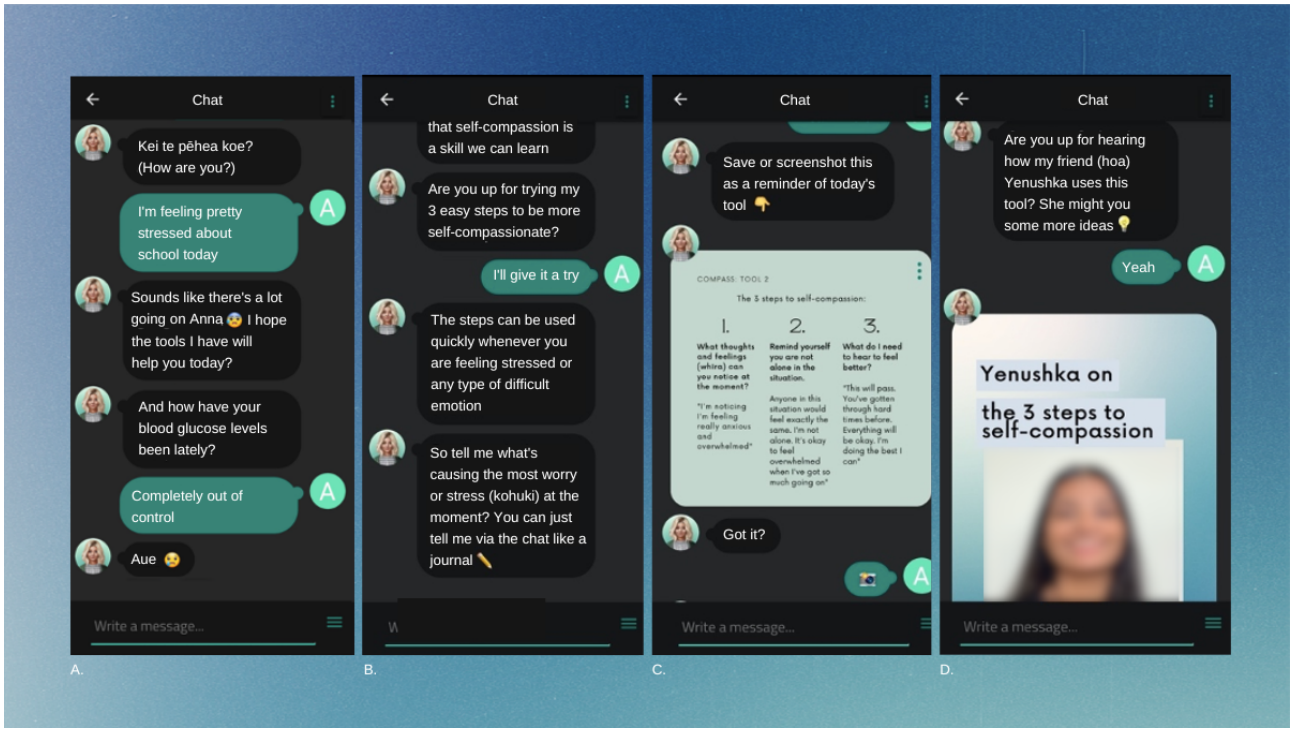
The chatbot delivers prewritten conversational lessons mostly via decision tree "rule-based" programming [40]. Therefore, the chatbot content is predominantly in dialog format that is based on predetermined "quick options" (such as "yes," "maybe," "no," "let's try it," "tell me more") that branch out the conversation along the user-chosen path. However, the COMPASS chatbot uses some instances of artificial intelligence to identify emotions; whether diabetes management is suboptimal or optimal; and risk words to deliver personalized, empathetic, and relevant responses and adequate information

to connect with further crises and mental health support services. Further format and functionality features of the current prototype version were informed by suggestions from a previous qualitative study conducted by our research team, which explored the functionality and content that adolescents with T1D wanted to see in future digital mental health programs [29].

When the user first engages with the COMPASS chatbot, an onboarding module explains how the chatbot is structured and emphasizes that it is an automated person (not a real-life human). These early exchanges encourage participants to try all the different activities over the following 2 weeks, ask the user for a nickname to call them, and ask the user to set a time for the chatbot to send a daily notification to check in with the chatbot and complete an activity. The chatbot also allows the user to pick an avatar to talk to, with options representing a range of gender identities and ethnicities. Subsequently, the chatbot then begins an introductory activity before asking for feedback. After the first day, the chatbot follows a general structure of daily notification, emotion and diabetes check-in, choice of daily activity, and activity feedback (Figure 2 shows examples of each component). Although the chatbot can deliver a new activity every day, there is an option to repeat activities that the user has previously completed by either looking at a brief summary or performing the activity again. Each daily interaction with the chatbot was designed to last approximately 5 minutes.

The written content is enhanced by additional features and media. For example, each module contains a summary infographic at the end of each activity (seen in Figure 2) so that adolescents can save images of the tools that they found helpful. The activities are also enhanced by using audio-guided meditations, Graphics Interchange Formats (GIFs), and videos from older Aotearoa New Zealand teenagers, young adults, and celebrities with T1D talking about common struggles. Videos discuss topics such as diabetes burnout, feeling isolated from peers, navigating relationships with peers and diabetes inner critics, how to be self-compassionate when experiencing diabetes burnout, communicating with others who do not understand T1D, and how to manage T1D in sports contexts. To improve accessibility and usability, all videos contained subtitles, and all meditations had written message adaptions.

Figure 2. Example of the daily structure of the self-compassion chatbot, in sequential order of features and activities. A. Example of the emotion and diabetes check-in. B. Example of the introduction to a daily activity. C. Example of a summary infographic included in all daily activities. D. Example of lived experience videos included in some activities.



Study Participants and Recruitment

A target sample size of approximately 15 to 20 adolescents with T1D (aged between 12 and 16 years) and 10 to 15 diabetes health care professionals were chosen as an achievable recruitment target. Informed by earlier qualitative work in this area [29] and reviews of qualitative research [41], we estimated that this sample size would allow data saturation to occur. However, if data saturation was not achieved, an ethical amendment would have been applied to expand the number of participants. The eligibility criteria for adolescents included the following: being aged between 12 and 16 years; living in Aotearoa, New Zealand; having a diagnosis of T1D for >6 months; having no diagnoses of serious developmental or psychiatric disorders; and being able to provide consent in English. In addition, we aimed to recruit at least 5 Māori and Pacific young people to allow for one group of solely Māori and Pacific participants. Diabetes health care professionals were eligible if they lived and worked in Aotearoa, New Zealand, and worked within a pediatric or young adult diabetes care team.

Adolescents who had participated in previous research [28,29] and had consented to be conducted for future research projects were invited to participate via email on a first-in-first-serve

basis. Concurrently, study flyers were given to eligible participants in pediatric diabetes clinics in the Auckland region by endocrinologists, PH and CJ, who were involved in the study, and study flyers were posted in web-based communities, such as Diabetes Youth Auckland and Type 1 Diabetes Youth in Aotearoa New Zealand Facebook pages. Diabetes health care professionals were recruited by emailing diabetes clinics in Auckland and using diabetes research special interest groups throughout Aotearoa, New Zealand.

Participants who expressed interest in the study via email or the link on our study flyer were directed to a secure website, REDCap (Research Electronic Data Capture; Vanderbilt University) [42], to assess eligibility and provide informed consent or assent. At the time of consent or assent, adolescents were asked to provide demographic variables, such as age, gender, ethnicity, length of diabetes diagnosis, current insulin regimen, and whether or not they use a continuous glucose monitoring system. Similarly, diabetes health care professionals were asked for their gender, ethnicity, role within the diabetes team, and length of time for which they worked with youth with T1D. All participants were mailed a voucher for NZD $50 (approximately US $34.86) after completing their focus groups or interviews.

Focus Group Procedures

Adolescent focus groups were conducted on the web using Zoom (Zoom Video Communications, Inc), with 3 to 5 adolescents per focus group and lasted up to 90 minutes. A total of 4 focus groups were conducted, with 1 focus group reserved solely for Māori and Pacific youth to ensure that their perspective on the cultural responsiveness of the app was emphasized. All adolescent focus groups were facilitated by the first author (AB, an Aotearoa New Zealand European female health psychology PhD candidate and a health psychology preintern) and another study author (CS, an Aotearoa New Zealand European or Māori male registered as a psychologist). Both focus group facilitators had experience in facilitating group sessions. Of note, ALB had existing relationships with some of the adolescent participants (11/19, 58%) who had participated in the previous research [28,29]. The adolescents were informed that ALB was completing the study for her PhD, which involved developing a digital well-being intervention for youth with T1D.

Diabetes health care professional interviews were conducted on the web using Zoom, depending on clinician availability, and lasted up to 90 minutes. All diabetes health care professional interviews were facilitated solely by AB. As mentioned earlier, ALB did have existing relationships with many diabetes health care professionals (9/11, 82%) because they participated in similar diabetes-related research and via professional clinical networks.

The focus groups and interviews followed a semistructured interview schedule devised by ALB and supervisors NSC and ASS. Participants were shown images and screen recordings from the chatbot prototype app and asked questions related to the domains included in the end user version of the mobile application rating scale, including engagement (eg, “How could we make this exercise more engaging?”), functionality (eg, “What features would you like to see added to the chatbot?”), aesthetics (eg, “What module do you like the look of the least?”), and information (eg, “Are there any topics you would like us to add?”) [43]. Questions were also included to gain feedback on cultural appropriateness (eg, “Do you think COMPASS is culturally appropriate for all young people with type 1 diabetes of different ethnic groups in New Zealand?” and “How do you think we could improve the cultural acceptability of the app?”). Furthermore, a summary of the key points and the possibility of data saturation was discussed between CS and ALB after each adolescent focus group. For diabetes health care professionals, this was conducted by ALB under the supervision of NSC and ASS.

Qualitative Analysis

All interviews and focus groups were digitally audio recorded and transcribed. The transcripts were then analyzed using directed content analysis [44], a qualitative data analysis approach suited for focus groups and interviews with predetermined categories and research questions exploring an existing theory or framework. A framework of usability categories from the user version of the mobile application rating scale questionnaire was also used to assist in categorizing themes under those features and content that were disliked, liked, and desired for future addition. Similar to the approach used in a previous qualitative work [29], the analysis was based on the following predetermined research questions: “what do adolescents with T1D and their health care professionals like about COMPASS?” “what do adolescents with T1D and their health care professionals dislike about COMPASS?” and “what future additions do adolescents with T1D and their health care professionals desire in a second prototype of COMPASS?”

Using this approach, transcripts were first coded independently by ALB and CS using NVivo (QSR International), a qualitative data analysis computer software package. The coders built lists of liked, disliked, and desired content and features and started to group these across the different research questions by common themes. This was chosen because similar themes were observed across the 3 research questions. For example, adolescents reported to dislike memes or jokes that were not age appropriate, liked the discussion of relevant and age-appropriate stressors, and expressed a desire for age-appropriate humor and relevant topics to be discussed, forming the overall “relevant and age-appropriate” theme. The coders then agreed on the final themes and subthemes before conducting coding independently for the second round of analysis. Any discrepancies in the coding were resolved by consensus.

Results

Participant Demographics

A total of 19 adolescents consented or assented to participate, and no participants dropped out of the study. In total, 4 focus groups were conducted, ranging from 82 to 107 minutes in duration (mean 91.89, SD 10.67 minutes). Each group averaged 4 participants (mean 4.75, SD 0.96). Just over half of the participants used a pump for their insulin treatment (10/19, 53%) compared with injections (9/19, 47%), and most participants (14/19, 74%) used continuous glucose monitors.

The number of years diagnosed with T1D ranged from 2.5 to 14.5 years (mean 7.63, SD 4.00 years). Ethnicity was divided between Aotearoa New Zealand European (13/19, 68%), Māori (2/19, 11%), Samoan (3/19, 16%), and Indian (10/19, 5%), and 58% (11/19) were female, a distribution that is broadly representative of the population living with T1D in Aotearoa, New Zealand: 51% female and 75% Aotearoa New Zealand European [45].

A total of 11 diabetes health care professionals consented to participate, and no participants dropped out of the study. In total, 2 focus groups, 1 with 18% (2/11) of participants and 1 with 27% (3/11) of participants, and 9 one-on-one interviews were conducted, ranging from 70.24 to 103.48 (mean 83.28, SD 11.19) minutes in duration. Most participants were female (8/11, 73%) and identified as Aotearoa New Zealand European (9/11, 82%), followed by Samoan (1/11, 9%) and Irish European (1/11, 9%). Health care professionals were from various backgrounds, including diabetes nurse specialists (3/11, 27%), health psychologists (3/11, 27%), dieticians (3/11, 27%), and endocrinologists (2/11, 18%), with an average of 13.97 (SD 11.58) years of experience working in diabetes management.

Qualitative Findings

Adolescents

Overview

Generally, adolescents rated COMPASS positively, with 68% (13/19) saying they would recommend COMPASS to a friend with T1D. The remaining 32% (6/19) of participants voted yes if the suggested improvements highlighted in the themes below, personalization, self-management support, relevant and age-appropriate content, ease of use, and connectivity with others, were included (Table 2). Overall, when asked what their favorite module was, adolescents most commonly reported “meet teens like me” (chosen by 8/19, 42%), “distract me” (3/19, 16%), and “be self-compassionate” (3/19, 16%). Conversely, the least appealing modules were reported to be “learn about my brain” (8/19, 42%) and “be mindful” (7/19, 37%).

Table 2. Summary of key qualitative themes, with example quotations and their corresponding prevalence.

Participant group and themes[a]	Prevalence—Participants, n (%; comments, content coverage)	Example quotation
Adolescents (N=19)		
1. Personalization	19 (100; in 51 comments, 29.62% content coverage)	"Just really add more ability to personalize it for what you wanna talk about and what you wanna do. Even with things like notifications or even the colors, or if you want it to link with your diabetes team or not" (male aged 15 years).
2. Self-management support	13 (68; in 39 comments, 30.89% content coverage)	"If we could have something like interactive with a video. It could start off, oh you're low and then it has a series of options you could choose of different things to try out... I think it's a good idea to give tips to help you manage it yourself" (female aged 12 years).
3. Relevant and age appropriate	14 (74; in 26 comments, 17.03% content coverage)	"If you have stuff like gifs or like memes I think it's sort of risky I guess. Like you have to kind of, you gotta figure out what most people would enjoy. Like not, 'cause you can see some memes and then they're like really old, like talking about weird things you haven't even heard of. So I think it's sort of gotta be like more, yeah, topical and current I guess" (male aged 13 years).
4. Ease of use	14 (74; in 26 comments, 10.94% content coverage)	"I think that with the videos, like the keyword type of thing would be helpful. Like having a search bar for either the information or the videos or whatever. Just because also if you get a lot of videos you don't wanna be scrolling trying to find the one that you were looking for, or the right thing for you" (female aged 16 years).
5. Connectivity with others	14 (74; in 24 comments, 11.52% content coverage)	"I think like having a moderated discussion board with other members would be a good idea, just to like see how everyone's doing and if anyone's struggling. Just knowing that there's others like me, we're here too for them if there's anything they need, advice or just, yeah. We're all in the same shoes I guess" (male aged 16 years).
Diabetes health care professionals (N=11)		
1. Clinical utility	11 (100; in 52 comments, 36.29% content coverage)	"I think it could help us by giving them a walk-through of what to do, say they say their blood glucose is way out of control, it could automatically go down the route first of basic things like have you had your insulin today, have you checked ketones, just some simple safety things and brief suggestions" (diabetes nurse specialist).
2. Breadth and flexibility of tools	10 (91; in 48 comments, 35.26% content coverage)	"The self-compassion content here is awesome and would be relevant to almost anyone I see but I would probably like to see more about problem-solving and what are your values and how do we get you to live towards those and your diabetes management comes under that" (health psychologist).
3. Cultural appropriateness	8 (73; in 19 comments, 13.88%)	"I think just having an even broader spectrum of cultures and stories from families with different backgrounds. So that then it's relatable for everyone" (diabetes nurse specialist).

[a]Key themes are organized by how many participants reported the theme in each participant group.

Personalization

All participants (19/19, 100%) emphasized personalization of both content and features as being important to them, the most prevalent theme for the adolescent sample. Although COMPASS was able to personalize notification timings, responses, and content, adolescents mentioned wanting to be able to personalize a wider range of content and features; for example, being able to personalize the included games, apps, background color schemes, and hobbies referenced in examples and videos; design their own chatbot avatar to talk to; and personalize the number of notifications further (eg, the amount per day and week); and change settings when their routine changes (eg, if they become sick or go on holidays).

Self-management Support

Of 19 adolescent participants, 13 (68%) expressed the desire for the chatbot to assist them with independent self-management, a feature not offered in the current prototype. Participants commonly said it was difficult to find reliable and trusted sources of information to support new scenarios, such as how to manage T1D when the test result is positive for COVID-19 or considerations when starting a new hobby (such as weightlifting). For example, "otherwise I'm on 20 different websites that are telling me different scary things and that is not easy and really stressful" (female aged 16 years). A problem-solving feature was also commonly suggested, with the chatbot offering things one could try to get in their desired range in a compassionate tone rather than asking "how have your blood glucose levels been lately?" Participants also

emphasized the added benefit if the app could also integrate with their other diabetes technologies to help with problem-solving. For example:

> *[I]t would be so good just having one app with everything there and just being able to look at your levels and have something there to give you ideas on how you could get your levels down.* [Female aged 12 years]

In the focus group with Samoan and Māori adolescents, including more features to assist with self-management, such as reminders to take their diabetes kits to school and the option to enter blood glucose levels into the app, were identified as being especially important.

Relevant and Age-Appropriate Content

Another central theme reported by most participants (14/19, 74%) involved not only ensuring that the content of the chatbot remains relevant and age appropriate, especially regarding humor, GIFs, and slang, but also including relevant topics. For example, drinking and drugs were highlighted as topics that were appropriate for this platform, where more private topics could be discussed safely. For example:

> *[I]f it could include like drugs and alcohol and diabetes cause we don't get that information given to us unless we ask our diabetes team and that's kinda awkward...like some people with diabetes don't even know that alcohol can affect them differently right...so getting that information might help them make better decisions as to whether they wanna drink or take drugs.* [Female aged 16 years]

Ease of Use

Similarly, 74% (14/19) of the adolescent participants suggested additional features to increase usability and autonomy, such as collating all the videos in one place, providing a search bar function if they wanted to find resources or videos on a specific topic, having a tab for offline resources, and being able to skip activities or videos more easily if they wanted to try something else. Some participants also mentioned that adding an element of artificial intelligence in which the algorithm would learn what videos and topics you like to watch and then tailor future topics and activities would make the chatbot easier to use and more engaging.

Connectivity With Others

Connecting with others with T1D was also identified as being important (mentioned by 14/19, 74% of participants). Although the videos of lived experiences in the chatbot were liked, most participants expressed a need for the social connection to go further and suggested having a moderated forum where people could post questions and share advice with others. For example:

> *I think having, like a forum like Reddit, so you know how Reddit has subchannels and stuff, and you can put a question and people can upvote and reply to it...just having the reassurance that there are other people like you who could help and talk to when you need to.* [Female aged 15 years]

Minor Themes

A total of 2 minor themes were also identified in the adolescent data: increased privacy (mentioned by 6/19, 32% of participants) and increased representation (mentioned by 3/19, 16% of participants). Although only 5% (1/19) of participants reported that they shared a phone with others in their household, privacy from friends or siblings using or looking through their phone when they were not looking was mentioned as being important. For example:

> *[J]ust in case friends or siblings or someone goes onto your phone maybe have like a login password or something for the whole app...that way people just can't go in and like see the texts and your mindfulness and all that.* [Male aged 15 years]

Second, although all the adolescent participants said that they thought the app was culturally appropriate for all young people with T1D of different ethnicities in Aotearoa, New Zealand, 16% (3/19) of participants expressed a desire for more representation in the included content and videos in terms of ethnicities and other languages, such as Samoan

Health Care Professionals

Overall, all health care professionals (11/11, 100%) rated the app positively and stated that they would recommend it to their patients. In the following sections, the identified strengths and suggestions for improvements are highlighted in the overall themes.

Clinical Utility

All participants (11/11, 100%) referenced the theme of clinical utility, both in terms of the COMPASS chatbot being useful in complementing current standard care (notably within the context of ongoing COVID-19 pandemic) and also in identifying additional features and applications to bring more benefit. Integration with diabetes technology to assist with problem-solving was offered as a suggestion, along with comments relating to COMPASS' potential utility to support parents or caregivers and older young adults. Clinical integration as a feature was discussed from various perspectives; one health care professional thought that clinical integration would be helpful, whereas others thought it was unfeasible and had negative experiences with integration attempts in the past. One dietitian suggested that a compromise could be the ability to ask the chatbot to remember any questions or topics that the adolescents wanted to ask their diabetes team and then set a reminder before their next clinic appointment.

Breadth and Flexibility of Tools

Although all health care professionals thought self-compassion was relevant, flexible, and clinically useful to their patients, some participants (10/11, 91%) expressed a desire for a greater range of tools to be included. These included adding more diabetes-specific content and examples (such as applying tools to more diabetes-specific stressors such as fear of highs or lows), a broader range of evidence-based tools (such as values and benefit finding), more tools for emotional distress (such as more guided breathing illustrations), and a broader range of lived experience videos (eg, being self-conscious about people noticing visible insulin pumps or continuous glucose monitors

and experiences with alcohol and T1D self-management). Some participants also identified the chatbot app as a suitable place to put commonly used tools to make it "the go-to place for those with T1D in Aotearoa" (mentioned by a diabetes nurse specialist), such as etiquette cards (ie, how to communicate with people who do not understand the challenges of T1D); easy math exercises for glucose levels and correction doses; and relevant information, such as updated diabetes COVID specific or managing diabetes self-management under exam settings. Some participants also expressed the desire for the chatbot to be more flexible and autonomous, for example, if an adolescent wanted to skip a check-in 1 day or conversely be talked through difficult feelings in more depth before moving on to exercise.

Cultural Appropriateness

In addition, of the 11 participants, 8 (73%) mentioned the need to increase the representation of different ethnicities and stories in lived experience videos. Tailoring self-compassion content to match cultural values was also identified as an area for possible improvement to further address some of the misconceptions about self-compassion. For example:

> *[F]or some, it could be hard to understand that you can still be self-compassionate and uphold and respect your family and cultural values...it doesn't mean that you've got to relinquish any of your personal responsibilities or ignore your personal health...looking after your own hauora [health and wellbeing in te reo Māori] is going to make you more responsive and able to care for your family.* [Health psychologist]

Although some participants identified the integration of te reo (one of New Zealand's national languages) as a strength of the chatbot, health care professionals also wanted to see other languages included, such as Tongan and Samoan.

Minor Themes

In addition, 3 minor themes were identified: reassuring tone (mentioned by 7/11, 64% of participants in 10 comments), creating a safe sense of community (mentioned by 5/11, 45% of participants in 10 comments), and equity of access (mentioned by 4/11, 36% of participants in 6 comments). The reassuring and validating tone of COMPASS was identified as a strength, and the importance of keeping the tone similar for the future was also emphasized. For example:

> *[Y]ou wanna balance it with being like a helpful friend rather than being a nagging parent or diabetes nurse.* [Diabetes nurse specialist]

Creating a safe sense of community was mentioned as both a strength of the videos but also in a future moderated forum or chat to ease the isolation health care professionals commonly see in their patients. Finally, equity of access was also mentioned as an essential consideration, ensuring that the app had available offline resources and was free to download. The provision of phones was also identified as necessary for inclusion in the future funding.

Discussion

Principal Findings

Building on the need for clinically usable psychological interventions during the challenging period posed by the COVID-19 pandemic, this study was designed to develop and examine the acceptability of COMPASS for adolescents with T1D and their health care professionals. Overall, most participants rated COMPASS positively as being appealing, engaging to use, relevant, and complementing standard care. The qualitative results illustrated the areas of most importance to adolescents with T1D, including personalization, support with self-management, relevant and age-appropriate content, ease of use and connectivity with others and their health care professionals, such as clinical utility, breadth and flexibility of tools, and cultural appropriateness. Although the 2 groups demonstrated different overall themes, several suggestions and features were shared across them, such as including more features to support self-management (eg, integration with diabetes technology, problem-solving assistance, and a source of up-to-date information); increasing the range of tools and topics (beyond self-compassion); creating a safe peer-to-peer community; and broadening the representation of different cultures, lived experience stories, and diabetes challenges.

These highlighted themes and features are consistent with previously identified effective and desirable chatbot and digital intervention components, such as personalization, relevant and age-appropriate content, and peer-to-peer support features. Previous reviews of digital interventions have noted the importance of these features both in the effectiveness and engagement of youth [46]. In addition, in our previous qualitative study among adolescents with T1D, perspectives on different digital intervention modalities, personalization, and peer-to-peer support were also identified as desirable features [29]. However, personalization was a more prevalent theme in this study, with desires for personalization extending to the personalization of content based on hobbies and interests and the people and voices in the videos and meditations, perhaps indicative of the potential utility chatbots can offer. The emphasis on the importance of personalization in chatbot delivery also mirrors related studies examining the user acceptability of chatbots among youth samples [47] and mental health chatbots more broadly [48]. Connectivity with other peers also emerged as an important theme, which was referenced in the previous study [29]. Although most participants liked the lived experiences videos, they still expressed the need to give and receive peer-to-peer advice and did not perceive discussions being moderated as a potential barrier to engagement. Interventions not being age appropriate or "cringey" were also referenced in the previous study, further emphasizing the importance of co-designing interventional content and delivery with adolescents. The desire for peer support is commonly referenced across youth interventions, especially among those with chronic health conditions [49]. This pattern is consistent with the notion that peer support features should be included in chatbot interventions in this group.

Another common feature suggested by both samples was the inclusion of features to support diabetes decision-making and self-management. Recent studies have investigated the efficacy and acceptability of chatbots in supporting users to make clinical and health-related decisions and problem-solving in contexts such as cancer care [50], nursing students [51], support for older adults [52] and problem-solving for anxiety and depression [53,54]. More specifically, recent work in diabetes care has explored using a chatbot to support individuals aged 15 to 18 years with T1D in interpreting blood glucose levels, suggesting what to do in hypoglycemia events, and providing self-care behavior reminders [55]. The results of this study show that such support is desired by both adolescents and their health care professionals and may offer further benefits when combined with psychological support.

Limitations

Although these identified strengths of COMPASS and desired future additions propose a novel and unique adapted chatbot, several possible sources of bias should be considered when interpreting our results. Many participants in both samples had previously been involved in focus groups or self-compassion interventions conducted by the first author (AB) or were known via professional networks. Although such connections help recruitment, they may also bias opinions and feedback to be more complimentary. Second, owing to the delays in app development and our focus on the acceptability and perceived potential clinical utility and usability of the chatbot features and content, participants were only shown screen recordings of the chatbot, which may have restricted the richness of the feedback we received. However, the subsequent planned study includes focus groups to explore the user experience in more detail. In addition, although data saturation was reached and the adolescent participants were broadly representative of the adolescent population with T1D in Aotearoa, New Zealand, the sample may not have been representative of the breadth of challenges those with T1D experience and those who experience additional barriers to accessing standard care. It is important for future studies to include provisions for supplying phones and features, such as being able to log and track blood glucose levels, and to reduce inequities between those who have technology, such as smartphones and continuous glucose monitors, and those who do not have or face barriers in accessing standard care. In addition, incorporating feedback at each stage of the development from a representative range of users to ensure culturally appropriate approaches are being used, especially for Indigenous populations [56].

Novel Contributions

Despite these considerations, this study has several strengths and novel contributions. To our knowledge, the COMPASS chatbot is the first chatbot to deliver psychological tools to adolescents with T1D, offering a novel intervention for this sample as a key strength of the study. Furthermore, including both adolescents and their health care professionals provided a deeper understanding of the potential acceptability and potential clinical utility of chatbots for this sample. As health care professionals commonly introduce their patients to mobile health apps [35], examining their perspective on a potential intervention is useful in ensuring that they would be comfortable recommending a chatbot app to their patients. As highlighted earlier, the qualitative results also provided more support for previously identified desired features and additions of digital interventions for this population, such as personalization of content and peer-to-peer support features. In addition, the results also offer new insights into what adolescents and their health care professionals want in an adapted version of the COMPASS chatbot and also provide guidance for those developing digital interventions for youth with T1D. For example, including problem-solving capabilities and integration with diabetes technology to support self-management along with psychological support is a unique contribution to the literature.

Conclusions

In conclusion, our study findings provide preliminary support for the acceptability and potential clinical utility of COMPASS for adolescents with T1D, and highlight important features to be included in future chatbot interventions for this group. The results highlight several shared features suggested by both adolescents and their health care professionals, such as problem-solving features and integration with diabetes technology to support self-management; increased personalization of content; the addition of moderated app user peer-to-peer support to ease isolation and increase connection to others; and increased representation of different cultures, lived experience stories, and diabetes challenges. As such, COMPASS is currently being updated ahead of being tested in a feasibility study. If shown to be feasible, the next step will be to test the COMPASS app for efficacy to determine whether it would assist in filling the gaps in both self-management and psychological support exacerbated by the COVID-19 pandemic in Aotearoa, New Zealand. Future applications could include extending this self-compassion–based tool to adolescents with T1D in the global population or more broadly to other chronic health conditions that present with frequent opportunities for self-criticism and for which supportive conversational assistance with problem-solving features could also reduce disease burden. Furthermore, if efficacy can be illustrated, the chatbot could be integrated with other technologies, such as wearables (eg, smart watches, continuous glucose monitors, or insulin pumps).

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Conflicts of Interest

None declared.

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Abbreviations

COMPASS: self-compassion chatbot
COREQ: Consolidated Criteria for Reporting Qualitative Studies
GIF: Graphics Interchange Format
REDCap: Research Electronic Data Capture
T1D: type 1 diabetes

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Original Paper

User Retention and Engagement in the Digital-Based Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (myDESMOND) Program: Descriptive Longitudinal Study

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Abstract

Background: Digital health interventions have the potential to improve the physical and psychosocial health of people living with type 2 diabetes. However, research investigating the long-term (≥1 year) retention and engagement of users within these programs is limited.

Objective: The aim of this study was to evaluate long-term user retention and engagement in the digital-based Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (myDESMOND) program, using real-world data.

Methods: Anonymized data from all myDESMOND users who registered with the program on or before November 16, 2020, were included in the analyses. User retention was defined as the period between the day a user registered with the myDESMOND program and their last day of access. The primary engagement outcome was defined as the total number of log-ins to the program per user. The associations between retention, engagement, and sociodemographic factors (age, sex, and ethnicity) were tested using Cox regression models and Wilcoxon rank sum tests.

Results: A total of 9522 myDESMOND users were included in this analysis. Of the 9522 users, 5360 (56.29%) remained on the program for at least a month, whereas 1676 (17.6%) remained on the program for at least 1 year. Retention was significantly higher among older users; the adjusted hazard ratio (representing the risk of users leaving the program within the first year) among users aged ≥50 years, compared with those aged <50 years, was 0.79 (95% CI 0.75-0.84; *P*<.001). The median number of myDESMOND log-ins per user was 8 (IQR 4-8); however, this was significantly lower among users aged <50 years (*P*<.001). Engagement metrics also differed according to sociodemographic characteristics; the estimated time spent per log-in was 5.35 (IQR 2.22-11.80) minutes among all users; however, this was significantly higher among female users (*P*<.001), users aged ≥50 years (*P*<.001), and users of White ethnicity (*P*=.02).

Conclusions: Although retention and engagement of users within myDESMOND were found to be high, these findings highlight the need for age- and culture-specific implementation strategies and content adaptations to improve retention and engagement among all users of self-management programs.

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KEYWORDS

retention; engagement; digital self-management; type 2 diabetes; mobile phone

Introduction

Background

Recent figures published by the International Diabetes Federation reported that an estimated 463 million individuals were affected by diabetes in 2019, with 90% of them constituting people with type 2 diabetes (T2D) [1]. It is anticipated that this global prevalence will increase to 578 million by 2030 and 700 million by 2045 [1]. T2D often leads to serious microvascular (neuropathy, nephropathy, and retinopathy) and cardiovascular complications, with the latter representing a major cause of comorbidity and mortality among this population [2-4]. Globally recognized as an essential component of T2D care [5], diabetes self-management education and support (DSMES) has been found to be highly cost-effective, reduce the developmental risk of health complications, and increase the well-being of individuals with T2D [6-8].

Despite significant clinical, psychological, and behavioral benefits, DSMES programs remain largely underused, with a significant proportion of the population with diabetes opting not to attend [9]. In 2020, data published by the National Diabetes Audit revealed that only 5.6% of the adults living with T2D in the United Kingdom attended a structured DSMES program within 12 months of their diagnosis [10]. Qualitative studies have identified several barriers contributing to the low uptake of traditional face-to-face structured DSMES programs, including physical and psychosocial comorbidities, a lack of accessibility, competing priorities (family and work), and diabetes-related shame and stigma [11-13]. Digital DSMES programs have the potential to overcome many of these barriers [14] and, in recent years, have become increasingly integrated into T2D care [6].

Digital-based Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (myDESMOND) [6], HeLP-Diabetes [15], the Low Carb Program [16], Patient-Centered Smartphone-Based Diabetes Care System [17], GlycoLeap [18], and GlucoNote [19] are some of the many digital or smartphone-based programs that have been tested for people living with T2D. Many of these programs, including myDESMOND [6], Healthy Living [20], the Low Carb Program [16], and GlycoLeap [18], have now become available to the wider public. Such DSMES programs have shown favorable results [5], with a meta-analysis of 14 randomized controlled trials evaluating digital self-management apps reporting a pooled mean reduction of −0.49% in glycated hemoglobin levels among T2D participants [21].

Despite promising outcomes, digital DSMES programs can suffer from low user retention and engagement [22-24], meaning that users are not able to fully experience the clinical and psychosocial benefits [25]. The evaluation of user retention and engagement as well as factors affecting retention (eg, participant demographics) [26] has the potential to highlight important indicators of real-world implementation barriers with regard to digital health programs [27], thus facilitating the development of informed and targeted retention strategies [26]. Nonetheless, few digital DSMES programs have evaluated such data, with the findings focusing predominantly on clinical and cognitive impact as well as usability [28].

Objectives

Current evidence surrounding user retention and engagement for people with T2D is limited to the following digital self-management programs: HeLP-Diabetes [15], My Care Hub [29], and GlucoNote [19]. These studies have reported conflicting findings, with 1-month retention rates varying from 9% (HeLP-Diabetes) [15] to 35.3% (GlucoNote) [19]. Furthermore, with both HeLP-Diabetes [15] and My Care Hub [29] evaluating data after short-term intervention periods of 4 weeks and 3 weeks, respectively, there is scarce information available regarding long-term retention and engagement in the existing digital literature. Long-term retention data are limited to a study in Japan by Yamaguchi et al [19], who analyzed retention rates across a 1-year period for 357 participants with access to GlucoNote. The findings from this study revealed an overall decrease in long-term retention, with rates reducing from 35.3% (at 1 month) to 22% (at 3 months) [19]. With Yamaguchi et al [19] focusing on user retention in a predominantly male (79.9%) participant group, it is clear that there is need for a better understanding of both long-term (≥1 year) user retention and engagement across a larger population-based sample of people living with T2D. Thus, this paper aimed to investigate long-term retention and engagement, in addition to associated factors, among >9000 users of myDESMOND.

Methods

The myDESMOND Program

The myDESMOND program, developed by a multidisciplinary team at the Leicester Diabetes Centre in Leicester, United Kingdom, and launched in 2018, is a digital self-management education program based on Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND), an evidence- and theory-based group education program for people living with T2D [30-32]. myDESMOND can be freely accessed via smartphones, tablet devices, laptops, and desktop computers and was developed using an iterative approach based on optimizing the learning and engagement of users [6]. Multiple core functions are available in the myDESMOND program, including interactive learning sessions; weekly booster sessions building on the topics covered in the learning sessions; health and activity trackers; and the *Decision Maker* tool, which allows users to set goals to improve their health. myDESMOND also offers other social features, such as the *Ask the Expert* function that allows users to seek advice and guidance from Leicester Diabetes Centre's multidisciplinary team, a chat feature whereby users can interact with other users in the myDESMOND community, and an innovative *Buddies* function that allows users to invite up to 5 family members or friends to join them in their myDESMOND journey and compete with them in weekly or daily activity challenges. myDESMOND

is part of routine care at 90 health care organizations across the United Kingdom and Ireland, and individuals participating in DESMOND are usually signposted to the program as an ad hoc resource. myDESMOND users have access to 10 weeks of booster sessions, but they can also have access for life if they want.

Data

With users' consent, demographic and use data are collected for all users and stored on an encrypted server. Anonymized data can subsequently be downloaded for analysis.

Ethical Considerations

As this study presents a service evaluation, no specific ethics approval was needed; however, all users of myDESMOND have agreed to the terms and conditions of the privacy policy before they use the program. This policy includes a statement regarding use of their anonymized data for service evaluations.

Study Population

Since myDESMOND was launched in 2018, a total of 21,285 users have registered with the program. Data were extracted on November 16, 2021. For user retention to be analyzed over a full year, only users registered with the program on or before November 16, 2020, were included in the analysis, meaning that all included users had at least 1 full year of data.

Variables

User retention was defined as the duration of time between the day a user registered with the myDESMOND program and the last day that they accessed the program. The primary user engagement outcome was the total number of log-ins per user. The following secondary user engagement outcomes were also analyzed:

- Total time spent using the program per user
- Estimated time spent per log-in (calculated as the total time spent in the program divided by the total number of log-ins, per user)
- Log-ins per week (calculated as the total number of log-ins divided by the number of weeks spent using the program, per user)

Data were also available for users' sex, age, and ethnicity.

Statistical Analysis

Sociodemographic variables (sex, age, and ethnicity) were summarized using median (IQR) or frequency (percentage), as appropriate. Age was used as a categorical variable (<50 years or ≥50 years). The effect of an alternative categorization of age (<40 years or ≥40 years) on the findings was explored in a supplementary analysis. Ethnicity was categorized as White, Black, Asian, other, or mixed. Because of the small number of users categorized as other or mixed ethnicity, only the White and Black or Asian ethnic groups were included in the analysis. Survival analysis was conducted to investigate the retention of users in the myDESMOND program during their first year of registration. Kaplan-Meier curves were generated for all users and stratified by age, sex, and ethnicity. As the assumption of proportional hazards was not violated, Cox regression models were subsequently run to estimate the hazard ratios of users leaving the myDESMOND program by sex, age group, and ethnicity. Both univariate and multivariable models were run, adjusted for sex, age group, and ethnicity, as appropriate. Complete case analysis was used throughout. Previous research has shown a substantial difference in overall program retention when users who left the program after <1 day were excluded from the analysis compared with analysis undertaken using data from all users [26]. Therefore, a further supplementary analysis was conducted that excluded users who spent <1 day on the program.

The primary and secondary user engagement variables were evaluated over the total duration of program use, which could range from <1 day to >1 year. The total number of log-ins and total time spent in the program were first summarized by calculating the median (IQR) of these metrics, stratified by duration in the program. All engagement metrics were then summarized, stratified by sex, age group, and ethnicity. As the data did not follow a normal distribution, Wilcoxon rank sum tests were conducted to investigate any differences in the engagement metrics by sex, age group, or ethnicity. The analysis was conducted in Stata (version 17.0; StataCorp LLC). Statistical significance was set at $P<.05$ throughout.

Results

Sociodemographic Characteristics of Users

This analysis included 9522 users of the myDESMOND program, of whom 3974 (41.73%) were male and 3843 (40.36%) were female. The median age of these users was 59 (IQR 51-68) years. Of the 9522 users, 532 (5.59%) were aged <40 years, whereas 1697 (17.82%) were aged <50 years, and 6135 (64.43%) were aged ≥50 years. The majority of the users (6478/9522, 68.03%) were White, whereas 11.96% (1139/9522) were Black or Asian, 1.79% (171/9522) reported an ethnicity classified as other or mixed, and 18.21% (1734/9522) had missing ethnicity data (Table 1). These sociodemographic characteristics were similar when users who spent <1 day using the myDESMOND program were excluded (Table S1 in Multimedia Appendix 1). Stratification of the age and sex variables by ethnicity showed that the median age in the Black or Asian ethnicity group (51, IQR 43-59, years) was far lower than that observed in the White ethnicity group (61, IQR 53-69, years; Table S2 in Multimedia Appendix 1).

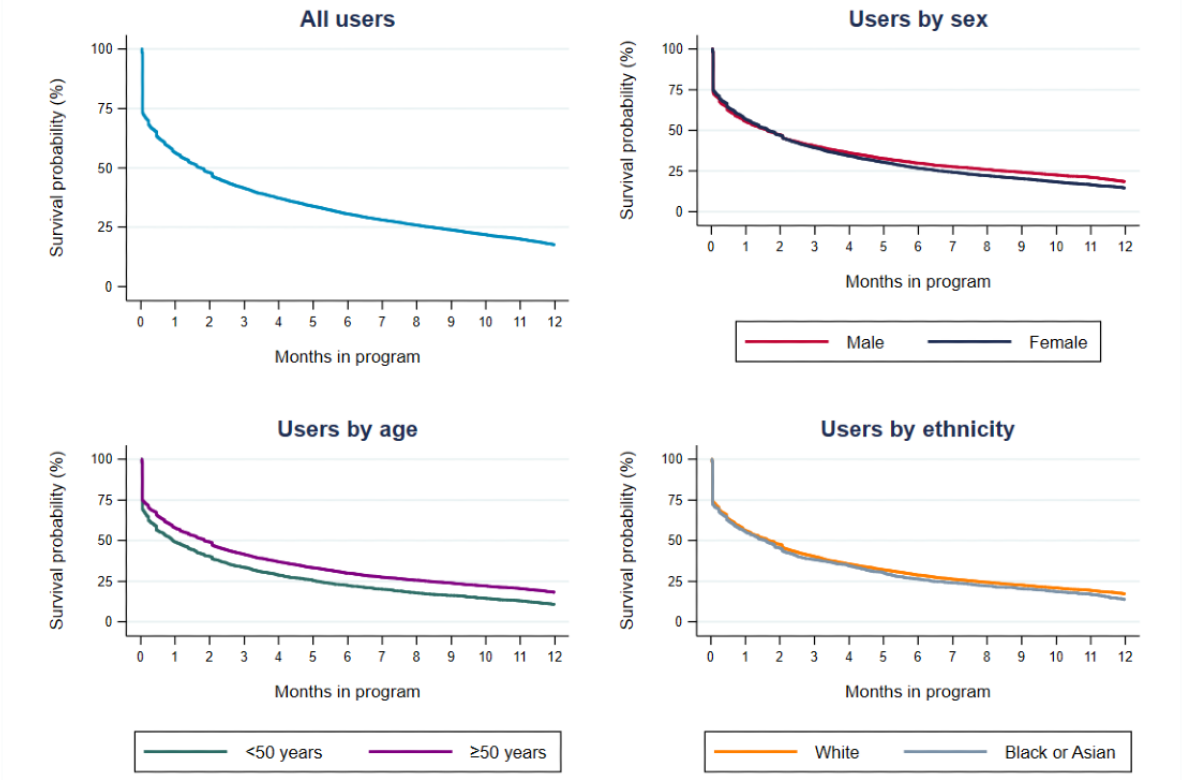
Table 1. Sociodemographic characteristics (N=9522).

	Values
Sex, n (%)	
Male	3974 (41.73)
Female	3843 (40.36)
Missing	1705 (17.91)
Age (years; n=7832), median (IQR)	59 (51-68)
Age (categorization: <40 years or ≥40 years), n (%)	
<40	532 (5.59)
≥40	7300 (76.66)
Missing	1690 (17.75)
Age (categorization: <50 years or ≥50 years), n (%)	
<50	1697 (17.82)
≥50	6135 (64.43)
Missing	1690 (17.75)
Ethnicity, n (%)	
White	6478 (68.03)
Black or Asian	1139 (11.96)
Other or mixed	171 (1.79)
Missing	1734 (18.21)

User Retention

The duration that users remained on the myDESMOND program ranged from <1 day to 40.4 months (3.4 years), with a median of 7.57 (IQR 0.00-36.43) weeks. Of the 9522 users, 5360 (56.29%) used the myDESMOND program for at least 1 month, 2914 (30.6%) used the program for at least 6 months, and 1676 (17.6%) remained on the program for at least 1 year (Figure 1).

Figure 1. Kaplan-Meier curves showing the time to users stopping use of the digital-based Diabetes Education and Self-Management for Ongoing and Newly Diagnosed app after the course of a year for all users, stratified by sex, age, and ethnicity.



When users who spent <1 day using myDESMOND were excluded from the analysis, 75.5% (5360/7099) of the users spent at least 1 month using the program (Figure S1 in Multimedia Appendix 1). Figure 1 displays survival curves stratified by sex, age group, and ethnicity. In both the univariate and multivariable analyses, older age was significantly associated with a lower likelihood of leaving the program during the analysis period. Corresponding adjusted hazard ratios were 0.79 (95% CI 0.75-0.84; *P*<.001) for users aged ≥50 years compared with those aged <50 years, and 0.77 (95% CI 0.70-0.85; *P*<.001) for users aged ≥40 years compared with those aged <40 years (Table 2; Table S3 and Figure S2 in Multimedia Appendix 1). Although the median duration of time spent in the program was slightly longer for female users compared with male users, female users had a significantly higher likelihood of leaving the program within the year in both the univariate (*P*=.003) and multivariable analyses (*P*=.03). No significant associations were observed between ethnicity and the likelihood of users leaving the program (Table 2). Similar results were observed when users who spent <1 day using the program were excluded from the analysis (Table S4 in Multimedia Appendix 1).

Table 2. Results from Cox proportional hazard models reporting associations between sex, age, ethnicity, and survival time in the program.

	Unadjusted model		Adjusted model	
	Hazard ratio (95% CI)	*P* value	Hazard ratio (95% CI)	*P* value
Sex				
Male	1.00 (reference)	N/A[a]	1.00 (reference)	N/A
Female	1.08 (1.03-1.13)	.003	1.06 (1.01-1.11)	.03
Age				
<50 years	1.00 (reference)	N/A	1.00 (reference)	N/A
≥50 years	0.79 (0.75-0.84)[b]	<.001	0.80 (0.75-0.85)	<.001
Ethnicity				
White	1.00 (reference)	N/A	1.00 (reference)	N/A
Black or Asian	1.08 (1.01-1.15)[c]	.03	1.01 (0.94-1.09)	.72

[a]N/A: not applicable.

[b]Sex, age, and ethnicity (as appropriate) included as confounders to generate adjusted hazard ratios.

[c]Includes users with nonmissing age and sex data, as well as users classified as White, Black, or Asian.

User Engagement: Primary Outcome

On average, users logged into the myDESMOND program 8 (IQR 4-18) times during their duration of myDESMOND use, which ranged from <1 day to 40.4 months. However, the total number of log-ins per user was significantly lower among younger users (*P*<.001), as well as among those from a Black or Asian ethnic background (*P*=.01; Table 3; Table S5 in Multimedia Appendix 1).

Table 3. Retention and engagement metrics by sex, age, and ethnicity[a].

	Duration in the program (weeks)	Total number of log-ins	Total time spent using program (minutes)	Estimated time spent per log-in (minutes)	Log-ins per week
Total, median (IQR)	7.57 (0.00-36.43)	8 (4-18)	63.74 (20.87-191.80)	5.35 (2.22-11.80)	0.77 (0.32-1.84)
Sex					
Male, median (IQR)	7.00 (0.00-36.86)	8 (4-20)	75.74 (24.45-221.17)	5.82 (2.60-12.57)	0.80 (0.35-1.89)
Female, median (IQR)	7.14 (0.14-28.57)	8 (5-18)	82.55 (28.80-232.43)	6.82 (3.07-14.00)	0.89 (0.41-1.93)
P value[b]	.37	.76	.02	<.001	.06
Age					
<50 years, median (IQR)	4.00 (0.00-22.14)	7 (4-15)	62.33 (20.33-161.58)	5.53 (2.35-12.38)	0.88 (0.36-2.17)
≥50 years, median (IQR)	8.00 (0.29-36.29)	9 (5-20)	86.10 (28.53-245.23)	6.53 (2.98-13.64)	0.84 (0.38-1.87)
P value	<.001	<.001	<.001	<.001	.13
Ethnicity					
White, median (IQR)	7.14 (0.14-33.43)	9 (5-19)	81.75 (28.0-227.85)	6.40 (2.88-13.53)	0.86 (0.38-1.97)
Black or Asian, median (IQR)	6.86 (0.00-28.14)	7 (4-17)	70.40 (20.85-223.33)	5.80 (2.50-13.28)	0.80 (0.35-1.75)
P value	.07	.005	.01	.02	.05

[a]Excludes users who spent <1 week using the web-based Diabetes Education and Self-Management for Ongoing and Newly Diagnosed program.

[b]*P* values were calculated using Wilcoxon rank sum tests.

User Engagement: Secondary Outcomes

Users spent a median total of 63.74 (IQR 20.87-191.80) minutes using the program. Younger users (*P*<.001), male users (*P*=.02), and Black or Asian users (*P*=.01) spent significantly less time, in total, using the program. On average, users spent 5.35 (IQR 2.22-11.80) minutes in the program per log-in. However, this metric was significantly lower for male users (*P*<.001), younger users (*P*<.001), and Black or Asian users (*P*=.02). The median number of log-ins per week was 0.77 (IQR 0.32-1.84) for all users included in the analysis (Table 3; Table S5 in Multimedia Appendix 1).

Users who spent ≤3 months using the myDESMOND program had an average of 5 (IQR 4-8) log-ins and spent a total of 39.40 (IQR 14.68-97.57) minutes using the program. These engagement metrics increased to 15 (IQR 8-30) log-ins and 152.17 (95% CI 64.79-355.93) minutes using the program among users who spent >9 months using myDESMOND (Table 4).

Table 4. Total number of log-ins and total time spent in the program, stratified by duration in the program.

Duration in the program (months)	Total number of log-ins, median (IQR)	Total time spent in the program (minutes), median (IQR)
≤3	5 (4-8)	39.40 (14.68-97.57)
>3 to 6	11 (6-19)	105.67 (36.05-252.27)
>6 to 9	14 (7-26)	132.68 (48.80-307.66)
>9 to 12	15 (8-30)	152.17 (64.79-355.93)

Discussion

Overview

To date, research evaluating long-term user retention and engagement with digital DSMES programs among adults with T2D has been limited, with long-term data focusing exclusively on retention in a small non–population-based sample of people with both T2D and prediabetes [19]. This is the first study to investigate both long-term retention and engagement (and associated factors) for a digital diabetes self-management program across a large and ethnically diverse sample of adults living with T2D. Our findings demonstrated high levels of user retention and engagement, which differed significantly according to sociodemographic characteristics.

User Retention

In comparison with previously reported 1-month retention rates of 9% (HeLP-Diabetes) [15] and 35.3% (GlucoNote) [19], our findings showed a favorable retention rate of 56% at 1 month among myDESMOND users. Furthermore, in contrast to the 3-month retention rate of 22% after 1 year's access to GlucoNote in the study by Yamaguchi et al [19], our retention rate of 31% over 6 months compares much more favorably, thus highlighting the potential of the myDESMOND program at sustaining long-term retention among users. myDESMOND offers quality educational content that is accompanied by a wide breadth of functionalities (booster sessions, health and activity trackers, *Ask the Expert*, chat feature, etc), meaning that the program has potential to accommodate a variety of user-specific needs. Further research looking at ways to investigate program-specific

functionalities associated with higher retention rates would be useful to facilitate the design of future digital self-management programs. Furthermore, it is important to note that some of the myDESMOND users would have attended the DESMOND group self-management program before registering, meaning that they already had an insight into the quality of the educational content and functionalities available. This suggests that information provision and supplementary group self-management programs may be a suitable way to encourage user retention across digital self-management programs.

Despite promising user retention rates, discrepancies in the existing definitions of retention make direct comparisons of our findings challenging. As our study was conducted using real-world data, we defined retention as the duration of time between the day a user registered with the myDESMOND program and their last day accessing the program; however, other studies have largely defined retention as the completion of a postintervention assessment [15,29]. It is clear that there is need for a standardized definition of retention that also takes into account the real-world application of digital self-management programs.

Our analysis also showed a median retention duration of 7.57 weeks, which is substantially greater than the 8-day median retention reported by Yamaguchi et al [19]. Furthermore, our findings also revealed both categorizations of age (40 years and 50 years) to be significantly associated with program retention in both the univariate and multivariable analyses (adjusting for sex and ethnicity), with younger users showing a significantly higher likelihood of leaving myDESMOND and significantly lower duration of use of the program than older users. Similar findings have also been reported by other digital health studies exploring retention indicators in long-term health conditions in addition to diabetes [26]. The 2 categorizations of age were used to observe whether retention differed in users with early-onset T2D versus those with usual-onset T2D. However, as the proportion of users aged <40 years was very low, the categorization of <50 years was used in the main analysis to maintain power, with the alternative categorization of <40 years being explored in the supplementary analysis.

Our study is not the first to report low retention among young users of a digital diabetes self-management program. A randomized controlled trial evaluating use of the Young with Diabetes app among young people with type 1 diabetes in Denmark also reported poor retention, with app use decreasing rapidly to a retention rate of 5% at 12 months [33]. According to Klasnja et al [34], after the initial diagnosis period, people with diabetes develop flexible self-management routines, with their focus shifting to quality of life; hence, their use of diabetes health technology may fluctuate accordingly with periods of infrequent use. On the basis of our findings and the existing literature [33,34], it is feasible to suggest that, for young people with diabetes, maintaining a high quality of life may involve focusing on other aspects of their lives, such as education, employment, independent living, and families, thus reducing their regular use of a digital self-management program that may not adequately address their presenting need or concern. Further research exploring how to adapt digital self-management programs to address these periods of infrequent or intermittent use by young people with diabetes may be a crucial step toward the development of age-specific retention strategies for this cohort.

User Engagement

Our findings revealed that myDESMOND users spent an average total of 63.74 minutes on the program, with an average of 5.35 minutes spent in the program per log-in. From a behavioral perspective, engagement with digital behavior change interventions has largely been defined as *use*, with a focus on rate, duration, and depth of use, in addition to associated factors [35,36]. Consistent with this definition, our study reported the number of user log-ins and time spent in the program per log-in (and associated factors) to evaluate user engagement. However, unlike our study, the studies conducted by Glasgow et al [37] and Adu et al [29] reported a wider range of use metrics to capture the multidimensional nature of user engagement [36,38]. Adu et al [29] explored user engagement using a modified version of the frequency, intensity, time, and type (FITT) principle, thus acknowledging the frequency (how often the user visits the app or intervention), intensity (depth of engagement; eg, number of app or intervention features used out of those available), time (length of use during a single visit to the app or intervention), and type (eg, reflective [self-reporting of behavior or health outcomes] or didactic [reading posts and completing quizzes or challenges] engagement) of engagement with the My Care Hub app [29,38,39]. The FITT principle has the potential to effectively capture all domains of use data relating to the behavioral conceptualization of engagement [38]. Therefore, further evaluation of engagement with the myDESMOND program and other digital programs using the FITT principle is recommended because this may allow investigation of the intensity and type of engagement across programs. Such evaluations may provide new insights into the appropriateness of this principle in the analysis of real-world use data, hence contributing to the development of an all-encompassing universal measure of engagement.

Our findings revealed age to be significantly associated with engagement with the myDESMOND program. In comparison with older users, younger users had a significantly lower median number of log-ins and average time spent in the program per log-in. The observed age-related differences in engagement may be attributable to the lack of age-appropriate content and functionality for younger users. Previous research has emphasized the need for the provision of tailored age-specific education, information, and peer support for young people with T2D to promote effective self-management of their condition [40-42]. Despite this, few age-appropriate digital self-management programs for T2D currently exist. Previous studies investigating the effectiveness of digital self-management programs tailored for young people with type 1 diabetes have shown potential for enhancing daily self-management through the emotional and social support benefits associated with the provision of an age-specific online peer support element [43,44]. More specifically, having a web-based platform to share and discuss personal experiences with other individuals of a similar age was found to reduce feelings of loneliness and isolation, thus motivating individuals

to implement daily self-management behaviors [43,44]. Furthermore, in both studies, the peer support element remained the most consistently and frequently used functionality across both self-management programs [43,44]. Therefore, it is possible that adapting the existing myDESMOND chat function to allow age-specific interactions may facilitate increased engagement with the program among younger users, as observed in the previously mentioned studies [43,44].

In line with previous research [45], our analysis also showed reduced engagement with the myDESMOND program among ethnic minority groups with T2D, with users of Black or Asian ethnicity showing significantly lower average number of log-ins and time spent in the program per log-in. Previous studies investigating the effectiveness of culturally tailored diabetes self-management education programs for ethnic minority groups have reported multifaceted benefits, with significant improvements shown across a range of clinical, knowledge, and psychobehavioral outcomes [46-48]. Although predominantly exploring face-to-face and telecommunication interventions or programs, these studies emphasize the importance of considering cultural and linguistic differences to promote increased uptake and overall health benefits among ethnic minority groups. Furthermore, Yardley et al [35] highlighted that a user's engagement with a digital behavior change intervention can be sustained, reduced, or molded by sociocontextual influences, including their wider cultural setting. Therefore, it is feasible to suggest that cultural adaptation of myDESMOND to meet the needs of ethnic minority groups with T2D may promote their increased engagement with the program. In addition, addressing existing ethnic disparities in digital health care [49,50], including accessibility to digital platforms such as myDESMOND, may also promote increased engagement among this cohort.

It is important to note, however, that the associations observed between ethnicity and user engagement may be confounded by age; users of Black or Asian ethnicity were substantially younger than users of White ethnicity.

Similar to age and ethnicity, sex was also revealed by our findings to be significantly associated with engagement with the myDESMOND program, with male users spending significantly less time in the program per log-in compared with female users. This is consistent with previous literature reporting significantly greater engagement in digital health care among female users [51]. Although limited literature exists regarding sex differences in engagement with digital diabetes self-management programs, it is well known that sex is a crucial characteristic affecting optimal diabetes self-management [52], with male individuals and female individuals living with T2D experiencing differing biological, psychological, and physical needs and challenges [53]. Female individuals with T2D have been found to experience less favorable long-term physical and mental health outcomes; yet, they have been known to exhibit better self-management behaviors than their male counterparts [54]. Consequently, it is unsurprising that research has frequently emphasized the need for sex-specific diabetes care and support to improve long-term health outcomes among both cohorts [54,55]. Although most research pertaining to sex-specific diabetes support has focused on female individuals and looked at routine self-management [52], our findings highlight the need for research exploring the unique sex-related barriers and challenges contributing to long-term engagement with digital diabetes self-management programs. Such research has the potential to highlight important aspects of sex-specific content and functionality that may enhance engagement with programs such as myDESMOND in both male and female users, thereby contributing to long-term improvements in health outcomes among both male and female individuals with T2D.

Strengths and Limitations

This analysis has many strengths; namely, it used real-world data from >9000 users, thereby capturing a highly valid picture of the retention and engagement of myDESMOND users. The analysis was limited by the inability to differentiate between changes in use over the time spent in the program and different types of myDESMOND use (eg, learning sessions vs social features), which would have allowed for a better understanding of the differences in retention and engagement in specific program features across users. However, the analysis of retention, various engagement metrics, and multiple potentially associated sociodemographic factors provided a comprehensive understanding of the differing retention and engagement levels observed among myDESMOND users. Future research should investigate the impact of increased engagement and retention on clinical outcomes, such as glycated hemoglobin levels. Finally, although the multiethnic nature of the sample allowed for a thorough investigation of the association between ethnicity and retention or engagement, a relatively high proportion of users had missing data for ethnicity and other sociodemographic variables, meaning that not all participants could be included in this analysis, potentially resulting in a lack of power in some supplementary analyses.

Conclusions

This study explored long-term retention and engagement among >9000 users of the myDESMOND program, finding a higher retention rate than has previously been reported from analyses of other digital T2D self-management programs. The levels of engagement with myDESMOND were also promising. Further analysis investigating engagement by type of use is required. In addition, the myDESMOND program would benefit from age- and culture-specific adaptations to improve the engagement of all users.

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Data Availability

The data that support the findings of this study are available from the Leicester Diabetes Centre, but restrictions apply to the availability of these data, which were used under license for this study; therefore, the data are not publicly available.

Authors' Contributions

MMB and RC are joint primary authors. MJD, KK, CB, MMB, and MH were involved in the discussions around the concept. MMB and CB carried out the analysis. RC and MMB drafted the manuscript with support from MH. MJD, MH, SS, AN, BS, and KK contributed to the review of the analysis. MJD, SS, AN, BS, KK, and CB reviewed the draft of the manuscript.

Conflicts of Interest

The authors do not hold any conflicts of interest; however, for transparency we provide the following statement of conflict: MJD is the principal investigator on the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) program. SS, AN, CB, BS, MJD, and KK are employed by the University Hospitals of Leicester National Health Service (NHS) Trust, which receives not-for-profit income for DESMOND. All authors are actively engaged in research and have previously received grants for DESMOND from the National Institute for Health and Care Research, Medical Research Council, and Diabetes UK to develop and test diabetes self-management education and support programs such as DESMOND. The University Hospitals of Leicester NHS Trust receives licensing fees to support implementation of the DESMOND program in clinical commissioning groups in the United Kingdom, Ireland, and Australia.

Multimedia Appendix 1
Sociodemographic characteristics, association between variables, and retention and engagement metrics by age.
[DOCX File , 153 KB - diabetes_v8i1e44943_app1.docx]

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Abbreviations

DESMOND: Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
DSMES: diabetes self-management education and support
FITT: frequency, intensity, time, and type
myDESMOND: digital-based Diabetes Education and Self-Management for Ongoing and Newly Diagnosed
T2D: type 2 diabetes

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Original Paper

Impact of a Combined Continuous Glucose Monitoring–Digital Health Solution on Glucose Metrics and Self-Management Behavior for Adults With Type 2 Diabetes: Real-World, Observational Study

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Abstract

Background: The BlueStar (Welldoc) digital health solution for people with diabetes incorporates data from multiple devices and generates coaching messages using artificial intelligence. The BlueStar app syncs glucose data from the G6 (Dexcom) real-time continuous glucose monitoring (RT-CGM) system, which provides a glucose measurement every 5 minutes.

Objective: The objective of this real-world study of people with type 2 diabetes (T2D) using the digital health solution and RT-CGM was to evaluate change in glycemic control and engagement with the program over 3 months.

Methods: Participants were current or former enrollees in an employer-sponsored health plan, were aged 18 years or older, had a T2D diagnosis, and were not using prandial insulin. Outcomes included CGM-based glycemic metrics and engagement with the BlueStar app, including logging medications taken, exercise, food details, blood pressure, weight, and hours of sleep.

Results: Participants in the program that met our analysis criteria (n=52) were aged a mean of 53 (SD 9) years; 37% (19/52) were female and approximately 50% (25/52) were taking diabetes medications. The RT-CGM system was worn 90% (SD 8%) of the time over 3 months. Among individuals with suboptimal glycemic control at baseline, defined as mean glucose >180 mg/dL, clinically meaningful improvements in glycemic control were observed, including reductions in a glucose management indicator (–0.8 percentage points), time above range 181-250 mg/dL (–4.4 percentage points) and time above range >250 mg/dL (–14 percentage points; all $P<.05$). Time in range 70-180 mg/dL also increased by 15 percentage points ($P=.016$) in this population, which corresponds to an increase of approximately 3.5 hours per day in the target range. Over the 3-month study, 29% (15/52) of participants completed at least one engagement activity per week. Medication logging was completed most often by participants (23/52, 44%) at a rate of 12.1 (SD 0.8) events/week, and this was closely followed by exercise and food logging.

Conclusions: The combination of an artificial intelligence–powered digital health solution and RT-CGM helped people with T2D improve their glycemic outcomes and diabetes self-management behaviors.

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KEYWORDS

type 2 diabetes; digital health; continuous glucose monitoring; artificial intelligence; glycemic outcomes; engagement; digital health intervention; mHealth; diabetes management

Introduction

Type 2 diabetes (T2D) affects over 10% of the US population [1], and management of it is complex and challenging. As a result, only about half of individuals diagnosed with diabetes are meeting the American Diabetes Association (ADA) treatment target of glycated hemoglobin (HbA_{1C}) <7% [1]. Several modifiable lifestyle factors that contribute to suboptimal glycemia include the challenge for a person with diabetes to easily and diligently execute all self-management behaviors as outlined in the Association of Diabetes Care and Education Specialists framework (ADCES-7) [2], including the management of medications, glucose, activity, diet, coping, risk, and problem-solving. The prevalence of infrequent and intermittent fingerstick blood glucose testing does not easily allow for a "teachable moment" whereby an individual with T2D can correlate cause (ie, a specific behavior) and effect (ie, glucose level).

In recent years, digital health solutions that aim to improve the lives of people with T2D have grown in both number and scale [3]. These digital health solutions include a smartphone app that aids in diabetes decision support and provides insights. Some also provide items and features such as connected blood glucose meters (BGMs), continuous glucose monitors (CGMs), medication management support, live coaching, artificial intelligence (AI) or other data-driven insights, or logs where users can track events such as physical activity, sleep, and medication use.

The ADA Standards of Medical Care in Diabetes recommends the use of digital health technology in treating diabetes for some individuals [4]. Systematic reviews found that the majority of technology-enabled diabetes management interventions are associated with HbA_{1C} reductions [5,6] and can improve self-efficacy, leading to greater self-confidence [5]. This was also seen in studies with multiple intervention types [7] that used connected BGMs [8] and in a digital diabetes management program that offers personalized educational content [9].

BlueStar (Welldoc) is a US Food and Drug Administration (FDA)–cleared digital health solution that guides individuals through the journey of living with diabetes by enabling them to self-manage their care while enhancing connections to their health care team. BlueStar is indicated for use by health care providers and their patients—aged 18 years and older—who have type 1 diabetes or T2D. The BlueStar app's novelty manifests in many dimensions. First, it supports all ADCES-7 self-management behaviors through scalable, evidence-based, and FDA-cleared software as a medical device. Second, it provides AI-driven motivational, behavioral, or educational coaching, both in real time and longitudinally. The AI insights identify key patterns and areas of concern that can be escalated to a health care provider, which may help overcome clinical inertia.

The use of real-time continuous glucose monitoring (RT-CGM) has the potential to overcome the challenge associated with infrequent and intermittent blood glucose testing. RT-CGM systems provide a glucose measurement of the interstitial fluid every 1-5 minutes and contain programmable alerts and alarms that warn users of current or impending glycemic excursions. The combination of RT-CGM and digital health and its combined effect on self-management behaviors and outcomes warrants further study. The aims of this real-world study of people with T2D using a digital health solution (BlueStar) and RT-CGM (G6; Dexcom) were to assess the changes in glycemic control and in engagement with the digital health solution over 3 months.

Methods

Study Details and Participants

This single-arm, retrospective, real-world study evaluated the change in glycemic control and engagement in people with T2D that participated in the combined BlueStar digital health and Dexcom RT-CGM program for 3 months. As this was a feasibility study under real-world conditions, the sample size was not predetermined. Participants were recruited from 3 health care clinics in the United States and were current or former enrollees in an employer-sponsored health program. Study enrollment occurred between February 2021 and January 2022.

Eligibility criteria included being aged 18 years or older, being willing to use the BlueStar app and the Dexcom G6 RT-CGM system, and having a diagnosis of T2D treated with basal insulin, oral medications, noninsulin injectables, or lifestyle management. Key exclusion criteria included prandial insulin use, pregnancy, cancer, dialysis, or the presence of a major psychiatric disorder.

Initial enrollment included downloading the BlueStar and Dexcom G6 mobile apps (compatible with Apple and Android phones), provision of a CGM transmitter and three 10-day sensors (1 month's supply), and optional training on CGM insertion and use. Participants were required to return to the clinic each month to obtain additional sensors. The BlueStar app is an integrated digital health platform that can sync with numerous devices, provide personalized feedback and digital coaching to its users, and help users track their medication, sleep, exercise, and other health behaviors. The Dexcom G6 mobile app allows users to view their glucose levels in real time with updates every 5 minutes. Trend arrows and access to retrospective data using Clarity reporting software (Dexcom, Inc) can help users identify short- and long-term patterns in their glucose levels.

Ethics Approval

Ethical review and full waiver of Health Insurance Portability and Accountability Act (HIPAA) authorization were obtained from Advarra Institutional Review Board (Pro00069142).

Outcome Measures

Glucose Metrics

The primary outcome was the change in glycemic control after 3 months, which was assessed from CGM data that participants uploaded to the Dexcom app. The International Consensus on Time in Range (TIR) guidelines were used to calculate standardized CGM metrics, including change in mean glucose, glucose management indicator (GMI), coefficient of variation

(CV), percentage of TIR (70-180 mg/dL), percentage of time above range (TAR) (level 1: 181-250 mg/dL or level 2: >250 mg/dL), and percentage of time below range (TBR; <70 mg/dL) [10]. The proportion of days with CGM use was also assessed.

Engagement

Engagement with BlueStar and its lifestyle tracking features was also analyzed. All participant interaction with the BlueStar app was recorded by the app software, including opening the app, logging activities, and accessing educational materials. The engagement outcome quantified "meaningful" activities: logging medication-taking or entering food details, blood pressure, weight, hours of sleep, or exercise. Instances of simply opening the app were excluded. Overall engagement was numerically defined as the proportion of participants with ≥1 engagement activity per week in the 3-month window.

Statistical Analysis

The program originally enrolled 122 participants. To be included in the analysis cohort, participants were required to have 10 contiguous calendar days of CGM readings with 70% data sufficiency within 30 days from activation on the BlueStar platform and a follow-up measurement of 10 contiguous calendar days of CGM readings with 70% data sufficiency between 80 and 110 days after activation on the BlueStar platform. After excluding participants treated with bolus insulin and applying the baseline and follow-up CGM data sufficiency criteria, the final analysis cohort was 52 participants. Average engagement per user per week was calculated for users who logged medication-taking, exercise, food, weight, sleep, and blood pressure events. To be included in the engagement analysis, a user had to have ≥1 engagement for a given event between the baseline and follow-up glycemic outcome measurement periods as noted above.

CGM metrics and engagement measures were then calculated for two population segments: (1) participants with mean baseline glucose >180 mg/dL (suboptimal control) and (2) participants with mean baseline glucose ≤180 mg/dL. The cutoff of 180 mg/dL was chosen because it is the upper bound of the International Consensus TIR guideline metric [10]. Given the small sample size, we tested the CGM data for normality using the Shapiro-Wilk test. The data were not normally distributed so a Wilcoxon signed rank test was used to evaluate 2 distributions of baseline and follow-up groups. The between-groups difference in the rates of engagement with BlueStar app features was evaluated using the Mann-Whitney *U* test. To test for significant differences in demographic information, we performed a 2-proportion *z* test for gender and medication regimen and a 2-tailed Welch *t* test for age, baseline GMI, and baseline mean glucose. Significance for all statistical tests was defined as $P<.05$.

Results

Overview

A total of 122 participants enrolled in the study; 94 initiated RT-CGM and 52 met the data sufficiency requirements at 3 months. There were no significant differences in age or gender between those who met the data sufficiency requirements (n=52) and those who did not (n=42). The combined digital health solution/RT-CGM program is depicted in Figure 1. Baseline demographic and clinical characteristics of participants are presented in Table 1. Participants (n=52) were 37% (19/52) female with an average age of 53 (SD 9) years. In their initial sensor session, 65% (34/52) of participants had a mean glucose ≤180 mg/dL and 35% (18/52) had a mean glucose >180 mg/dL.

Figure 1. Dexcom G6 real-time continuous glucose monitoring system and Welldoc BlueStar digital health solution.

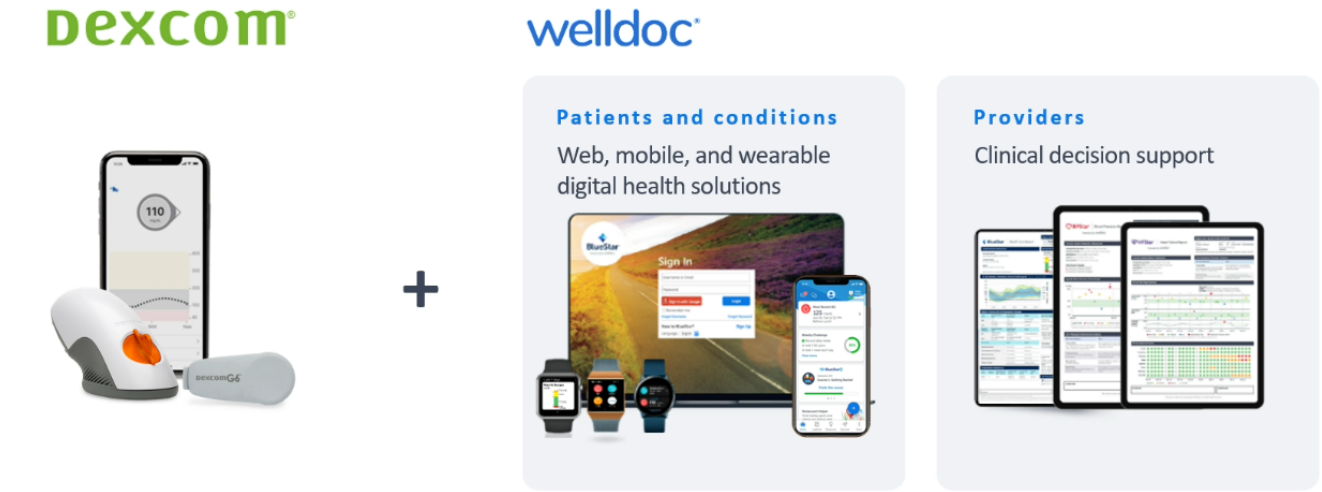

Table 1. Participant characteristics.

Baseline characteristics	Overall (n=52)	Baseline glucose ≤180 mg/dL (n=34)	Baseline glucose >180 mg/dL (n=18)	*P* value[a]
Age (years), mean (SD)	53 (9)	53 (7)	50 (11)	.07
Female, n (%)	19 (37)	14 (41)	5 (28)	.35
GMI[b], mean (SD)	7.5 (1.1)	6.8 (0.5)	8.7 (0.9)	<.001
Mean glucose (mg/dL), mean (SD)	174 (47)	147 (20)	227 (36)	<.001
Diabetes medication regimen, n (%)				
Basal insulin	6 (12)	3 (9)	4 (22)	.18
GLP-1 RA[c]	3 (6)	2 (6)	1 (6)	.96
Oral medications	16 (31)	13 (38)	3 (17)	.11
No medications	26 (50)	16 (47)	10 (56)	.56

[a]*P* values describe the comparisons between the ≤180 mg/dL cohort and the >180 mg/dL cohort. Between-group differences were tested using the 2-proportion *z* test for gender and medication regimen and a 2-tailed Welch *t* test for age, glucose management indicator (GMI), and mean glucose.

[b]GMI: glucose management indicator.

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

Glycemic Outcomes

The mean proportion of days with sensor wear was 90% (SD 8%). Glycemic outcomes for the 3-month study are presented in Table 2. Among individuals with baseline mean glucose >180 mg/dL, significant improvements in glycemic metrics were observed. Specifically, GMI decreased by 0.8 (IQR –1.0 to 0.1) percentage points, TIR increased by 15 (IQR 1-47) percentage points, and TAR 181-250 mg/dL and >250 mg/dL decreased by 4.4 (IQR –20.2 to 2.1) and 14 (IQR –18.3 to 1.4) percentage points, respectively (all $P<.05$). This TIR improvement corresponds to an increase of over 3.5 hours per day in target range and is clinically meaningful [10]. Glycemic control among participants with a baseline mean glucose ≤180 mg/dL was maintained [10]. The proportion meeting the international consensus guidelines of >70% TIR [10] increased from 0% to 28% among individuals with baseline glucose >180 mg/dL.

Table 2. Change in continuous glucose monitoring metrics from baseline at 3-month follow-up stratified by baseline mean glucose.

Continuous glucose monitoring metric	Overall			Baseline glucose ≤180 mg/dL			Baseline glucose >180 mg/dL		
	Baseline	Follow-up	Change	Baseline	Follow-up	Change	Baseline	Follow-up	Change
Glycemic control, median (IQR)									
Mean glucose (mg/dL)	164 (138 to 198)	155 (130 to 188)	–9 (–35 to 17)	145 (126 to 164)	141 (127 to 181)	–4 (–11 to 22)	221 (198 to 233)	187 (160 to 214)	–34 (–42 to 6)[a]
GMI[b] (%)	7.2 (6.6 to 8)	7 (6.4 to 7.8)	–0.2 (–0.8 to 0.4)	6.8 (6.3 to 7.2)	6.7 (6.3 to 7.6)	–0.1 (–0.3 to 0.5)	8.6 (8 to 8.9)	7.8 (7.1 to 8.4)	–0.8 (–1 to 0.1)[a]
CV[c] (%)	22 (19.7 to 24.7)	22.2 (19.4 to 25.9)	0.2 (–2.2 to 2.9)	22 (19.7 to 24.7)	21 (18.8 to 25.5)	–1 (–2.1 to 2.1)	21.8 (20 to 25.6)	22.9 (20.2 to 27.7)	1.1 (–2.4 to 3.7)
Time in, above, or below range (%), median (IQR)									
TIR[d] 70-180 mg/dL	71.1 (31 to 88)	72.2 (47 to 92)	1.1 (–14 to 19)	82 (72 to 94)	83 (56 to 94)	1 (–19 to 7)	21 (15 to 38)	36 (25 to 72)	15 (1 to 47)[a]
TAR[e] 181-250 mg/dL	23.3 (10 to 40)	21 (6 to 38)	–2.3 (–10 to 6)	16.2 (5.1 to 24.3)	13.1 (6.4 to 36.3)	–3 (–7.2 to 11.1)	40.2 (33.1 to 56.3)	36.3 (23.1 to 48.2)	–4.4 (–20.2 to 2.1)[a]
TAR >250 mg/dL	2.1 (0.3 to 12.1)	2.3 (0.1 to 11.3)	–0.2 (–5.2 to 4.4)	1.2 (0.1 to 2.2)	0.2 (0.3 to 5.2)	1 (0.1 to 5.3)[a]	25 (11.1 to 43.4)	11 (1.2 to 27.2)	–14 (–18.3 to 1.4)[a]
TBR[f] <70 mg/dL	0.2 (0.1 to 0.6)	0.4 (0.2 to 1.3)	0.2 (–0.2 to 1.1)	0.2 (0.1 to 0.8)	0.6 (0.2 to 0.7)	0.4 (–0.1 to 0.9)	0.2 (0.1 to 0.5)	0.5 (0.2 to 1.5)	0.3 (0.1 to 0.9)

[a]*P*<.05; significance of the within-group differences was tested using the Wilcoxon signed rank test.

[b]GMI: glucose management indicator.

[c]CV: coefficient of variation.

[d]TIR: time in range.

[e]TAR: time above range.

[f]TBR: time below range.

Engagement

The proportion of individuals with at least one engagement activity per week over the 3-month study period was 29% (15/52). Logging of specific engagement activities overall and stratified by baseline mean glucose is shown in Table 3. The weekly engagement rate per user who logged events is shown in Table 4. Among individuals who logged events, there was a significantly higher total rate of event logging in the cohort with baseline mean glucose ≤180 mg/dL (*P*=.006). Medication-taking was logged most often in both cohorts, closely followed by exercise and food logging. Between the 2 cohorts, there were significantly higher rates of medication (*P*<.001), exercise (*P*<.001), food (*P*=.007), and sleep (*P*<.001) logging among participants with baseline mean glucose ≤180 mg/dL.

Table 3. Summary of event logging.

Participant engagement	Overall (n=52), n (%)	Baseline mean glucose ≤180 mg/dL (n=34), n (%)	Baseline mean glucose >180 mg/dL (n=18), n (%)	*P* value[a]
Medications	23 (44)	15 (44)	8 (44)	>.99
Exercise	21 (40)	13 (38)	8 (44)	.70
Food	19 (37)	12 (35)	7 (39)	.80
Weight	18 (35)	12 (35)	6 (33)	.90
Sleep	16 (31)	11 (32)	5 (28)	.80
Blood pressure	7 (13)	6 (18)	1 (6)	.20

[a]*P* values were calculated using a 2-proportion *z* test and describe comparisons between the ≤180 mg/dL cohort and the >180 mg/dL cohort.

Table 4. Average engagement rate among participants who logged events.

Average engagement (per user per week)	Overall, mean (SD)	Baseline mean glucose ≤180 mg/dL, mean (SD)	Baseline mean glucose >180 mg/dL, mean (SD)	*P* value[a]
Medications	12.1 (0.8)	15.2 (1.5)	6.4 (0.7)	<.001
Exercise	5.0 (0.2)	5.5 (0.4)	4.4 (0.4)	<.001
Food	3.8 (0.6)	4.5 (1.1)	2.4 (0.7)	.007
Sleep	2.4 (0.2)	2.5 (0.2)	2.1 (0.4)	<.001
Blood pressure	1.1 (0.2)	1.2 (0.3)	0.2 (N/A[b])	N/A
Weight	0.7 (0.1)	0.7 (0.1)	0.6 (0.1)	.62
Total	25.0	29.7	16.1	.006

[a]*P* values were calculated using the Mann-Whitney U test and describe the comparisons between the ≤180 mg/dL cohort and the >180 mg/dL cohort.
[b]N/A: not applicable (not enough data for statistical analysis).

Discussion

Principal Results

In this real-world study, participation in a digital health program combined with RT-CGM use was associated with significant improvements in glycemic control in adults with T2D and suboptimal glycemic control at baseline. This included a significant decrease in mean glucose and a clinically meaningful increase in TIR of approximately 15 percentage points, corresponding to an increase of approximately 3.5 hours per day time in the target glucose range [10]. Glycemic control was maintained in the group of participants meeting glycemic targets (mean glucose ≤180 mg/dL) at baseline. There was high RT-CGM use and regular engagement with the BlueStar app. Regardless of baseline glucose control, a similar proportion of participants engaged with the BlueStar app and logged self-management events.

Comparison With Prior Work

There are a variety of digital health programs that incorporate CGM. Some use only live lifestyle coaching; others use live coaching and telemedicine visits; some exclusively use AI-based lifestyle programs; and others use hybrid models of AI-based and live coaching, with or without telemedicine visits. Studies of these programs have reported glycemic and other outcomes; however, it is not possible to directly compare the results to those in this study due to differences in the program models for delivering diabetes educational support and coaching, live clinician management, and CGM wear patterns (continuous vs intermittent wear) [8,9,11-17]. For example, a study by Majithia et al [12] of a digital health program incorporating telemedicine visits found a 10.2 percentage point increase in TIR at 4-month follow-up among participants with suboptimally controlled T2D versus a 15 percentage point increase in this study. However, CGM was worn nearly continuously in this study versus intermittent use in the report by Majithia et al [12]. A retrospective study of people with T2D using CGM continuously as part of an intensive diabetes management program also reported a significant decrease in CGM-derived mean glucose (147.4, SD 59.1 mg/dL to 122.6, SD 33.3 mg/dL; *P*<.001), and significant improvement in HbA_{1C}, insulin resistance, and fasting blood glucose at 90 days [15]. As in our study, other studies of combined telehealth and CGM programs in people with T2D have reported greater glycemic improvements among those with a higher baseline value and maintenance of glycemic control in those meeting targets at baseline [13,14].

Beyond glycemic outcomes, participation in digital health programs incorporating CGM has been associated with other beneficial outcomes. Participants in telehealth programs that incorporated RT-CGM reported an increased understanding of their diabetes [13], lower diabetes distress [16,18], and improved quality of life [16]. In a previous study of users in a combined BlueStar and connected BGM application, emergency department visits decreased by 30% and costs decreased by 55% [11].

Engagement metrics are not commonly reported in studies on digital health or telehealth solutions. In one study, two-thirds of participants in a telehealth program incorporating RT-CGM had at least one coaching interaction, with most having greater than 4 during the 26-week follow-up period [14]. In another report, among users of a telehealth mobile app, 84% used coaching and 13% used telemedicine at least once [17]. Notably, those who used CGM had some of the largest improvements at follow-up [17].

It is noteworthy that while the proportion of participants that logged events was similar between groups, among those who logged events, the weekly rate was higher in the group with better glycemic control at baseline. This is reported in other studies where individuals with good glycemic control maintain it through the intervention [13,15]. While our study did not query participants on their engagement behaviors, we hypothesize that individuals with higher average baseline glucose primarily focused on their glucose data and related insights, whereas individuals with better glycemic control had increased availability to log other behaviors. This will be a topic of future research.

The BlueStar digital health solution is designed for high scalability in its use of AI-powered insights rather than live, lifestyle coaching with diabetes educators or telemedicine visits with clinicians. These insights from RT-CGM data can aid users in successful problem-solving, a critical ADCES7 self-care behavior [2], and potentially lead to behavioral change in other ADCES7 self-care behaviors. For example, glucose changes

following exercise, a healthy meal, or taking medication as prescribed could clarify the importance of these diabetes self-management behaviors. The combination of a digital health solution and RT-CGM allows for personalized problem-solving and is likely to lead to improvements in diabetes management.

Strengths and Limitations

Strengths of this study include the significant improvements in participant outcomes, the use of a real-world, outpatient setting, and the sustainability of the intervention related to the scalability of the digital health solution. Limitations include the all-US population covered under one employee health plan, limited demographic information (such as education level), and the modest sample size, which could have limited statistical significance. In addition, the effect of the digital health solution or RT-CGM system individually could not be quantified in this single-arm study design. Longer studies are needed to evaluate the durability of outcomes. We also acknowledge the potential attrition bias with the use of a 70% data sufficiency requirement; however, our aim was to assess the use of the combined digital health and RT-CGM program and determine its efficacy.

Conclusions

This study suggests that engagement with a combination of RT-CGM and an AI-driven digital health solution helps users improve their glycemic metrics. Those with the highest baseline glycemic metrics were more likely to see significant, meaningful improvements. Behavioral change stemming from AI-derived insights and interaction with RT-CGM data likely contributes to these improvements without the need for live coaching or telehealth visits.

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Conflicts of Interest

All authors are employees of Dexcom, Inc, or Welldoc, Inc.

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Abbreviations

AI: artificial intelligence
ADA: American Diabetes Association
ADCES: Association of Diabetes Care and Education Specialists
AI: artificial intelligence
BGM: blood glucose meter
CGM: continuous glucose monitor
CV: coefficient of variation
GMI: glucose management indicator
HbA_{1C}: glycated hemoglobin FDA: Food and Drug Administration
HIPAA: Health Insurance Portability and Accountability Act
RT-CGM: real-time continuous glucose monitor
T2D: type 2 diabetes
TAR: time above range
TBR: time below range
TIR: time in range

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Original Paper

Health Outcomes Following Engagement With a Digital Health Tool Among People With Prediabetes and Type 2 Diabetes: Prospective Evaluation Study

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Abstract

Background: Diabetes is a worldwide chronic condition causing morbidity and mortality, with a growing economic burden on health care systems. Complications from poorly controlled diabetes are associated with increased socioeconomic costs and reduced quality of life. Smartphones have become an influential platform, providing feasible tools such as health apps to deliver tailored support to enhance the ability of patients with diabetes for self-management. Gro Health is a National Health Service division X–certified digital health tool used to deliver educational and monitoring support to facilitate the development of skills and practices for maintaining good health.

Objective: This study aims to assess self-reported outcomes of the Gro Health app among users with diabetes and prediabetes and identify the factors that determine engagement with the digital health tool.

Methods: This was a service evaluation of self-reported data collected prospectively by the developers of the Gro Health app. The EQ-5D questionnaire is a standardized tool used to measure health status for clinical and economic appraisal. Gro Health users completed the EQ-5D at baseline and 6 months after using the app. Users provided informed consent for the use of their anonymized data for research purposes. EQ-5D index scores and visual analogue scale (VAS) scores were calculated at baseline and 6 months for individuals with prediabetes and type 2 diabetes. Descriptive statistics and multiple-regression models were used to assess changes in the outcome measures and determine factors that affected engagement with the digital tool.

Results: A total of 84% (1767/2114) of Gro Health participants completed EQ-5D at baseline and 6 months. EQ-5D index scores are average values that reflect people's preferences about their health state (1=full health and 0=moribund). There was a significant and clinically meaningful increase in mean EQ-5D index scores among app users between baseline (0.746, SD 0.23) and follow-up (0.792, SD 0.22; P<.001). The greatest change was observed in the mean VAS score, with a percentage change of 18.3% improvement (61.7, SD 18.1 at baseline; 73.0, SD 18.8 at follow-up; P<.001). Baseline EQ-5D index scores, age, and completion of educational modules were associated with significant changes in the follow-up EQ-5D index scores, with baseline EQ-5D index scores, race and ethnicity, and completion of educational modules being significantly associated with app engagement (P<.001).

Conclusions: This study provides evidence of a significant positive effect on self-reported quality of life among people living with type 2 diabetes engaging with a digital health intervention. The improvements, as demonstrated by the EQ-5D questionnaire, are facilitated through access to education and monitoring support tools within the app. This provides an opportunity for health

care professionals to incorporate National Health Service–certified digital tools, such as Gro Health, as part of the holistic management of people living with diabetes.

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KEYWORDS

application; diabetes; digital health tool; digital health; eHealth; mHealth; mobile app; mobile health; prediabetes; quality of life; type 2 diabetes

Introduction

Type 2 diabetes (T2D) is a chronic condition that is a leading cause of morbidity and mortality worldwide [1]. It is an emerging public health crisis with a growing clinical, social, and economic burden on both patients and health care systems. Worldwide, there are around 462 million individuals affected by T2D, and the numbers are dramatically rising in every country [2]. In the United Kingdom, 1 in 14 people is estimated to have diabetes, with type 2 accounting for 90% of cases [3]. Complications arising from poorly controlled diabetes include coronary heart disease, kidney disease, along with retinopathy and neuropathy, which can lead to blindness and limb amputation, respectively [4]. These systemic complications have been associated with both increased socioeconomic costs and a reduced quality of life. In a landmark UK-based study, the cost for T2D was estimated to be £8.8 billion (US $11 billion) and £13 billion (US $17 billion) in direct and indirect costs [5]. The burden of diabetic complications has not only translated to worsening health outcomes with increased risk of mortality but also to a lower health-related quality of life (HRQoL) [6-8]. The global burden of disease study identified diabetes as one of the top 10 causes of reduced life expectancy and demonstrated that high fasting glucose level was the third most common risk factor for disability-adjusted life years [9].

The treatment of T2D aims to establish control over blood glucose to reduce the associated risk of complications and disability. In addition to medical management, this can also be achieved through lifestyle modifications, including healthy eating, physical activity, and regular blood sugar monitoring, among others. It is well established in the literature that lifestyle interventions are capable of yielding significant clinical improvements, including remission, in patients with diabetes, as demonstrated in a 2021 study in the Netherlands [10,11]. However, these lifestyle modifications often depend on the development of skills and practices that aim to facilitate self-management. The term self-management refers to the responsibility given to patients to adhere to good health practices to enable them to monitor and manage their own disease outside clinical settings [12,13]. Research has shown that education and self-management play a crucial role in helping people living with diabetes achieve metabolic control [14,15], which consequently reduces their risk of developing complications and eases the burden on health care systems by encouraging patient autonomy. This highlights the importance of developing technologies to facilitate self-care and the achievement of therapeutic goals for people living with diabetes [16].

Smartphones have become an influential platform, providing digital tools (often in the form of an app) to deliver tailored support and support self-management [16,17]. There is a growing body of evidence to support the use of health apps as successful adjuvants in diabetes management, which has yielded clinically significant metabolic improvements. A 2010 meta-analysis showed that there was strong evidence supporting the notion that the use of mobile app interventions can lead to significant improvements in glycemic control among patients with T2D [17]. This finding was further reinforced in a systematic review by Bonoto et al [18], which also confirmed the efficacy of mobile apps in the management of patients with diabetes.

In addition to clinical benefits, digital tools can improve an individual's quality of life by providing mental health support and personalized coaching, leading to greater confidence to manage day-to-day life [19,20]. Improved quality of life has been long regarded as a fundamental goal for all diabetic management interventions, with HRQoL measures being used in the evaluation of health care interventions, including cost-effectiveness [21]. The EQ-5D-5L questionnaire is a standardized HRQoL tool used to measure health status for clinical and economic appraisal [22]. The EQ-5D allows for health states to be reported as calculated index values, which can be used for economic evaluation [22,23]. These health index scores reflect how good or bad a health state is according to the preferences of the population within a certain country [22].

In this study, we assess the impact of engagement with a digital behavioral change app (Gro Health) that is certified by the National Health Service (NHS) on the self-reported health outcomes among people diagnosed with T2D or prediabetes. The EQ-5D questionnaire was used to capture outcomes as it is a widely recognized and validated tool. We also aim to identify the factors that determine engagement with digital technologies and posit that greater use of the digital platform will lead to improvements in HRQoL.

Methods

Intervention

Gro Health is an NHS-certified digital health tool used to deliver health prevention, chronic disease management, home monitoring, and elective care support for people waiting for treatment before treatment and posttreatment rehabilitation. A clinical dashboard enables clinical teams to remotely assess user engagement with the app and monitor patients' health. The platform itself provides personalized education and behavioral change program streams developed in conjunction with NHS clinical teams specifically for people living with T2D, prediabetes, gestational diabetes, obesity, nonalcoholic fatty liver disease, polycystic ovarian syndrome, hypertension, high

cholesterol, or cardiac rehabilitation (Multimedia Appendix 1). Gro Health is the highest Organisation for the Review of Care and Health Apps (ORCHA)–rated health app (96%), assessed on user experience, data assurance, and clinical validation [24]. The Gro Health platform facilitates personalized digital health by providing evidence-based structured education, guided behavioral change activities, weekly digital meetups and community support, health tracking, and data-driven insights to users based on their data collected on signup and as it changes through use of the platform. Gro Health uses the capability, opportunity, motivation, and behavior model of behavior change, which identifies 3 factors (capability, opportunity, and motivation) that need to be present for any behavior to occur [25]. These factors interact over time, so that behavior is seen as part of a dynamic system with positive and negative feedback loops. A recently reported study demonstrated that users (general population, rather than people living with T2D) of Gro Health had improvements in symptoms of stress, anxiety, and depression measured through standardized questionnaires over 12 weeks [25].

Ethical Considerations

This was a service evaluation of self-reported data collected prospectively by the developers of the Gro Health digital tool, Diabetes Digital Media. Participants were not paid for their participation, and they accessed the Gro Health app for free as part of their NHS care. Participants downloaded the app and agreed to the terms of service and privacy policy of the Gro Health app, which included informed consent to use their anonymized data for research purposes. Minimal deidentified user data required for the analyses were collected. The local hospital research and development department was contacted and confirmed that no registration was necessary. This was an analysis of already collected data that users consented to sharing for research purposes.

Participant Selection

The Gro Health app was offered to people, aged 18 years or older with a confirmed diagnosis of T2D or prediabetes, who presented for any reason between January and August 2021 at 13 NHS primary care settings in England, as part of their clinical care if the consulting health care professional felt it was appropriate. People who accepted signposting were given a Gro Health referral card or emailed a digital referral code, which was redeemed on the app or website. Those who did not have a diagnosis of prediabetes or T2D were not offered the Gro Health app. However, since the diagnosis of T2D or prediabetes was predetermined in primary care, we had no means of verifying that each participant included in this study met the clinical criteria for diagnosis as the data were anonymized. Of 2114 registrations from NHS primary care setting referrals, 1767 Gro Health study participants completed the EQ-5D at baseline and 6 months after registering on the app (1767/2114, 83.6%).

Study Measures

Upon study sign-up (baseline), participants were asked to report their age, sex, health goal, race and ethnicity, monthly income, and diagnosis of any preexisting health conditions. They were also asked to complete the EQ-5D questionnaire. At 6 months, participants were asked to complete the same scale again in the same format. User engagement with the Gro Health app was monitored and recorded as completion of the education program tailored for patients with prediabetes and T2D, respectively.

Assessment of HRQoL was undertaken using the EQ-5D questionnaire. The EQ-5D involves self-reporting of health status in terms of 5 dimensions, including mobility, self-care, usual activities, pain, and anxiety or depression (Multimedia Appendix 2). Each dimension is rated on a 1-5 severity scale. Responses from these dimensions are then coded for each patient and converted into a single-weighted index score using population preference scores. In this study, we used the EQ-5D-5L value set for England to derive the index scores [23]. These EQ-5D index scores reflect how good or bad a health state is according to the preferences of the population within a certain country. A range of –0.594 to 1 can be obtained for EQ-5D index scores, where a value of 1 represents perfect health, 0 represents a health state equivalent to death, and a score of less than 0 represents a state worse than death. User data on EQ-5D index scores and visual analogue scale (VAS) scores were calculated from the EQ-5D responses at baseline and 6-month follow-up for all users included in the study.

Statistical Analysis

Descriptive statistics were used to summarize the socioeconomic demographics and clinical characteristics of participants. Percentages were used to summarize categorical variables and continuous variables, were summarized by the mean and SD according to the published user guide by EuroQol for analyzing EQ-5D-5L data [22]. Differences between socioeconomic demographic and clinical factors on self-reported HRQoL outcomes (eg, EQ-5D index scores and VAS scores) were evaluated using 2-tailed *t* tests for continuous variables and chi-square tests for categorical variables. Stepwise multiple linear regression modeling was used to evaluate the impact of predictor variables such as age, sex, race and ethnicity, income, engagement with education, baseline EQ-5D index scores on the outcome variables, EQ-5D index scores at the follow-up, and time spent on the app, which was a surrogate marker for engagement with the app. A *P* value of <.05 was considered statistically significant. All statistical analyses were carried out in SPSS software (version 27.0; IBM Corp).

Results

Overview

Of 2114 registrations from NHS primary care setting referrals, 1767 Gro Health participants completed the EQ-5D at baseline and 6 months after registering on the app (1767/2114, 83.6%). App engagement was measured through total minutes of use, an analytic indicator used in previous studies to evaluate the effective engagement of digital health apps [25]. The mean number of engaged minutes with the Gro Health app was 268 (SD 98.3) minutes, as recorded during the 6-month study period.

Baseline Sociodemographic Characteristics of Participants

Table 1 summarizes the baseline socioeconomic and clinical characteristics of the participants. Among 1767 users, 1129 (63.8%) were female, mean age was 49 (SD 12.7) years, 1536 (86.9%) were White, and 840 (47.5%) had an income of more than £21,000 (US $26,600). Regarding their clinical status, 76.7% (1355/1767) had T2D and the rest had prediabetes at the time they signed up for the app.

Table 1. Baseline demographic and clinical characteristics (n=1767). Not all users agreed to share their data, and hence the total numbers may not sum up to 1767.

Characteristic	Values
Age (years), mean (SD)	49.2 (12.7)
Sex, n (%)	
Female	1129 (63.8)
Male	616 (34.8)
Race and ethnicity, n (%)	
White	1536 (86.9)
Southeast Asian	105 (5.9)
Black	46 (2.6)
East Asian	13 (0.7)
Multiracial	40 (2.3)
Income (£1=US $1.3), n (%)	
<£13,000	234 (13.2)
£13,000-£20,999	220 (12.5)
£21,000-£25,999	163 (9.2)
£26,000-£31,999	144 (8.1)
£32,000-£39,999	153 (8.7)
£40,000-£49,999	122 (6.9)
>£50,000	258 (14.6)
Time spent on the app (minutes), mean (SD)	268 (98.3)
Educational program completed, n (%)	
Yes	896 (50.7)
No	560 (31.7)
Clinical status, n (%)	
Type 2 diabetes	1355 (76.7)
Prediabetes	412 (23.3)

Changes in Health-Related Quality of Life (EQ-5D Questionnaire)

Participants' responses over 5 levels in each of the 5 domains of the EQ-5D questionnaire at baseline and at 6-month follow-up are shown in Table 2. Of the 1767 participants, no problems at all at baseline in mobility, usual activities, self-care, pain, and anxiety or depression were reported by 1073 (60.7%), 1127 (63.8%), 1538 (87%), 665 (37.6%), and 847 (47.9%) participants, respectively. No significant differences in the reported outcome of the individual EQ-5D domains were noted at follow-up, as seen in Table 2 (chi-square test: P=.98 for mobility, P=.93 for self-care, P=.94 for activity, P=.20 for pain, and P=.47 for anxiety or depression).

Table 2. Number and percentage of user responses in the 5 domains of the EQ-5D at baseline and follow-up.

	Baseline, n (%)	Follow-up, n (%)
Mobility		
Unable to walk	13 (0.7)	18 (1)
Severe problems	120 (6.8)	102 (5.8)
Moderate problems	225 (12.7)	272 (15.4)
Slight problems	336 (19)	281 (15.9)
No problems	1073 (60.7)	1094 (61.9)
Self-care		
Unable to wash or dress	2 (0.1)	6 (0.3)
Severe problems	38 (2.2)	25 (1.4)
Moderate problems	74 (4.2)	57 (3.2)
Slight problems	115 (6.5)	81 (4.6)
No problems	1538 (87)	1598 (90.4)
Activity		
Unable to do usual activities	26 (1.5)	27 (1.5)
Severe problems	73 (4.1)	50 (2.8)
Moderate problems	183 (10.4)	119 (6.7)
Slight problems	358 (20.3)	379 (21.4)
No problems	1127 (63.8)	1192 (67.5)
Pain		
Extreme pain or discomfort	36 (2)	25 (1.4)
Severe pain or discomfort	98 (5.5)	98 (5.5)
Moderate pain or discomfort	317 (17.9)	197 (11.1)
Slight pain or discomfort	651 (36.8)	489 (27.7)
No pain or discomfort	665 (37.6)	958 (54.2)
Anxiety or depression		
Extremely anxious or depressed	17 (1)	8 (0.5)
Severely anxious or depressed	73 (4.1)	30 (1.7)
Moderately anxious or depressed	265 (15)	326 (18.4)
Slightly anxious or depressed	565 (32)	389 (22)
Not anxious or depressed	847 (47.9)	1014 (57.4)

Overall health state, combining all of these domains, showed that 353 out of 1767 participants (20%) reported no problems in any of the EQ-5D domains (described as perfect health); 1164 out of 1767 users (65.9%) reported problems in at least 1 domain not worse than a level 3 (described as moderate health); and the remaining 250 (14.1%) users reported problems worse than a level 3 in at least 1 domain (described as severe health; Multimedia Appendix 3).

Changes in EQ-5D Index Scores and VAS Scores

EQ-5D index scores reflect how good or bad a health state is, and this is adjusted according to the preferences of the population within a certain country. EQ-5D index scores were calculated at baseline and at follow-up for all participants, who were all based in the United Kingdom. The mean EQ-5D index score for this cohort significantly improved from 0.746 (SD 0.23) at baseline to 0.792 (SD 0.22) at 6-month follow-up (paired *t* test: $P<.001$). VAS scores were also analyzed for participants, and these also demonstrated a significantly positive change over time (mean 61.7, SD 18.1 at baseline and mean 73.0, SD 18.8 at follow-up; $P<.001$).

Table 3 shows the association of socioeconomic and clinical factors with the mean EQ-5D index and VAS scores between baseline and follow-up. EQ-5D index scores were higher at follow-up for female individuals (paired *t* test: $P<.001$), participants of White race ($P<.001$), participants with income of more than £25,999 (US $33,000; $P=.009$), and participants

with both diabetes and prediabetes (P<.001). Mean EQ-5D index scores were only noted to be lower at follow-up in participants of Southeast Asian ethnicity (paired t test: P=.04). In contrast, average VAS scores significantly improved for all users at follow-up, irrespective of any differences in sociodemographic factors or clinical status (P<.001).

Table 3. Mean EQ-5D index scores and visual analogue scale scores according to sex, race, ethnicity, income, and clinical status.

Scales and patient demographics	Baseline	Follow-up
EQ-5D index value, mean (SD)		
Sex		
Female	0.730 (0.23)	0.789 (0.22)
Male	0.777 (0.24)	0.797 (0.23)
Race and ethnicity		
White	0.737 (0.24)	0.792 (0.22)
Southeast Asian	0.827 (0.16)	0.773 (0.25)
Black or Caribbean	0.825 (0.16)	0.834 (0.16)
East Asian	0.821 (0.23)	0.846 (0.09)
Mixed	0.764 (0.20)	0.786 (0.22)
Income (£1=US $1.3)		
<£13,000	0.646 (0.28)	0.765 (0.23)
£13,000-£20,999	0.695 (0.26)	0.785 (0.22)
£21,000-£25,999	0.730 (0.20)	0.790 (0.24)
£26,000-£31,999	0.760 (0.22)	0.777 (0.22)
£32,000-£39,999	0.794 (0.19)	0.806 (0.02)
£40,000-£49,999	0.789 (0.23)	0.819 (0.22)
>£50,000	0.818 (0.17)	0.805 (0.21)
Clinical status		
Prediabetes	0.772 (0.20)	0.807 (0.21)
Type 2 diabetes	0.738 (0.24)	0.788 (0.23)
Visual Analogue Scale score, mean (SD)		
Sex		
Female	60.9 (18.5)	72.3 (19.4)
Male	63.3 (17.4)	74.5 (17.7)
Race and ethnicity		
White	61.5 (18.3)	72.9 (18.8)
Southeast Asian	62.5 (16.7)	72.9 (18.4)
Black or Caribbean	67.5 (14.4)	79.5 (15.2)
East Asian	62.9 (15.0)	74.5 (15.3)
Mixed	60.5 (20.4)	72.5 (20.8)
Income (£1=US $1.3)		
<£13,000	55.9 (20.8)	67.1 (21.4)
£13,000-£20,999	59.4 (19.0)	70.8 (19.7)
£21,000-£25,999	61.2 (16.7)	72.2 (17.9)
£26,000-£31,999	61.4 (19.5)	72.2 (20.4)
£32,000-£39,999	64.7 (16.6)	75.8 (17.3)
£40,000-£49,999	63.6 (16.5)	75.1 (16.4)
>£50,000	64.8 (14.7)	75.9 (16.2)
Clinical status		
Prediabetes	63.5 (15.7)	74.8 (16.9)
Type 2 diabetes	61.2 (18.8)	72.5 (19.3)

Engagement With the Educational Program and Predictors of EQ-5D Index Scores at Follow-Up

Time spent in the app averaged 268 (SD 98.3) minutes, with roughly half of users (896/1767, 50.7%) completing the educational component of the app. The Gro Health app includes a personalized educational program as a component for people with prediabetes and T2D, respectively. Completers of the educational program spent a mean of 282.1 (SD 86.8) minutes on the app, compared to just 241.1 (SD 110.4) minutes for users who did not complete the educational component (independent samples *t* test: $P<.001$).

The results from the stepwise multiple linear regression modeling, where the dependent variable was the follow-up EQ-5D index score, are presented in Table 4. Predictor variables evaluated in the model included baseline EQ-5D index scores, time spent on the app, age, income, engagement with the educational program, race and ethnicity, and sex. The best-fitting model accounted for approximately 11% ($R^2=0.11$) of the variation in EQ-5D index scores at follow-up, with the estimated regression coefficients and 95% CIs reported in Table 4. The model showed that EQ-5D index score at baseline, completion of the educational program, time spent on the app, and age were all significantly positively associated with follow-up EQ-5D index scores.

Table 4. Summary of multiple linear regression for EQ-5D index scores at follow-up.

Variables	Coefficient (95% CI)	*P* value
Baseline EQ-5D index score	0.214 (0.171-0.257)	<.001
Completion of educational program	0.061 (0.041-0.082)	<.001
Age	0.001 (0.000-0.002)	.02
Time spent on the app	0.0003 (0.0002-0.0004)	<.001

Predictors of App Engagement (Time Spent on App)

Another stepwise multiple linear regression model was used to evaluate the predictor variables for time spent on the app with results reported in Table 5. The predictor variables evaluated in the model included baseline EQ-5D index scores, age, income, engagement with educational program, race and ethnicity, and sex. The best-fitting model accounted for approximately 4.1% ($R^2=0.041$) of the variation in time spent on the app, with the estimated regression coefficients and 95% CIs reported in Table 5. The model showed that baseline EQ-5D index scores were significantly positively associated with app engagement, while incompletion of the educational program and Southeast Asian ethnicity were significantly negatively associated with app engagement.

Table 5. Summary of multiple linear regression for app engagement.

Variables	Coefficient (95% CI)	*P* value
Baseline EQ-5D index score	30.8 (11.1 to 50.5)	<.001
Incompletion of educational program	–35.5 (–45.3 to –25.6)	.002
Southeast Asian ethnicity	–21.4 (–40.5 to –2.32)	.03

Discussion

Overview

The growing burden of T2D continues to pose a serious public health risk with the increasing prevalence of the disease worldwide. It is recognized in the literature that, to a great extent, T2D arises due to the contribution of unhealthy lifestyle choices, such as poor diet and lack of physical activity, among other factors. Therefore, with no definitive cure for diabetes, self-management remains a vital component in the management of these patients.

The fast-developing nature of digital health applications means that these tools can be used to facilitate the self-management of many chronic conditions, including T2D. One of the fundamental goals of all diabetic management interventions is to improve quality of life. In this study, we used the self-reported EQ-5D-5L outcomes to assess the impact on HRQoL measures of participants following the 6-month use of the Gro Health app. Previous studies have supported the use of the EQ-5D-5L questionnaire as it is more discriminative than the EQ-5D-3L [26]. This study showed that engagement with the Gro Health digital app resulted in both statistically and clinically significant improvements in the self-reported quality of life outcomes among users with T2D and prediabetes. In a 2021 meta-analysis on the effectiveness of digital interventions on the self-management of patients with diabetes, no statistically significant changes in self-reported HRQoL were found [27]. Despite no statistical significance being noted in this study in any of the individual 5 domains of the EQ-5D when analyzed separately, the cumulative impact of combining these domains using the EQ-5D index scores revealed significant results at follow-up. The clinical significance of the EQ-5D index scores in this study was determined based on the findings reported by McClure et al [28] in adults with T2D, which showed that a change of at least 0.03 in the index score was significant. Additionally, the catalog of EQ-5D scores for the United Kingdom by Sullivan et al [29] discussed the loss of utility associated with T2D in the United Kingdom at 0.06, and our results showed that by follow-up, our cohort had a significant EQ-5D index score change of 0.05. This finding is supported

by a 2016 review and a 2019 study by Jeffrey et al [30] confirming the benefits of mobile health apps in the care and self-management of patients with T2D [31].

This study showed 6% and 18% improvement from baseline in the EQ-5D index and VAS scores, respectively, among users. The mean baseline EQ-5D index scores for our cohort were 0.746 (SD 0.23) and the mean VAS score was 61.7 (SD 18.1), which were similar to findings reported by Grandy et al [32] among a population of patients with diabetes in the United Kingdom. Using the classification system used by Alshayban and Joseph [33] in a 2020 study of HRQoL among patients with T2D, we found that 66% (1164/1767) of our cohort had a moderate health state at baseline, with only 14% (250/1767) reporting severe health states. This could perhaps suggest that, contrary to the assumption that patients with more severe health states are more likely to engage with health apps, it is actually patients with a better health state who often engage with digital health tools. This was discussed by Birnbaum et al [34], where socioeconomic factors often associated with disease morbidity could be a potential barrier affecting patient engagement with digital health. This also raises the question of the responsiveness of the EQ-5D in populations that are not old or severely disabled, such as our cohort. In such cases, it is perhaps important to incorporate other condition-specific measures along with the EQ-5D as discussed by Payakachat et al [35] to improve the reliability of the HRQoL in the evaluation of interventions. Nevertheless, the reporting of the EQ-5D continues to remain valuable due to their role in measuring quality-adjusted life years, which is used in determining health economics and commissioning policies.

Several studies have reported lower HRQoL among female individuals with T2D compared to their male counterparts [36,37]. This study confirmed this, with female individuals having lower EQ-5D index scores at baseline compared to male individuals (Table 3). This finding could perhaps explain why significant improvements in EQ-5D index scores at follow-up were only noted among female individuals, since users with a lower EQ-5D index score are more likely to experience an improvement with time compared to those starting with a higher score at baseline. Users of the White race, along with those with an income of <£26,000 (US $33,000) were also noted to have positive improvements in EQ-5D index scores at follow-up compared to their counterparts. As highlighted earlier, this finding could be due to users with these ethnic and economic factors having a lower baseline EQ-5D index score compared to other groups in the subanalysis. In contrast, users of Southeast Asian ethnicity were found to have a lower EQ-5D index score at follow-up, despite an improvement in mean VAS score over the same period. This may be partially explained by the existing barriers to digital health access faced by patients from ethnic minority backgrounds, as described by Poduval et al [38] in their research, and the cultural appropriateness of the health advice could potentially affect its impact on users. Nevertheless, in this study, this subgroup of users was a minority of the sample, and therefore, this finding may not be adequately representative.

Despite the apparent impact of sex, race and ethnicity, and income on follow-up EQ-5D index scores, these variables were not identified as statistically significant in the regression analysis models. However, it is well established in the literature that socioeconomic and demographic factors are all known to contribute to HRQoL, and this would affect the EQ-5D index score at baseline, which was indeed found to be a positive predictor of EQ-5D index scores at follow-up. Furthermore, this study also identified age as a positive predictor variable of EQ-5D index scores at follow-up, although the effect of this was small and could have arisen due to the higher representation of younger users in the study sample, where more than half of the users (954/1767, 54%) were aged 50 years or younger. Engagement with the educational program and time spent in the app were also identified as significant positive predictors of follow-up EQ-5D index scores. This is consistent with findings by Kar et al [39] who also supported the effectiveness of digital educational interventions in the management of patients with T2D.

Engagement with the app was analyzed as time spent on the app, and this was positively associated with baseline EQ-5D index scores, although negatively associated with incompletion of the educational component and Southeast Asian ethnicity. This could be due to a lack of Southeast Asian language content while also consolidating the impression of existing ethnic inequalities in accessing digital health tools, which is similar to that described by a 2018 UK study [38]. Additionally, this finding could also explain why Southeast Asian users were the only group of users that were noted to have a lower EQ-5D index score at follow-up. Nonetheless, the Gro Health app is working to mitigate this by widening access through the development of more culturally sensitive features, including expanding the languages of the app.

There were several limitations to this study. Given the nature of the study as a service evaluation, there was no control group to assess changes in EQ-5D index scores in people with diabetes who did not use the Gro Health app. People who were more engaged could have opted to use the app as compared to those who are less likely to make positive changes to lifestyle, leading to a selection bias. The data were self-reported and collected in-app, with no measures to verify the accuracy of the data, potentially leading to information bias. Since this was a real-world data collection study, external factors such as changes in social circumstances, loss of employment, changes in physical health, or new medical comorbidities could have affected the index scores over the 6-month period that were not accounted for. Lastly, modeling of EQ-5D data is generally an unresponsive measure in populations that are not old or very disabled. As a result, no significant differences were identified in any of the 5 individual domains, despite overall improvements in the EQ-5D index and VAS scores during follow-up. Future areas of research should aim to assess the influencing factors of HRQoL in people with T2D in order to establish more sensitive outcome measures, either better or in addition to the EQ-5D, to assess the benefits of interventions on HRQoL. Additionally, a randomized clinical trial will be able to provide clear evidence while minimizing bias and confounding factors.

Conclusions

Our findings demonstrate a significant positive effect on self-reported quality of life among people living with T2D and prediabetes engaging with a digital health intervention, Gro Health. This is likely facilitated through access to education, information provision, and monitoring support tools within the app. More efforts should be made to target ethnic minorities, who are known to have poor engagement with digital tools. Overall, this study contributes to the evidence supporting the incorporation of NHS-certified digital tools as an adjunct to the holistic management of people living with diabetes.

Conflicts of Interest

CS and AP are the founders of Diabetes Digital Media (DDM), which developed the Gro Health app. MDLF is the chief operating officer of DDM. The rest of the authors declare no conflicts of interest.

Multimedia Appendix 1
The GroHealth app.
[PDF File (Adobe PDF File), 973 KB - diabetes_v8i1e47224_app1.pdf]

Multimedia Appendix 2
EuroQoL EQ-5D-5L Questionnaire.
[PDF File (Adobe PDF File), 107 KB - diabetes_v8i1e47224_app2.pdf]

Multimedia Appendix 3
Summary of EQ-5D index scores according to baseline health status.
[PDF File (Adobe PDF File), 61 KB - diabetes_v8i1e47224_app3.pdf]

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Abbreviations

HRQoL: health-related quality of life
NHS: National Health Service
ORCHA: Organization for the Review of Care and Health Apps
T2D: type 2 diabetes
VAS: visual analogue scale

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Original Paper

Secure Messaging for Diabetes Management: Content Analysis

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Abstract

Background: Secure messaging use is associated with improved diabetes-related outcomes. However, it is less clear how secure messaging supports diabetes management.

Objective: We examined secure message topics between patients and clinical team members in a national sample of veterans with type 2 diabetes to understand use of secure messaging for diabetes management and potential associations with glycemic control.

Methods: We surveyed and analyzed the content of secure messages between 448 US Veterans Health Administration patients with type 2 diabetes and their clinical teams. We also explored the relationship between secure messaging content and glycemic control.

Results: Explicit diabetes-related content was the most frequent topic (72.1% of participants), followed by blood pressure (31.7% of participants). Among diabetes-related conversations, 90.7% of patients discussed medication renewals or refills. More patients with good glycemic control engaged in 1 or more threads about blood pressure compared to those with poor control (37.5% vs 27.2%, *P*=.02). More patients with good glycemic control engaged in 1 more threads intended to share information with their clinical team about an aspect of their diabetes management compared to those with poor control (23.7% vs 12.4%, *P*=.009).

Conclusions: There were few differences in secure messaging topics between patients in good versus poor glycemic control. Those in good control were more likely to engage in informational messages to their team and send messages related to blood pressure. It may be that the specific topic content of the secure messages may not be that important for glycemic control. Simply making it easier for patients to communicate with their clinical teams may be the driving influence between associations previously reported in the literature between secure messaging and positive clinical outcomes in diabetes.

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KEYWORDS

secure messaging; patient-provider communication; veterans; message content; diabetes; patient portal; T2D; management; support; messaging; glycemic control; communication; engagement; health information; diabetic control; disease outcomes

Introduction

Approximately 29 million Americans have been diagnosed with diabetes [1]. The prevalence of diabetes among veterans is even higher than that in the general population, affecting nearly 25% of Veterans Health Administration patients [2]. Diabetes can lead to other serious problems, including cardiovascular disease, stroke, and loss of limbs [3]. Diabetes is estimated to cost the US health care system US $245 billion annually [2]. Effective management of diabetes is centered around glycemic control, requiring a multifaceted, continuous, and proactive approach that includes patient monitoring and education, lifestyle management, and pharmacologic therapy [4].

Online patient portals such as the Department of Veterans Affairs (VA) My Health*e*Vet, expand patients' access to health care by facilitating communication with health care teams, such as through secure messaging. Secure messaging offers an electronic exchange of messages between patients and clinical team members. Through secure messaging, patients can inform clinical team members of their health status and progress and receive self-management or remote support. Secure messaging can increase patient engagement and self-management [5], and can further improve patient outcomes [6,7]. Previous work has found improved glycemic control in patients who used secure messaging for 2 or more years compared to nonusers of secure messaging [8]. Moreover, there appears to be a positive association between the frequency and intensity of secure messaging use and glycemic control [9]. However, the exact message content being exchanged between patients and clinical teams, and how that content supports improved diabetes self-management, is less clear.

Previous work has examined the content of patient-team secure messages. In a general patient population, one secure messaging content analysis across two VA primary care clinics documented that medication renewals and refills, scheduling requests, medication issues, and health issues were the most common patient-initiated requests via secure messaging [10]. To our knowledge, only one study to date has examined the content of secure messaging in patients with diabetes and the association with diabetes outcomes [11]. Specifically, Heisey-Grove et al [11] examined a sample of patient-initiated secure messages that were saved to the patients' charts in one medical center. This analysis found greater improvements in glycemic levels (ie, decreased hemoglobin A_{1c} [HbA_{1c}]) when patients engaged in secure messaging where they *sought* information (ie, information-seeking messages) or received messages about procedures or treatments from clinical team members. Conversely, glycemic levels worsened (ie, HbA_{1c} increased) among patients who engaged in secure messages where they *shared* information with clinical team members [11]. The work of Heisey-Grove and colleagues thus offers foundational insights into how patients and their clinical teams leverage secure messaging for diabetes management.

The current study expands on this earlier work by examining a representative selection of patient- and team-initiated secure messages from a national sample of patients with type 2 diabetes. We sought to understand how patients and clinical teams use secure messaging to communicate with one another about diabetes management. Leveraging a mixed methods analytic approach, we adapted and applied a theoretically based taxonomy to analyze the content of secure messages between patients and clinical teams (described in further detail below). We examined differences in secure message content, the role of the secure message initiator (clinical team member role or patient), and associations with glycemic control.

Methods

Recruitment

We used data collected for a larger study performed between 2017 and 2020 examining patient portal use in diabetes management [5,12,13]. Participants included veterans with type 2 diabetes who had uncontrolled blood glucose (2012 mean HbA_{1c}>8.0% and less than 25% of the year with HbA_{1c}<8.0%), as well as *repeated* and *current* use of key portal features. *Repeated use* was defined as having at least two instances of each of the following in 2 out of 3 years between 2013 and 2015: requesting a prescription refill, viewing or downloading health information, and using secure messages. *Current use* included having sent at least four secure messages between January 2016 and June 2017. Surveys about My Health*e*Vet and diabetes management were mailed to a total of 1200 veterans and 448 were returned. Further details regarding the sampling methodology are available elsewhere [5].

Ethics Considerations

All survey respondents consented for their recent secure messages to be accessed and analyzed. The Institutional Review Board at VA Bedford Healthcare System approved this research (review number 0008).

Secure Message Thread Coding

Survey respondents' five most recent secure messaging threads were pulled in 2018. Every message and/or thread was coded based on previously published message coding methods [10], which were inspired by elements of the Taxonomy of Requests by Patients [14]. Binary indicators were created to indicate which threads were initiated by the patient and which were initiated by the clinical team. At the message level, we used binary codes to indicate whether the message was related to a diabetes theme, including blood pressure, cholesterol, physical activity, diet/nutrition, mental health, and specific diabetes-related content. Messages were coded as including diabetes-related content if the message explicitly mentioned diabetes, blood glucose, "sugars," insulin, endocrine, or other diabetes medications. Messages that were potentially related to diabetes but not explicitly tied to the condition by either the patient or provider were not coded as a diabetes-related message (eg, blood pressure, diet, exercise). Within each message that was specifically coded as diabetes-related, additional subcodes were applied to further describe whether the diabetes content related to one of the following topics: scheduling, referrals, or consults; medication renewals, refills, or other medication-related issues; test results; test issues; health issues; self-reporting; informational; My Health*e*Vet; life issues;

complaints; establishing a personal connection; and care coordination.

Each message could be coded for more than one topic (eg, refills and scheduling). The research team met frequently to discuss coding questions, discrepancies, and codebook updates. A codebook was developed prior to reviewing messaging data and was further refined at the beginning of the coding stages. To ensure consistency, two of three research assistants independently coded each message. Interrater reliability (Cohen κ) was calculated iteratively (range 0.57-1.00 across the coding period), and joint coding continued throughout. Coding at the thread level was informed by the codes applied to the content at the message level (ie, if a thread contained one or more messages related to the specified topic, the thread was coded as discussing that topic). Coding at the individual level was informed by the codes applied to the thread level (ie, if a patient or clinical team member engaged in one or more threads related to the specified topic, the message initiator was coded as having discussed that topic over secure messaging).

Glycemic Control

To determine the percent time in glycemic control in 2018, we calculated the percentage of time in the baseline year a patient was estimated to have sustained control in HbA_{1c} (<8.0%). Time spent in control was calculated based on the Rosendaal method [15,16], using linear interpolation to assign values to each day between successive measurements. After interpolation, we calculated the percentage of time during the year that the interpolated values fell inside the region of control (eg, HbA_{1c}<8.0%). Participants whose HbA_{1c} was below 8.0% for more than 75% of 2018 were considered to be in "good" glycemic control. Conversely, participants who spent less than or equal to 75% of the year with an HbA_{1c} level under 8.0% were considered to be in "poor" glycemic control. The χ^2 test was used to examine differences in frequency of content codes between patients in good and poor glycemic control.

Results

Patient and Message Characteristics

The patients' mean age was 67.4 (SD 7.5) years and the mean HbA_{1c} was 8.1% (SD 1.2). The sample was majority male (94%), white (84%), and married (50%). We examined secure messages across 2240 threads (5442 total messages) from 448 patients who responded to our survey. All 5442 messages were coded. Each thread contained a mean of 2.4 secure messages (SD 1.7), ranging from 1 to 24 messages per thread. Among the 2240 coded threads, 87.86% (n=1968) were initiated by the patient (n=1890) or the patient's caregiver/proxy (n=78). The remaining 12.14% (n=272) of threads were initiated by the clinical team. Among the clinical team–initiated threads, registered nurses initiated the most threads (109/272, 40.1%), followed by physicians (32/272, 11.8%), licensed practical nurses (30/272, 11.0%), other VA staff (28/272, 10.3%), pharmacists (15/272, 5.5%), medical support assistants/health technicians (4/272, 1.5%), other providers (eg, psychologists; 4/272, 1.5%), and nurse practitioners (3/272, 1.1%). The clinical team member was not clearly identifiable in 17.3% (n=47) of the team-initiated threads.

Message Content

All patients (N=448) initiated at least one thread and 36.4% (n=163) received at least one team-initiated thread (Table 1). Most patients (n=323, 72.1%) engaged in at least one thread pertaining to diabetes-related content, 31.7% (n=142) of the sample engaged in at least one thread about blood pressure, 15.2% (n=68) engaged in at least one thread about cholesterol, 13.8% (n=62) engaged in at least one thread about mental health, 9.4% (n=42) about diet and nutrition, and 4.0% (n=18) about physical activity. Among patients who engaged in at least one thread related to diabetes content (n=323), 90.7% (n=293) engaged in at least one thread related to medication renewals or refills; 81.4% (n=263) discussed scheduling, referrals, or other administrative content; and 63.5% (n=205) discussed medication or equipment issues. Table 2 presents sample secure messages representing each content type as found within the first message in a patient-initiated thread.

Content contained in team-initiated threads was similar to that found in patient-initiated threads. Of the 163 patients that received a team-initiated thread, 74% (n=121) received at least one thread with content related to diabetes. This was followed by blood pressure (n=48, 29%), diet and nutrition (n=19, 12%), physical activity (n=12, 7%), mental health (n=24, 15%), and cholesterol (n=24, 15%). Among the 121 patients who received a team-initiated thread related to diabetes, 88% (n=107) received a thread about medication renewals of refills; 85% (n= 103) about scheduling, referrals, or consults; and 73% (n=88) about medication issues (Table 1). Table 3 presents sample secure messages of each content type as found within the first message in a team-initiated thread.

Table 1. Frequency of patients who engaged in at least one secure message thread by thread content (N=448).

Thread content	Patients who initiated a thread (n=448), n (%)	Patients who received a team-initiated thread (n=163), n (%)
General health topics		
Blood pressure	142 (31.7)	48 (29.4)
Cholesterol	68 (15.2)	14 (14.7)
Physical activity	18 (4.0)	12 (7.4)
Diet/nutrition	42 (9.4)	19 (11.7)
Mental health	62 (13.8)	24 (14.7)
Diabetes content		
Overall	323 (72.1)	121 (74.2)
Subtopics[a]		
Health issue	96 (29.7)	41 (33.8)
Medication renew or refill	293 (90.7)	107 (88.4)
Medication/equipment issue	205 (63.5)	88 (72.7)
Test issue	79 (24.5)	36 (29.8)
Test result	81 (25.1)	43 (35.5)
Self-reporting	67 (20.7)	34 (28.1)
Scheduling/referral/consult	263 (81.4)	103 (85.1)
Life issue	19 (5.9)	14 (11.6)
Technology	36 (11.1)	13 (10.7)
Complaint	41 (12.7)	12 (9.9)
Informational	264 (81.7)	26 (21.5)
Personal connection	5 (1.5)	3 (2.5)
Care coordination	42 (13.0)	14 (11.6)

[a]Percentages for diabetes-related subtopics are based on the n values for “overall” (ie, n=323 for patients who initiated a thread and n=121 for patients who received a team-initiated thread).

Table 2. Example patient-initiated secure messages representative of specific content.

Content	Representative secure message
Health topics	
Blood pressure	My blood pressure has been running about 170 over 90. Is that acceptable? Also am I supposed to come in every three months to have my blood drawn?
Cholesterol	Good Morning [name], when I was in to see you I forgot to tell you I needed a refill on my Simvastatin 20mg Qty 90 at [pharmacy]. Thank You
Physical activity	Our last appointment, we discussed the move program. I think I am interested after all. Please put my name in. Also my nifedipine has fallen off my list of refills. Could you refill it for me. Thanks
Diet/nutrition	I have a question about blood sugar. What can I do to keep my blood sugar from going low in the middle of my night or early morning? I end up eating more than I should and/or the wrong things.
Mental health	Tried the Buspirone but does not seem to work. Still using 1/2 tablet twice a day (most days) of the [Lorazepam]. Should we talk again? I will be over there first week of Dec.
Diabetes content	
Medication renew or refill	Dear Sir, I need new prescriptions for Fluoxetine, Lisinopril, and Novo fine disposable needles to go with the Solostar insulin pen. Thank you!
Informational	Made my oncology appointment in [VA[a] Site] and they referred me to Choice here in [VA CBOC[b] Site]. That has worked out great. Cancelled my diabetic appointment in [VA Site] and also requested Choice.
Scheduling/referral/consult	I have an appointment on [date]. If possible I would like to have some time with [team member] to talk about better Insulin management with my pump. Thank you
Medication/medical equipment issue	My Glucose test meter has stopped functioning. It no longer recognizes the blood sample. Changed the battery but it did no good. What do I need to do to replace it?
Health issue	Hi, I wanted to let you know that I did not go to my cardiac appt. yesterday as I woke up and it felt like the room was spinning.....I could not drive and had no ride to the VA....the dizziness continued all day into this morning.....it has tempered [sic.] off at this point, but my head still feels a little dizzy at times.....it is 19:30 at this time.....am feeling better; but wanted to make you aware...
Test result	Just saw my lab results. A_{1c} was 13.5 June to lowered to 10.4 August. Not scheduled to see DR until December. Still haven't gotten an appointment for Diabetic Eye exam. Please could I get a direct # to call and schedule in [VA site].
Test issue	…My blood sugar has really spiked over the last three days…My diet has not changed ie no great ingestion of sweets or heavy carbs…My thinking is that the glucose meter is on the fritz. If so can you order me one through the pharmacy? I have a few issues that I'd like to share with you when we meet. Thanks for your attention.
Self-reporting readings/measures	I am needing less insulin to maintain low sugars. (See Heath Buddy readings My last A_{1c} was 5.8). I haven't taken any Novolog in several months. I am taking 50 units in the morning of Lantus and 60 at night. How should I proceed with insulin? [Physician name] Kidney doctor has made several Med changes. Thank you.
Care coordination	I forgot to tell you that I had blood test run here in [State] at the [VA CBOC Site] for my diabetic Dr at [VA Site] he raised insulin to 100 units three times a day and started me on a new pill called saxagliptin HCL…I said I was willing to try anything to get sugar under control. See you when I get back. Thank you
Complaint	Recently I received 300 1/2 ml insulin needles. Who ordered these? Who is consistently making these errors? If I'm taking 300 units of U-500 insulin 3 times per day; isn't that .6 ml? And the needles are .5 ml. Why does this happen every time?
Technology	I need a referral to [physician name] as she is no longer in my secure messaging list. Thanks
Life issue	…I really need to see you by the end of the month because my DOT [Department of Transportation] medical card runs out on [date]. I was given only a 90 day temporary card because of glucose levels in my urine dip. If this isn't done I will lose my CDL [commercial driver's license] and will be up the creek…
Personal connection	N/A[c]

[a]VA: Department of Veterans Affairs.

[b]CBOC: community-based outpatient clinic.

[c]N/A: not applicable; no message within a patient-initiated thread fell under this code.

Table 3. Example team-initiated secure messages representative of specific content.

Topic	Representative secure message
Health topics	
Blood pressure	I am unable to assess your blood pressure control on the spironolactone as there are no recent BP reports to review from... I have an appointment available on [date and time options]. Could you come in on Weds. at one of those times so that we could assess your blood pressure appropriately? Thanks!
Cholesterol	The two medications from the cardiologist have been processed and are on the way to you. They are Metoprolol 100mg twice a day and Atorvastatin 40mg daily. Metoprolol 50mg was discontinued when the cardiologist wrote for the higher dose. Thanks
Physical activity	Good afternoon [patient name], I hope the weather in [state] is starting to warm up for you… Have you been able to get into the pool to start your exercise?...
Diet/nutrition	I got a recommendation back from [team member] in regards to your recent secure message. She says that she would be willing to send you to the Endocrine clinic [VA[a] site] for diabetes management if you would like…You always have the option of working with me but you would need to send in your blood sugar logs after every insulin change. More importantly though, you will need to find a way to eat more consistently so that insulin changes could be made. I could set you up with our Dietician if you would like help in meal planning.
Mental health	Scheduled you to see [physician name], psychiatrist here at [VA site] for [date and time] for hour visit. Please let us know if this does not work for you. appointment letter will be mailed. Take care.
Diabetes content	
Medication renew or refill	I put in an order for more Accu-chek glucose strips and a renewal for your glucose meter so you are able to check and track of your sugar levels. If you have any questions or concerns feel free to ask. Hope all is well.
Informational	N/A[b]
Scheduling/referral/consult	I know you and [team member] (our RN[c]) talked about diabetes case management but thought I would send a clarification. Your ophthalmologist did request diabetes case management through the "main" VA but that consult was discontinued because you are currently a patient here in [VA CBOC[d] site]. IF you would like to change providers (both primary care and thus a pharmacist case manager), then you would need to make an appointment with a provider at ["main" VA site] for a transfer of care and he/she will then place the consult for pharmacy diabetes management. You can call [phone number] and follow the prompts to make an appointment. Even if you choose to transfer your primary care/pharmacist providers to the "main" VA; you are still welcome to come here to [VA CBOC site] for lab draws; Vitamin B12 shots and Mental Health with [team member]. Those are still all available for you. Please let me know if I can be of any further help; either to facilitate transfer to another provider or to assist in diabetes management.
Medication/medical equipment issue	I am following up from our visit [date] when we increased your Lantus insulin dose to 68 units daily. What have your morning fasting blood sugars been running since this change? The goal range for fasting blood sugar is between 80 and 130. Let me know how I can assist you with improved diabetes control. Thank you
Health issue	Unfortunately, we have not been able to reach you by phone. Please be advised that if your blood sugar is over 500 that is a medical emergency and you have to seek care. If you do not have a ride to an ER [emergency room] you will need to call 911. Also consider that being dizzy could be a cardiac issue and also needs to be addressed as an emergency. I hope you did get treatment. Please follow up with us so we know you are ok and can provide the medical care that you require. Also if you are experiencing concerning symptoms call the clinic you will get an advice nurse quicker than sending a secure message.
Test result	[Team member] has reviewed your recent lab results: 1)Your a_{1c} resulted at 9.3%. This means that your blood sugar has been averaging 219 over the past 3 months. [Team member] strongly recommends that you keep the appointment on [date and time] with the Clinical Pharmacist. This appointment will focus on your diabetes. Please bring your blood sugar meter...
Test issue	I ordered an A_{1c} for you to get Jan but it is not done. Could you go to the lab on [date] and get it drawn? I appreciate the averages you sent earlier this month, but that does not give me enough information
Self-reporting	How have your blood sugars been running? Have you been able to get into the pool to start your exercise? If you have a moment would you be able to send me 1-2 weeks worth of blood sugar readings to see if we need to change the doses of your medication. Any issues or concerns we need to address?
Care coordination	Thank you for providing me with [physician name]'s contact information. As you already signed the release of information form, I will fax it on Monday and await for them to send me your records. I already placed a reminder in my system, if I have not received them within 7 business days, I will contact them directly by phone and have you give them a call as well.
Complaint	N/A
Technology	Hi [name]… Hope this works right with your email address!
Life issue	N/A

Topic	Representative secure message
Personal connection	Hi [name] I know about getting older and arthritis, dealing with that myself. To be able to do 7,000 steps is great. Just keep watching the calories and you will be fine. Take Care.

[a]VA: Department of Veterans Affairs.

[b]N/A: not applicable; no message within a team-initiated thread fell under this code.

[c]RN: registered nurse.

[d]CBOC: community-based outpatient clinic.

Association Between Content and Glycemic Control

From the initial 448 participants, 431 had at least one HbA_{1c} value in 2018. Of the 431, 44.6% (n=192) met our definition of good glycemic control and 55.5% (n=239) met our definition of poor glycemic control in 2018. A significantly larger proportion of patients with good glycemic control (n=72, 37.5%) engaged in at least one thread about blood pressure, compared to those with poor glycemic control (n=65, 27.2%; *P*=.02). Noting this significant difference, we further examined the content among blood pressure–related messages. Similar to the diabetes-related messages, we found that, among patients who engaged in at least one blood pressure–related message (n=142), most patients engaged in messaging related to medication renewals or refills (n=138, 97.2%); followed by scheduling, referrals, or other administrative content (n=108, 76.1%); and medication issues (n=86, 60.6%).

Among those who engaged in at least one thread related to diabetes content (n=312), 43.3% (n=135) were in good glycemic control and 56.7% (n=177) were in poor glycemic control. Significantly more patients in good glycemic control (32/135, 23.7%) engaged in at least one thread related to informing their clinical team about facts relevant to their health care compared to those in poor glycemic control (22/177, 12.4%; *P*=.009). There were no other significant differences related to the proportion of patients in good and poor glycemic control among other health topics of diabetes-related content codes (Table 4).

Among patients in good glycemic control (n=192), 39.9% (n=63) received at least one team-initiated thread. Among patients in poor glycemic control (n=239), 39.8% (n=95) received at least one team-initiated thread. However, this difference was not statistically significant (*P*=.14).

Table 4. Proportion of participants who engaged in at least one thread by glycemic control status.

Topic	Poor HbA_{1c}[a] control (n=239), n (%)	Good HbA_{1c} control (n=192), n (%)	*P* value
Health topics			
Blood pressure	65 (27.2)	72 (37.5)	.03
Cholesterol	35 (14.6)	32 (16.7)	.74
Mental health	33 (13.8)	25 (13.0)	.98
Diet/nutrition	24 (10.0)	17 (8.9)	.61
Physical activity	10 (4.2)	7 (3.6)	.85
Diabetes-related topics			
Overall	177 (74.1)	146 (69.9)	.32
Subtopics[b]			
Medication renew or refill	161 (91.0)	122 (90)	.86
Scheduling/referral/consult	148 (83.6)	105 (78)	.19
Medication/equipment issue	117 (66.1)	85 (63)	.57
Health issue	60 (33.9)	34 (25)	.10
Test result	47 (26.6)	33 (24)	.18
Test issue	48 (27.1)	30 (22)	.32
Self-reporting	37 (20.9)	27 (20)	.85
Complaint	23 (13.0)	17 (13)	.92
Technology	22 (12.4)	14 (10)	.57
Informational	22 (12.4)	32 (24)	.01
Care coordination	22 (12.4)	19 (14)	.18
Life issue	11 (6.2)	7 (5)	.15

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

[b]Percentages for diabetes-related subtopics are based on the n values for "overall" (ie, n=177 for patients with poor control and n=146 for patients with good control).

Discussion

Principal Findings

We used mixed methods to examine the content in a national sample of patient-team secure messages, and the relationship between content and glycemic control. Approximately one-third of the veterans in our sample received at least one secure message thread that was initiated by a member on their clinical team. The initiator on the clinical team was most frequently a registered nurse. We found that more than half of our sample used secure messaging to discuss diabetes-related content. Among those who used secure messaging to discuss diabetes-related content, more than half discussed medication renewals or refills, scheduling, and medication or equipment issues. The proportion of patients who discussed these topics was similar among patients who received at least one team-initiated secure message. This work is aligned with earlier content analyses [10]. Previous work, which was not specific to patients with diabetes, found that the most common messages are transactional (eg, requests for refills, appointment scheduling, administrative requests), followed by informational (eg, patients providing health measurements or updates on care) or interactional (eg, request for input on medical symptoms or medication issues) [10]. The content of the secure messages was similar in both patient- and team-initiated messages, although patients more frequently initiated a thread to seek a medication renewal, whereas team members most frequently initiated a thread to inquire about medication and medical equipment issues.

There were few differences in secure messaging content between participants in good and poor glycemic control. One exception was that compared with participants in poor glycemic control, significantly more participants in good glycemic control engaged in secure messaging related to blood pressure. There is a well-established risk inherent in the combination of poor glycemic control and uncontrolled hypertension in patients with type 2 diabetes [17]. As such, blood pressure control is also clinically recommended as an important target for diabetes management [18]. Post hoc analyses revealed that patients who engaged in secure messaging about blood pressure tended to discuss similar topics to those who engaged in secure messaging about diabetes-related content: medication renewals or refills, scheduling, and medication issues. It is possible that patients who were able to obtain good glycemic control are, in general,

more active in their disease self-management, and thus leveraging secure messaging to manage other important aspects of their health (ie, blood pressure).

Compared with those in poor glycemic control, significantly more patients in good glycemic control used secure messaging to provide their clinical team with information simply for the sake of keeping them informed about their health status or health care received elsewhere. This contrasts with earlier work, in which Heisey-Grove et al [11], counter to their hypothesis, reported that patients sharing information with clinical team members experienced an increase in HbA_{1c}. A plausible explanation as to why our findings differ may be that our definition of information sharing was more constrained. In their analyses, they combined three subtypes of information sharing—clinical updates, self-reporting, and responses to clinician messages—and were unable to detect a statistically significant association for any of the three subtypes with glycemic control. Additionally, these represent both proactive and reactive messages, whereas we focused on proactive messages from patients to inform their teams, which they called "clinical updates." Patients who engage in this type of proactive communication may be more activated patients, in the sense that they are engaged in managing their own condition and recognize the importance of care coordination. Heisey-Grove et al [11] did find that patients who initiated secure messaging threads experienced HbA_{1c} improvements compared to those who did not. Previous work has found that use of online patient portals and accompanying features such as secure messaging can increase measures related to patient activation [19] and subsequent self-management [5]. This is echoed in the eHealth Enhanced Chronic Care Model [20], which outlines the role that eHealth plays in supporting productive interactions between activated, informed patients and prepared, proactive clinical teams to support chronic disease outcomes. Patient and staff training is crucial to support portal use [21] and may in turn support patient activation and engagement in their care.

The current analysis expands on Heisey-Grove et al's [11,22] earlier work by examining the association between information sharing and glycemic control with a more complete selection of secure messages (ie, all of a patient's most recent secure messaging threads, not just those saved to the patient's chart). We analyzed all secure messages that the patient and team engaged in from the patients' most recent five secure messaging threads, whereas earlier work only examined secure messages that were selectively saved to the patients' charts [11]. Secure messages that the clinical team chose to save to patients' charts may be perceived to have greater clinical relevance, and therefore frequencies of message content and the associations between the content and clinical outcomes may also be biased. For example, at a site that saves only select messages, a team member may be more likely to save a secure message if the patient reported concerning HbA_{1c} levels and the team responded with recommendations for action. They may be less likely to do so if self-reported HbA_{1c} levels were not a cause for concern and no action or change is recommended. Thus, our study adds to the literature by presenting a less biased picture of how veterans living with diabetes and their clinical teams use secure messaging to support diabetes management.

The current analysis also expands on earlier work by examining both patient- and team-initiated secure messaging threads. Compared to a prior study examining the prevalence of team-initiated secure messaging threads in VA [10], we observed more team-initiated threads (10.8% of the threads) in this analysis of 2018 data than we did in 2013 (5.5%). This increase is promising given that clinical team–initiated secure messaging can significantly and positively influence diabetes self-management [5]. By including team-initiated messages, we enhance our understanding of patient-team communication for diabetes via secure messaging. Finally, another novel aspect of the current analysis is that we were able to leverage the United States' largest integrated health system, the Veterans Health Administration, and examine secure messages from across the nation. Examining the content of secure messages within one medical center may not capture the heterogeneous needs of patients with diabetes. For example, a rural patient with difficulty accessing in-person care may be more reliant on using secure messaging than a patient who lives closer to the medical center [23].

Limitations

The strengths of the current analysis include the number of secure messages coded, rigorous coding methods, and link to clinical outcomes in a national sample of US veterans with diabetes. There are also several limitations. For one, the sample is predominantly white male US veterans and thus we are limited in the generalizability of these findings. Additionally, we focus on a set of specified topics related to diabetes, although we did not include a specific code about self-management that may have likely led to a change in clinical team action (eg, medication titration) or patient action (eg, decrease a medication dose). Future work should analyze other content areas beyond topic, such as shared decision-making, to perhaps further understand how other content may influence diabetes management. Another avenue for future work would be to explore the impact of training on patient and clinical team use of secure messaging. For example, teaching both patients and clinical teams how to use secure messaging to support disease management may support the adoption and effectiveness of secure messaging for disease management [24].

Another important consideration of this work is that we analyzed the content of secure messaging among patients who were sustained users of secure messaging. As such, our findings may not be generalizable to patients who use secure messaging less frequently or not as recently. Another limitation is that this research examines cross-sectional associations between secure messaging and glycemic control and cannot confirm a causal pathway. For example, patients who share information via secure messaging may be more proactive in their disease self-management, which may lead to improvements in glycemic control. Conversely, patients who share information may be struggling more with controlling their HbA_{1c}, which may be associated with worse glycemic control. Future work that examines how secure messaging adoption, and subsequent content of the messages, influences glycemic control will further

our understanding of the directionality between content and clinical outcomes.

Conclusions

This is one of the first studies to perform a content analysis of secure messaging specific to diabetes, and to explore associations between message content and glycemic control. Focusing on a chronic condition where patients' self-management behaviors drive outcomes allowed for a nuanced exploration of the relationship between secure messaging and health outcomes. In addition to reducing bias in how messages were sampled (ie, coding all patient-team messages as opposed to a sample saved to the patient's chart), this work adds a complementary perspective to earlier content analyses [11] with supplementary qualitative examples of secure messages. We sought to understand whether secure message content was associated with good or poor glycemic control. It appears that, overall, the specific topic of the secure messaging may not be as clinically important for diabetes management. Rather, the act of engaging (compared to not engaging) in secure messaging may be most influential. Secure messaging makes it easier for patients to communicate with their clinical teams, and this may be the main driver of better clinical outcomes. Clinical teams should be encouraged to communicate, both responsively and proactively, with their patients through secure messaging to support their diabetes management.

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Data Availability

The US Department of Veterans Affairs (VA) prohibits unauthorized sharing of data. The data used for this study are not permitted to be shared outside the VA firewall without a Data Use Agreement. This limitation is consistent with other studies based on VA data; however, VA data are available to researchers behind the VA firewall with an approved VA study protocol. For more information, please visit the VA Information Resource Center (VIReC) website [25] or contact the VIReC at VIReC@va.gov.

Conflicts of Interest

None declared.

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Abbreviations

HbA_{1c}: hemoglobin A_{1c}
VA: Department of Veterans Affairs

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Original Paper

Perspectives on Promoting Physical Activity Using eHealth in Primary Care by Health Care Professionals and Individuals With Prediabetes and Type 2 Diabetes: Qualitative Study

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Abstract

Background: The trend of an exponential increase in prediabetes and type 2 diabetes (T2D) is projected to continue rising worldwide. Physical activity could help prevent T2D and the progression and complications of the disease. Therefore, we need to create opportunities for individuals to acquire the necessary knowledge and skills to self-manage their chronic condition through physical activity. eHealth is a potential resource that could facilitate self-management and thus improve population health. However, there is limited research on users' perception of eHealth in promoting physical activity in primary care settings.

Objective: This study aims to explore the perspectives of health care professionals and individuals with prediabetes and T2D on eHealth to promote physical activity in primary care.

Methods: A qualitative approach was applied using focus group discussions among individuals with prediabetes or T2D (14 participants in four groups) and health care professionals (10 participants in two groups). The discussions were audio-recorded and transcribed verbatim. Qualitative content analysis was used inductively to code the data.

Results: Three main categories emerged: utility, adoption process, and accountability. The utility of eHealth was described as a motivational, entertaining, and stimulating tool. Registration of daily medical measurements and lifestyle parameters in a cohesive digital platform was recognized as a potential resource for strengthening self-management skills. The adoption process includes eHealth to increase the accessibility of care and personalize the support of physical activity. However, participants stated that digital technology might only suit some and could increase health care providers' administrative burden. Accountability refers to the knowledge and skills to optimize eHealth and ensure data integrity and security.

Conclusions: People with prediabetes and T2D and health care professionals positively viewed an integration of eHealth technology in primary care to promote physical activity. A cohesive platform using personal metrics, goal-setting, and social support to promote physical activity was suggested. This study identified eHealth illiteracy, inequality, privacy, confidentiality, and an increased workload on health care professionals as factors of concern when integrating eHealth into primary care. Continuous development of eHealth competence was reported as necessary to optimize the implementation of eHealth technology in primary care.

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KEYWORDS

eHealth; focus groups; health care professionals; physical activity; prediabetes; primary care; qualitative research; self-management; type 2 diabetes

Introduction

The prevalence of prediabetes and type 2 diabetes (T2D) is steadily increasing worldwide [1]. Prediabetes is an intermediate stage between normal glycemia and diabetes [2] and a risk factor for progression to T2D and cardiovascular diseases [3]. Previous randomized controlled studies, including diabetes prevention programs, have shown that lifestyle therapy prevents or delays T2D and improves cardiometabolic markers [4]. T2D is a highly heterogeneous disease and includes people with different clinical characteristics, disease progression, drug response, and risk of long-term complications [5] (ie, macrovascular and microvascular complications [6]). These long-term complications imply that persons with T2D must adhere to a lifelong healthy lifestyle and access to medical care management [7]. An evidence-based sustainable effort is crucial at the individual and health care system levels to prevent or delay these complications [8].

Emphasis should be given to primary care as it is considered an ideal setting for supporting lifestyle changes [9]. A well-designed self-management support system is needed to enable patients to deal with this lifelong challenging disease [10]. Developing person-centered diabetes self-management skills and obtaining the support needed to facilitate knowledge and decision-making skills are necessary for diabetes management [11]. However, the current health care infrastructure faces challenges due to the sustained shortage of health care professionals (HCPs) and a significant increase in the prevalence of T2D [12].

Physical activity is recommended as a critical self-management activity in individuals with T2D [13]. The positive impact of physical activity on glycemic control, insulin sensitivity, and other diabetes-related health complications is evident [14]. Yet, providing support for physical activity that matches the current health status and physical capabilities of people with T2D is challenging [15]. Studies have shown that physical activity among adults with T2D is generally low [16-18]. Thus, promoting physical activity in persons with T2D is necessary to improve their quality of life [19].

eHealth is a potential resource in the health care system for facilitating self-management support, such as continuously recording the health status with countermeasure responses, allowing self-monitoring options, and providing information that helps patients to make informed decisions related to their chronic condition [20,21]. According to the World Health Organization, eHealth is about using digital tools and sharing information digitally to achieve and maintain a high level of health [22]. Technology (ie, hardware, devices, and software) should be customized based on the patient's needs, desires, skill level, and availability of devices [23]. The use of eHealth and mobile health interventions is a cost-effective approach that reaches many individuals with a high level of engagement in the short-term [24,25]. eHealth interventions also have had a considerable impact on physical activity and healthy eating. However, eHealth interventions have not shown a long-term effect and have not been applied to large-scale implementations [26]. The implementation of eHealth might depend on consumers' satisfaction with using communication platforms efficiently and sustainably with their health care providers [27].

eHealth has been applied as a self-management tool option in current health care practice. It is also used to create an effective communication channel between patients and HCPs in diabetes disease control [28,29]. There is an inefficiency in promoting physical activity by the HCPs during their encounters with their patients in primary care [30,31]. Therefore, there is a clear need to identify strategies to integrate eHealth tools to promote physical activity in primary care settings. A review focusing on physical activity counseling to patients in primary health care has shown the potential of using eHealth tools and highlights the importance of identifying facilitators of and barriers to the usability of eHealth tools in the setting [32]. Previous researchers have noted a high rate of attrition in eHealth interventions. Explanations to the problem of the high dropout rate are required to find solutions [33,34]. Few studies have investigated the perspective of individuals living with chronic diseases on the use of eHealth and its integration with person-centered care [35-37].

Therefore, this study aimed to explore the perspectives of HCPs and individuals with prediabetes and T2D on eHealth to promote physical activity in primary care, which may provide insight into how eHealth can be optimized to promote physical activity.

Methods

Research Design

An exploratory descriptive qualitative study design was applied. The data were collected using semistructured focus group discussions to explore the participants' experiences and perceptions [38]. COREQ (Consolidated Criteria for Reporting Qualitative Research) was used to notify the critical aspects of the research method (Multimedia Appendix 1).

Recruitment and Participants

Two groups of participants with different positions regarding their contact with the primary care center, care providers (HCPs), and patients were eligible. A total of 53 individuals were asked to participate in the study.

HCPs were eligible if they were working in primary care. The recruitment locations were six primary care centers in Stockholm (an urban area) and two in villages in the south of Sweden (a rural area). Convenience sampling was used to recruit the participants who were willingly available. A total of 18 HCPs were approached by author JR face to face or by telephone in January 2019. They were all willing to participate in the study, but 8 participants canceled due to a lack of time and scheduling conflicts. A total of 10 female HCPs took part in the focus group

discussion; 2 of them were physicians, and 8 were diabetes specialist nurses.

The second group consisted of patients with prediabetes and T2D. This group was eligible if registered as patients in primary care centers and diagnosed with prediabetes or T2D. A total of 34 individuals were approached face to face by authors JR and LÅ, and were willing to participate in the study. This group was divided further into the Sophia Step Study (SSS) group and the non-SSS group. Participants from the SSS were recruited using a purposeful sampling method to identify individuals with specific eHealth experiences. They had previously participated in a 2-year intervention program using pedometers and a website to register their daily steps [39]. A total of 14 patients were included in the study, 2 of whom were diagnosed with prediabetes, and 9 patients participated in the SSS intervention. Most of the participants' cancelations were due to a lack of time and personal issues.

Data Collection

The data were collected in February-April 2019. JR and LÅ conducted a total of six semistructured focus group discussions. Two focus group discussions with the HCPs, with 5 participants in each group, and four group discussions with SSS and non-SSS participants. The focus group discussions with patients had 2 to 6 participants per session. The focus group discussions were held in Swedish and lasted from 55 to 82 minutes. All the focus group discussions were conducted in rooms with a group discussion–friendly environment at the primary care centers. Interviews were audio-recorded, and field notes were made during the discussions.

Participants filled out a brief questionnaire asking for demographics and experiences on the use of eHealth at the beginning of each group session. At the start of the group discussion, JR introduced the purpose of the study and the procedural activities during the session. Information was also given about recording focus group discussions using a digital recorder and that observational notes would be taken to capture the context of the discussions by LÅ. The focus group discussions were based on semistructured interview guides (Multimedia Appendix 2). Open-ended questions were used to explore patients' and HCPs' perspectives regarding eHealth technology to promote the physical activity of patients with diabetes in a primary care context.

Data Analysis

Audio recordings were transcribed verbatim by a professional transcriber. The transcripts were analyzed using inductive content analysis [40]. A procedure consisting of five phases was developed before the study began to enhance the trustworthiness and credibility of the data analysis. In the first phase, authors U-BJ and YW independently checked for the accuracy of the transcribed text against the audio-recorded files. In the second phase, U-BJ, JR, and YW read and repeatedly listened to the transcribed material to better understand the content and identify meaning units. The meaning units were condensed in the third phase without losing the original meaning. After that, the research group (JR, U-BJ, and YW) discussed the differences in the selected meaning units and reached a consensus. In the fourth phase, the research group, including author SA, started extracting the meaning units and assigning codes. The researchers thoroughly discussed the meaning units to identify differences and similarities of the codes. Lastly, the codes were examined for relations, sub-merged from meaning units, and grouped under potential subcategories. These subcategories were grouped into categories and appropriately named after reaching a consensus. Quotes were selected to represent the variations of the participant groups. Finally, a professional translator translated the results and quotations from Swedish to English.

Descriptive statistics were calculated and summarized for demographic characteristics using SPSS version 27.0 for Windows (IBM Corp). Data are presented as mean (SD) or number (percentage) as appropriate. The qualitative data were organized and analyzed manually; no software application was used.

Ethics Approval

The study was approved by the Regional Ethical Review Authority in Stockholm (2018/28-31/2). All invited participants gave informed written consent to participate in the study, and it was performed according to the Helsinki Declaration [41].

Results

Participants

The mean age of the 14 patients was 69 (SD 9.5) years, 71% (n=10) were males, and 86% (n=12) had T2D. More than half of the patients used different eHealth technologies privately, such as smartphones, computers, blood glucose meters, and activity bracelets. In connection with the health care system, patients used smartphones and blood glucose meters at higher percentages than other tools (Tables 1 and 2). The HCPs were all female and had a mean age of 49 (SD 12.3) years. All HCPs had experience with eHealth technologies (computers, blood glucose meters, pedometers, web-based guides) in the workplace in connection with patients at primary care centers (Table 3).

The analysis from the focus group discussions revealed three main categories and nine subcategories representing the different perspectives on eHealth to promote physical activity (Textbox 1).

Table 1. Characteristics of individuals with prediabetes or type 2 diabetes (n=14).

	Patients
Age (years), mean (SD)	69 (9.5)
Men, n (%)	10 (71)
Type 2 diabetes, n (%)	12 (86)
University education, n (%)	7 (50)
Retired, n (%)	11 (79)
Participants of Sophia Step Study, n (%)	9 (64)
Participants from Stockholm, n (%)	9 (64)

Table 2. Use of eHealth of individuals with prediabetes or type 2 diabetes (n=14).

Use of eHealth (yes)	Privately, n (%)	In contact with health care, n (%)
Smartphone	12 (86)	12 (86)
Computer	9 (64)	6 (43)
Tablet	5 (36)	2 (14)
Blood glucose meter	10 (71)	8 (57)
Pedometers	8 (57)	2 (14)
Exercise app	4 (29)	3 (21)
Activity bracelet	13 (93)	0 (0)

Table 3. Characteristics of health care professionals (n=10).

	Health care professional participants
Age (years), mean (SD)	49 (12.3)
Women, n (%)	10 (100)
Participants from Stockholm	6 (60)
Profession, n (%)	
Nurse	8 (80)
Physician	2 (20)
Specialization, n (%)	
Diabetes nurse	4 (40)
District nurse	4 (40)
Specialized physician	2 (20)
Use of eHealth in the workplace (yes), n (%)	
Smartphone	4 (40)
Computer	8 (80)
Tablet	0 (0)
Blood glucose meter	9 (90)
Pedometer	5 (50)
Exercise app	3 (30)
Activity bracelet	1 (10)

Textbox 1. Categories and subcategories on the promotion of physical activity.

Utility

- Motivating means
- Cohesive platform
- Social support

Adoption process

- Transition to personalization
- Not suitable for everyone
- Adaptation

Accountability

- Digital skills support
- Confidentiality
- Liability

Utility

Utility refers to the usefulness of eHealth as a motivational and multifunctional tool, and as a facilitator of social interactions.

Motivating Means

eHealth products and tools were described as motivational, entertaining, and stimulating as a support for physical activity. Participants used eHealth technologies through websites as information sources offered by health care authorities (eg, to acquire information about their illness and tips and advice on lifestyle modification). They also mentioned eHealth technologies that assess personal metrics including daily physical activity and blood sugar levels as well as by adding features on goal setting. The ability to compare results with yourself and against others was considered fun and uplifting.

> *But sometimes you go down and sometimes up [registration of steps on a website] and there was such an intoxication, a real joy. This week I'm the best. Next week may not be as good.* [SSS patient, urban area]

> *Here, if you set reasonable goals, they can achieve and come up with something positive instead of working randomly.* [HCP, urban area]

Cohesive Platform

Participants described the possibilities of improving the self-management of physical activity from primary care with the help of digital technology. Combining services (eg, daily clinical measurements and lifestyle parameters in a cohesive platform) was seen as an opportunity by patients and HCPs. According to the participants, this would simplify reviewing and examining the characteristics of different metrics. Such a multifunctional platform was suggested as a guide to determine how behavior and health outcomes are interrelated. They also considered it a functional tool in supporting patients to be physically active if, for example, educational games, rewards, and reminders could be built into the platform.

> *I would like to see a common portal or app in which pedometers are located, where you combine a pedometer with blood sugar measurements during the day.* [non-SSS patient, urban area]

HCPs also reported that technology could be used as an educational tool to improve their practice in supporting the self-management of physical activity. Tracking patients through a cohesive platform could help evaluate patients' self-management and provide rewards and encouragement. In addition, HCPs believed that one could better prepare for visits if the patient's metrics were made available to the HCP in advance or if the health care system could use a web-based form linked to the medical record. The patients could also see an opportunity to participate in the care process by evaluating their activity level and development with HCPs to receive feedback by sharing their data in advance. The patients stated that this might increase the participation of patients in disease management.

> *That during the meeting you do an evaluation. I think that health care providers find out how far you have walked and how much you usually walk. It is important that the health care providers evaluate how the patient uses these aids (e-health tools) and if so, what do they show.* [SSS patient, rural area]

Social Support

The participants were optimistic about using a digital communication platform for groups living with T2D. Patients stated that sharing experiences among individuals with the same disease could create mutual encouragement and support. It was also suggested that meeting new people with a common interest could add value through group activities (eg, real-time chat and competition-integrated features).

> *It's always fun to meet new people with novel ways of thinking.…it's more about common interests. It's not about the physical part; rather, it's about having a common interest.* [SSS patient, urban area]

Patients suggested that creating a functional digital group might be challenging for security reasons, especially if HCPs could not have accountability in facilitating the platform to avoid potential harassment and keep track of what is said. The HCPs doubted that they would have time to take the role of a moderator who facilitated and guided the groups. However, they indicated that patients should conduct and moderate the group discussions.

> *There are patient associations where we are not involved or do not have any responsibility, so that it could be an online patient group. But then they have to appoint someone in charge of what is being said.* [HCP, urban area]

> *I think you should perhaps get user details and passwords via your diabetes nurse so you can log in there.* [SSS patient, urban area]

Adoption Process

The adoption process refers to the challenges of ensuring individualization, creating equal opportunity, and finding the right balance in the use of eHealth.

Transition to Personalization

The participants reflected on the idea that implementing new eHealth tools in primary care may facilitate increasing the accessibility and personalizing the support of the physical activity. Whereas the HCPs mentioned that care might be flexible and easily accessible using digital tools and services, eHealth designs should be tailored to individual needs and preferences.

> *I think that in the future, the focus will be on how to develop the care provision, and you [as a clinic] put in what you want so that it can be personalized to the person at hand.* [HCP, urban area]

HCPs also mentioned that work routines with personalized approaches using eHealth tools can be challenging if more technical skills are also necessary. It can also lead to many administrative and time-consuming tasks overseeing vast amounts of data and increasing patient contact.

> *But, of course, it will hopefully give an objective image of how the patient moves. However, there can be a lot more contacts, and more administrative work if you get data that come in that you don't want to handle...* [HCP, rural area]

Not Suitable for Everyone

HCPs and patients emphasized that technology and eHealth are not suitable for everyone because of language difficulties, costs, and different technological habits between age groups. Consequently, the participants expressed concern about increasing the risk of inadvertently creating unequal care in the community.

> *...equal care for everyone, but it will not be so when you use apps and mobile phones. Some groups will disappear, partly because of language challenges and partly because of age , or because they don't own a mobile.* [HCP, urban area]

> *But then it's a little different how people get used to this. Older people, such as you and me, can have difficulties when it comes to technology* [non-SSS patient, rural area]

Participants expressed that it can be challenging for some to use eHealth technology if they have not used it earlier and must rely on the help of others. Some patients preferred using traditional paper forms or a diary for their metrics.

> *I completely agree that it must not replace the physical meetings, but it can be an accompaniment, and then it can be an advantage.* [HCP, urban area]

Adaptation

Personal motivation was considered a crucial factor in using eHealth, and it was vital to find the right balance in its use. The HCPs highlighted that there could be an inconvenient situation if some patients do not want or are not motivated to use digital tools to increase physical activity. It could be challenging to manage if the individual becomes stressed either by excessive interactions or an unexpected malfunctioning of the technology. One drawback of introducing eHealth could be that some patients may agree to use digital tools only to please the HCPs.

> *I think, above all, the technical aids are very good to have, but if you don't have the right attitude to take care of yourself, it doesn't matter how many technical aids you have.* [non-SSS patient, urban area]

> *So, it can only be a stressor...Then maybe some fill in [register the daily steps] just to make us happy and satisfied.* [HCP, urban area]

HCPs were concerned that using eHealth technology could increase screen time, adversely affecting the daily level of physical activity. It could also increase patients' dependency on HCPs rather than enhanced self-management behavior.

> *...you can constantly measure and send messages to your doctor or diabetes nurse, or some people could become more dependent on advice and support in the app and thus end up taking less responsibility for their care...* [HCP, rural area]

Accountability

Accountability refers to authority agencies being responsible for digital skills development and integrity and security concerns.

Digital Skills Support

Participants stressed that the rate of technological development is high, which could require continuous technical skills development for participants. New eHealth services or digital tools might be particularly challenging for older adults unless the designs and features are adapted to this age group. Accordingly, the participants stated that eHealth products and services should be clear and straightforward. The participants pointed out the need for knowledge and skills to optimize eHealth. In addition, they noted the need for informative and well-designed instructions for digital tools (tutorials).

> *...If it concerns e-health, it should be easily accessible and that you get knowledge about how it works, that is, education.* [non-SSS patient, rural area]

Confidentiality

The participants specifically highlighted that the integrity and security of physical activity and health data must be ensured while using eHealth services and digital tools. The patients expressed the importance of data transfer and exchange among HCPs. However, they underscored the need for a secure and safe platform for accessing personal data among HCPs and other providers.

> *...then there are privacy rules and things like that as well, but maybe it [personal data] should be available to only doctors and a few others.* [SSS-patient, urban area]

Liability

Participants agreed on the importance of a credible source of information about physical activity. They stated that the sources need to be credible and scientific and provide adequate knowledge. They felt that the companies in charge of developing eHealth technology should be accountable for building trust and harmony. They also addressed the importance of critically analyzing new workflow procedures and conducting assessments to use health care resources effectively. It was proposed that eHealth and health care authorities take the overall responsibility for new eHealth services and digital tools.

> *Yes, but it generally feels like the entrepreneurs are responsible for the development...the e-health authorities would have been fantastic, if it is they who pick up...and follow the development.* [HCPs, urban area]

Discussion

Principal Findings

This study focuses on exploring the perspectives of HCPs and patients on promoting physical activity using eHealth technology in primary care. The findings of the focus group discussions revealed three main categories: utility, adoption process, and accountability.

The category utility was built on the subcategories motivating means, cohesive platform, and social support. The participants described how eHealth technologies with a cohesive platform design could be a source of motivation and social networking for patients. In general, participants showed positive perspectives on the opportunities and usefulness of eHealth technologies to promote physical activity in primary care. Similarly, a recent review found that consumers see opportunities to use eHealth to promote physical activity and healthy dietary behaviors. However, the study elicited that several points need to be considered to optimize eHealth tools [42], which includes considering a logical and practical approach rather than pure theoretical principles [32].

The shared perspectives of participants in this study were that eHealth technologies have the potential to support assessing personal metrics and stimulating users to reflect upon them. These strategies may boost people's motivation to change their level of physical activity and maintain it for the long-term. Similarly, a study exploring patients' perspectives on a digital lifestyle intervention showed the importance of working on the possibility of tracking the changes, setting goals, and having tailored information to enhance the motivation and acceptability of digital health intervention support [43]. Thus, eHealth technology was seen as a motivational means of developing a personal action plan and assessing the level of achievement toward one's goal.

Moreover, participants felt that eHealth technologies could facilitate the opportunities to have a cohesive platform for combined services to understand the relationship between behavioral changes and the body's physiological responses. Whelan et al [44] explored the level of engagement in individuals with prediabetes using real-time feedback on their physical activity and glucose level. The authors showed that the participant's level of engagement increased and changed their physical activity level due to real-time feedback and recognizing the link between behavior and the act on the body. As demonstrated in this study, identifying the physiological responses of being physically active might help in understanding how the body functions and stimulate the patients' level of engagement.

In this study, having a digital communication platform for the patients to interact with their peer group was seen positively. The participants stated that the platform could create an opportunity to share experiences and deal with psychosocial problems. A cross-sectional study showed that the diabetes online community benefited from peer health experiences as a complementary resource for diabetes self-management information to enhance health literacy [45]. However, participants in our study were concerned about the potential hazards (eg, misinformation) and risk of intimidation in eHealth communication platforms (social media, blogs, discussion boards, etc).

The HCPs and patients expressed conflicting views as to who should host these social platforms. The patients believed that, to ensure efficient use, HCPs should serve as the moderator. In contrast, HCPs felt patients should take on the role of the moderator. A previous study noted that the type of social support might influence the level of engagement in eHealth in persons with diabetes [46]. The study showed that both professional and nonprofessional (friends, peers, families) social support positively impacted a person's use of eHealth technology. However, the study also showed that patients' private networks either facilitated or hindered the use of mobile technology for self-management [46]. The explanation might be that the level of engagement may depend on the level of supportive or unsupportive behavior among nonprofessionals. Therefore, Petroviki and Zivkovic [47] emphasized the importance of evaluating patients' readiness and capability to handle information on social media by the HCPs to minimize the risk of misinformation and confidentiality and privacy concerns.

The second category, adoption process, was divided into three subcategories (transition to personalization, not suitable for

everyone, and adaptation). eHealth technology was believed to promote person-centered care by facilitating the partnership between the patient and HCPs. A qualitative study exploring the views of different stakeholders found that the integration of person-centered care with eHealth services in primary care settings strengthens the partnership between caregivers and patients [48]. However, the HCPs in our study were concerned about the imbalance between the increased accessibility and a personalized approach and managing managerial and time-consuming tasks. A similar concern was discussed in a study about the significance of examining nurses' workload in the integration process of eHealth services in primary health care [49].

In this study, participants raised some issues concerning the suitability of eHealth for everyone. HCPs were also concerned that patients might increase their dependency on HCPs and might not always be motivated to use eHealth technologies for disease management. Conversely, they felt that some patients might overly engage in eHealth technology and raised the possibility that the eHealth implementation process might require modification regarding health care workflow. Samarasinghe and Miras [50] considered the versatility and popularity of digital platforms in diabetes prevention interventions; however, emphasis should be given to widening opportunities at the population level with good quality and at low cost without ignoring face-to-face interaction. Moreover, a study assessing diabetes management using remote monitoring technology stressed the importance of identifying determinants that activate and engage patients in their care [51].

Our findings showed that adapting eHealth technology could increase the risk of disregarding certain groups of people (eg, those who do not use eHealth technology because of language difficulties or cost, or who have a low level of technological skills). In addition, our participants suggested that if digital inequalities could not be resolved, traditional care in combination with eHealth services should be anticipated. A review confirmed our finding that digital inequalities might occur among specific patient groups. However, the demand for an improved and advanced application to improve digital equality in eHealth services might be compelling [52]. Determinants of telemedicine use among different subgroups were, for example, being young, having a high educational level, having a higher income, and being born in Sweden. Therefore, particular consideration for people with low use of eHealth should be a priority in policy-making [53].

The accountability category included three subcategories: digital skills support, confidentiality, and liability. This category highlights the need for continuous development in the use of eHealth technology in terms of digital skills support and enhanced confidentiality. Participants were concerned about their ability to optimize technical skills on eHealth technologies for promoting physical activity. They expressed a need for clear and straightforward eHealth products and services customized for diverse groups. It was noted that the ever-changing technological progress might need a rigorous technical design and require an introduction and educational program for users. Several studies have confirmed that continuous training and proper support of eHealth services in primary care create a simplified workflow and optimal interaction between caregivers and patients [48,49,54]. In addition, eHealth services might be attainable if the integration process can accommodate staff, patient flow, and the health care data system [55].

The participants mentioned uneasiness about the integrity and confidentiality of the storage and exchange of personal data on physical activity and health. They stated that the responsibility of securing the integrity and confidentiality of the collected data should be given to eHealth and health care governmental authorities. A recent review addressed eHealth system security and privacy concerns. The review showed that the current solutions have been promising but are still inadequate because of the complexity of health systems in advanced health care services [56]. Therefore, HCPs and patients need to possess knowledge and skills to safely exchange data and secure the integration with other eHealth systems.

The focus group interviews of this study were done before the outbreak of the COVID-19 pandemic. This period might have impacted the participants' perspectives as the consumption of digital health in primary care settings likely increased during and after the pandemic. On the contrary, a review summarizing the role of eHealth, telemedicine, or telehealth in delivering health care services during the COVID-19 pandemic showed that there was still inconsistency in the evidence on the provision of eHealth services to patients with chronic conditions [57].

Methodological Discussion

One strength of our study was the heterogeneity of the participants. The sample includes both genders, people with prediabetes or T2D, varied experiences of using activity trackers, people from different geographical locations (urban and rural), and HCPs from several primary care contexts. Such diversity ensures a broader perspective when exploring the needs and preferences of eHealth to promote physical activity. A researcher (JR) led each focus group and engaged in the data-collecting process to maintain a higher level of consistency and avoid discrepancies. The focus group discussions of HCPs and patients were done independently. This approach created an environment for both groups to express their views freely and without reservation since the notion of power imbalance was minimized.

The trustworthiness of this study was enhanced throughout the analysis process according to Graneheim and Lundman [58]. Two researchers (U-BJ, YW) checked and rechecked the data before and during the analysis stage to confirm the data analysis outcome. It is also a strength that the two researchers were not involved in the facilitating role of the focus group, thus avoiding bias concerning the interpretation of emerging data. The process of condensation, coding, and agreeing on the categorization was made in close collaboration within the research group, which assured the credibility of the findings [58]. For instance, the researchers had different preunderstandings due to different professional backgrounds and research experiences that helped avoid unconsciously creating biases. Four of the authors (U-BJ, JR, SA, and YW) read the complete transcribed material, enabling a full picture of the content.

A limitation of the study was the use of a convenient sampling method to recruit HCP participants. Therefore, this study did

not include the broader target group's perspective and experiences, and caution needs to be taken with the generalizability of the study results. Another limitation of this study is that the group discussions were done before the outbreak of the COVID-19 pandemic, and participants might have changed perspectives on the use of eHealth after the pandemic. One of the focus group sessions included only 2 participants, which could be considered a weakness. However, the session developed into an 82-minute conversation between 2 persons, adding rich data. These issues might affect the transferability of the findings to other diabetes populations and groups of HCPs.

Conclusions

People with prediabetes and T2D and HCPs positively viewed an integration of eHealth technology in primary care to promote physical activity. A cohesive platform using personal metrics, goal setting, and social support to promote physical activity was suggested. This study identified eHealth illiteracy, inequality, privacy, confidentiality, and an increased workload on HCPs as factors of concern when integrating eHealth into primary care. Continuous development of eHealth competence was reported as necessary to optimize the implementation of eHealth technology in primary care.

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Authors' Contributions

JR, LÅ, and U-BJ, contributed to the conception and design of the study. JR and LÅ conducted the focus group discussions and collected the data. JR, SA, U-BJ, and YW contributed to the data analysis and interpretation of data. YW drafted the manuscript, and all authors revised it critically for important intellectual content. All authors approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
COREQ (Consolidated Criteria for Reporting Qualitative Research).
[PDF File (Adobe PDF File), 481 KB - diabetes_v8i1e39474_app1.pdf]

Multimedia Appendix 2
Interview guide.
[DOCX File , 19 KB - diabetes_v8i1e39474_app2.docx]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
HCP: health care professional
SSS: Sophia Step Study
T2D: type 2 diabetes

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Original Paper

Disparities in Insulin Pump Use Among Spanish-Speaking Children With Type 1 Diabetes Compared to Their Non-Hispanic White Peers: Mixed Methods Study

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Abstract

Background: Disparities in Insulin Pump Use Among Spanish-Speaking Children With Type 1 Diabetes Compared to Their Non-Hispanic White Peers: Mixed Methods Study

Objective: We aimed to investigate the use of insulin pumps and continuous glucose monitoring (CGM) devices among Spanish-language–preferring children in our clinic population and to identify specific barriers to technology use.

Methods: First, we assessed rates and patterns of diabetes technology use (eg, insulin pumps and CGM devices) in a sample of 76 children (38 Spanish-language preferring and 38 non-Hispanic White). We compared rates of technology use, average length of time between diabetes diagnosis and initiation of insulin pump or CGM device, and rates of discontinuation of these devices between the Spanish-language–preferring and non-Hispanic White children. Second, to understand specific barriers to technology use, we compared responses to a questionnaire assessing decision-making about insulin pumps.

Results: Spanish-language–preferring patients had lower rates of insulin pump use, even after controlling for age, gender, age at diagnosis, and type of health insurance. Spanish-language–preferring participants were more likely to report concerns over learning to use an insulin pump and were more likely to discontinue using an insulin pump after starting one.

Conclusions: These data confirm demographic disparities in insulin pump use among children with T1D and provide new insights about insulin pump discontinuation among Spanish-language–preferring children. Our findings suggest a need for improved patient education about insulin pump technology in general and improved support for Spanish-language–preferring families with T1D after initiation of pump therapy.

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KEYWORDS

disparities; type 1 diabetes; Spanish-speaking; insulin pump; children; diabetes; diabetes mellitus; insulin; glucose monitoring

Introduction

In children with type 1 diabetes (T1D), insulin pumps and continuous glucose monitoring (CGM) devices can improve glycemic control, decrease rates of severe hypoglycemia and diabetic ketoacidosis, and reduce risk of microvascular complications [1,2]. Prior work has reported racial disparities in both diabetes outcomes and rates of technology use among Hispanic children compared to non-Hispanic White children [3-8]. Further, differences in attitudes about diabetes technology

between ethnic groups have also been identified [9]. The specific effects of a language barrier on diabetes technology uptake are not fully understood, and we hypothesized that children from Hispanic families with a language barrier (ie, those whose families identify Spanish as their primary language) would be less likely than their White counterparts to use diabetes technologies and might have differing barriers to technology use. Our study was thus designed to determine rates and patterns of insulin pump and CGM device use among Spanish-language–preferring Hispanic children with T1D receiving care at an academic medical center and to further identify specific barriers to technology use in these children. A recent study [9] has shown differences in technology use between Spanish-speaking and English-speaking Latinx families, with significant differences found in technology use and attitudes about diabetes technology between the 2 language groups. Our study, therefore, builds upon what is currently known about differences in care outcomes among children with T1D by examining specific experiences and potential barriers to diabetes technology use among Spanish-language–preferring patients with T1D compared to their White peers.

Methods

Ethics Approval

Study approval was provided by the UC Davis Institutional Review Board (assessing rates and patterns: 1458281-2; assessing barriers: 1460830-1), and consent requirements were waived for this portion of the study.

Procedure

First, to assess differences in rates and patterns of diabetes technology use, we evaluated medical records for 76 children (38 Spanish-language preferring and 38 non-Hispanic White) with T1D who received their routine diabetes care at our academic children's hospital. Spanish-language–preferring children were eligible for medical record review if they were aged 0-18 years, had a prior diagnosis of T1D, had received care in our diabetes clinic in the prior 12 months, and identified Spanish as their family's primary language (indicated by demographic data in their electronic health records and verified by study personnel). Children were excluded if they lived with a household member also diagnosed with T1D (n=1) and had a severe allergy to adhesive material (n=0) or if there were significant learning disabilities in the child or either parent (n=1), due to the likelihood of these factors influencing diabetes technology uptake. All of the Spanish-language–preferring children seen in our practice who met the inclusion and exclusion criteria were included in the study. The same inclusion and exclusion criteria were used for the non-Hispanic White participants, except for primary language (which was required to be English). From among the pool of eligible non-Hispanic White patients, participants were selected via random matching to the Spanish-language–preferring participants based on current age and diabetes duration using a computer algorithm. Families were not compensated for participation in this portion of the study, which only involved medical record review.

From each participant's electronic health record, we recorded the date of T1D diagnosis, age at diabetes diagnosis, diabetes duration, gender, ethnicity, and type of health insurance (public vs private). Data on technology use were collected, including if the child had ever used an insulin pump or CGM device, if the child was currently using an insulin pump or CGM device, and the dates the insulin pump or CGM device were used. Participant selection and data abstraction were both performed in 2019.

We then compared the rates of technology use (eg, insulin pump and CGM device), the average length of time between diabetes diagnosis and initiation of technology use, and the rates of device discontinuation between the Spanish-language–preferring and non-Hispanic White groups. We initially compared data for Spanish-language–preferring participants to the data of non-Hispanic White participants using 2-tailed student *t* test for continuous variables and chi-square test for categorical variables. We then used logistic regression analyses to determine whether differences in technology use persisted after adjusting for the effects of other covariates, such as sex and type of health insurance.

Second, to better understand specific barriers to technology use, all Spanish-language–preferring participants and their families identified from the previous cohort were asked to complete a written questionnaire detailing their decision-making surrounding technology use. The questionnaire contained items pertaining to both pump and CGM use; however, as Spanish language preference was not predictive of CGM use in the first portion of the study, we did not conduct further analyses on survey responses related to CGM use. Questions and response options included in the questionnaire can be accessed in Table S1 in Multimedia Appendix 1. Translation of the questionnaire from English to Spanish was provided by the institution's interpreting and translation services department. Participants for this portion of the study were enrolled by the study personnel during outpatient diabetes visits over a 6-month period in 2019-2020. For this portion of the study, participants received a US $20 gift card as compensation.

To gather comparable perspectives about insulin pump nonuse by non-Hispanic White patients, we identified a cohort of non-Hispanic White patients who met our initial inclusion criteria but were not using insulin pumps. These participants were again matched to our Spanish-language–preferring cohort based on age and diabetes duration. Non-Hispanic White control participants were enrolled at the time of a regularly scheduled clinic visit, similar to our Spanish-language–preferring participants, and completed the same written questionnaire about diabetes technology decision-making during the same study period. All non-Hispanic White control participants completed the questionnaire in English. The non-Hispanic White survey group was selected for pump nonuse (to capture an adequate sample of pump nonusers from among an ethnic cohort with a majority using the pump); therefore, the non-Hispanic White sample was larger than the Spanish-language–preferring sample for this part of the analysis. We did not select for insulin pump never-use to allow for analysis of rates of pump discontinuation. Questionnaire responses in the Spanish-language–preferring and non-Hispanic White groups were compared using Fisher exact test.

Results

Participant Selection

A total of 43 children with T1D aged 0-18 years with Hispanic ethnicity and Spanish-language preference, who were listed in the electronic medical record, were initially identified and had their primary language confirmed by the study personnel. Of these, 2 failed to meet all inclusion criteria, and 3 lacked information in their medical records necessary for accurate data retrieval. Thus, 38 Spanish-language–preferring children were included for analyses assessing rates of technology use. In addition, 583 non-Hispanic White children were identified as potential controls, and 38 of them were matched to the Spanish-language–preferring participants via an Microsoft Excel-based computerized formula using date of birth and date of diabetes diagnosis.

Rates of Technology Use

Demographic characteristics of the study groups are shown in Table 1.

In univariate analyses, Spanish-language–preferring participants were less likely to use both insulin pumps (13/38, 34% vs 24/38, 63%; *P*=.01) and CGM devices (19/38, 50% vs 30/38, 79%; *P*=.01). Among families using pumps, the Spanish-language–preferring participants started use at approximately the same time after diagnosis as the non-Hispanic White participants (26.6 months vs 25.7 months; *P*=.91). CGM device use began later in Spanish-language–preferring participants (42.3 months vs 24.4 months; *P*=.07), but the difference was just short of statistical significance. Of note, there were significantly more patients with public insurance in the Spanish-language–preferring group than in the non-Hispanic White group (35/38, 92% vs 13/38, 34%). Overall, those with public insurance were significantly less likely to use a CGM device (*P*=.01), but there was no difference in insulin pump use by health insurance type (*P*=.11).

In multivariable analyses, ethnicity or language group and diabetes duration continued to be significant predictors of insulin pump use, after adjusting for age, gender, age at diagnosis, and type of insurance (Table 2).

Table 1. Demographic and clinical characteristics of the study participants (N=76)

Characteristics	Spanish-language preferring (n=38)	Non-Hispanic White (n=38)	*P* value for comparison of the groups
Age (years), mean (SD)	11.9 (3.3)	11.8 (3.4)	N/A[a]
Age at diagnosis (years), mean (SD)	7.1 (3.9)	7.1 (3.9)	N/A
Diabetes duration (years), mean (SD)	4.8 (3.8)	4.7 (3.8)	N/A
Sex (male), n (%)	12 (32)	19 (50)	.10
Public insurance, n (%)	35 (92)	13 (34)	<.01
Current pump use, n (%)	13 (34)	24 (63)	.01
Current CGM[b] device use, n (%)	19 (50)	30 (79)	.01

[a]N/A: not applicable.

[b]CGM: continuous glucose monitoring.

Table 2. Predictors of diabetes technology use (multivariable analyses).

Variable	Coefficient (95% CI)	*P* value
Insulin pump use		
Spanish-language preference	–1.38 (–2.62 to –0.13)	.03
Male sex	–0.03 (–1.11 to 1.05)	.96
Public insurance	0.06 (–1.27 to 1.39)	.93
Diabetes duration	0.02 (0.004 to 0.03)	.01
Age	–0.06 (–0.21 to 0.09)	.45
CGM[a] device use		
Spanish-language preference	–0.95 (–2.22 to 0.32)	.14
Male sex	–0.54 (–1.68 to 0.59)	.35
Public insurance	–0.91 (–2.38 to –0.57)	.23
Diabetes duration	–0.01 (–0.02 to 0.004)	.20
Age	–0.05 (–0.22 to 0.13)	.61

[a]CGM: continuous glucose monitoring.

In regard to CGM device use, ethnicity was no longer predictive of device use after adjusting for age, gender, age at diagnosis, and type of insurance. Analyses of barriers to technology use therefore focused on participants who were not using insulin pumps, and we did not conduct further analyses pertaining to CGM use.

Barriers to Technology Use

Of the 38 Spanish-language–preferring families identified through medical record review, 30 were seen in clinic during the 6-month study period and completed the questionnaire assessing barriers to technology use. These 30 participants were then matched to a group of 30 non-Hispanic White pump nonusers based on age and diabetes duration (Table 3).

Of the Spanish-language–preferring participants, 19 were current pump nonusers, and 13 had never previously used an insulin pump. To avoid having prior pump users reporting on decision-making about pump use, only the participants who had never used a pump were included in these analyses. Although the non-Hispanic White control participants were selected based on current insulin pump nonuse (not insulin pump never-use), none had ever previously used a pump.

In response to questions regarding pump use, Spanish-language–preferring patients were far more likely to report previously using an insulin pump but discontinuing it due to dislike of the technology (6/19, 32% vs 0/30, 0%; *P*=.002; Table 4). There were not differences seen between the 2 groups with regard to primary reason(s) for pump nonuse, such as lack of perceived need or fear of error (Table 5).

In questions assessing familiarity with pumps among insulin pump never-users, no difference was seen between the Spanish-speaking (n=13) and non-Hispanic White (n=30) groups in terms of having ever seen someone use an insulin pump (7/13, 54% vs 25/30, 83%; *P*=.06) or in whether they had discussed pump use with health care providers (11/13, 85% vs 29/30, 97%; *P*=.21).

In the question assessing impressions and major concerns about pump use, Spanish-language–preferring participants were less likely to report confidence in learning to use the device (median questionnaire score 3 vs 5; *P*=.001) and more likely to cite concern over cost (median questionnaire score 4 vs 2; *P*=.05) compared to non-Hispanic White participants.

Table 3. Characteristics of pump nonusers reporting on technology barriers.

	Spanish-language preferring (n=19)[a]	Non-Hispanic White (n=30)	*P* value for comparison of the groups
Age (years), mean (SD)	12.9 (2.7)	12.9 (4.1)	.98
Age at diagnosis (years), mean (SD)	8.8 (3.9)	8.8 (3.9)	.98
Diabetes duration (years), mean (SD)	4.1 (3.4)	4.1 (3.3)	.97
Current CGM[b] device use, n (%)	9 (47)	19 (63)	.27

[a]n=19 due to inclusion of pump nonusers only.

[b]CGM: continuous glucose monitoring.

Table 4. Pump discontinuation rates among insulin pump nonusers.

Rates of pump discontinuation	Spanish-language preferring (n=19)	Non-Hispanic White (n=30)	*P* value for comparison of the groups
History of prior pump use (cited “previously tried/didn’t like” on survey), n (%)	6 (32)	0 (0)	.002

Table 5. Reasons cited for insulin pump nonuse among insulin pump never-users.

Reason	Spanish-language preferring (n=13[a]), n (%)	Non-Hispanic White (n=30), n (%)	*P* value for comparison of the groups
No perceived need	4 (30)	11 (37)	>.99
Difficult to understand	4 (30)	6 (20)	.46
Does not want something attached	5 (39)	15 (50)	.53
Cost	1 (8)	1 (3)	.52
Fear of error	2 (15)	10 (33)	.29
Did not qualify for use	1 (8)	1 (3)	.52

[a]n=13 due to inclusion of participants who had never used an insulin pump. Totals do not equal 100% as study participants could select all answers that applied.

Discussion

Principal Findings

Recent literature has highlighted racial and ethnic disparities in both glycemic outcomes and diabetes technology use among children with T1D [3-10]. Common barriers to pump therapy adoption in pediatric patients include concerns about having a device attached to the body, therapeutic effectiveness compared to insulin injection regimens, and cost burden [11-13]. Additional barriers faced by historically marginalized racial and ethnic groups can include difficulties with access to care, provider bias, and socioeconomic disparities [14-16]. The specific effect of a language barrier on diabetes technology use is uncertain in the existing pediatric literature, and preliminary data [9] suggest technology use and attitudes may vary among Spanish-speaking versus English-speaking Hispanic patients and families. Our study was designed to explore specific experiences and potential barriers to diabetes technology use among Spanish-language–preferring patients with T1D.

Our results are consistent with the existing literature in that we found lower rates of insulin pump use in Spanish-language–preferring children compared to non-Hispanic White controls. This finding held true even after adjusting for age, sex, diabetes duration, and type of insurance. However, we did not find that ethnicity was a significant predictor of CGM device use after adjustment for health insurance type, which was strongly associated with CGM device use in our study population. Differences in access to CGM device based on health insurance may therefore have obscured differences related to ethnicity within our cohort. Of note, our clinic protocol for CGM initiation was relatively straightforward compared to the protocol for insulin pump initiation at the time of this study. For pump initiation, our patients were required to attend a pre–pump use class (during which they learned about insulin pump therapy and various device options) and complete a pre–pump use checklist, which included a skills assessment on various aspects of diabetes management. For CGM initiation, our patients indicated interest to their diabetes provider and received basic information on the device from a registered nurse/certified diabetes care and education specialist. It is possible that the process for pump initiation presented additional barriers to our Spanish-language–preferring patients and that this contributed to the differences seen between pump and CGM use in our clinic.

In other settings, provider bias has been widely identified as a contributing factor to racial and ethnic disparities in health outcomes [17,18]. In our study, reported frequencies of discussion about diabetes technologies with care providers were similar between our Spanish-speaking and non-Hispanic White groups, suggesting that bias in clinician's decisions about introducing diabetes technology may not have played a major role in the differences we observed. However, our questionnaire did not assess the content of these clinician discussions, which may have influenced whether Spanish-language–preferring participants felt adequately educated and encouraged about technology use. The fact that our Spanish-language–preferring families felt less confident that they could learn to use a pump suggests that additional education from their health care teams may be needed to prepare them for successful technology use.

In sum, our findings suggest that further work is needed to better understand how to best support diabetes technology use among the Spanish-language–preferring community. Improved Spanish language teaching materials and in-person Spanish instructions are likely needed as well as increased contact with peer groups using diabetes technology, to reduce the observed disparities in insulin pump use between Spanish-language–preferring patients and their non-Hispanic White peers. In addition, our novel finding that Spanish-language–preferring children are more likely to discontinue insulin pump use after starting it highlights the need for improved support after initiation of pump therapy. Shared medical appointments that include group education have been associated with increased technology adoption among Spanish-language–preferring children and adolescents [19], but additional studies are needed to determine how to best maintain insulin pump and CGM device use in these patients and families.

Strengths and Limitations

A strength of our study was the relatively high study completion rates for eligible participants, minimizing issues with sampling bias. However, the study also has several limitations. First, the study sample was small due to the single center analysis, and generalizability is limited by possible variations in clinical practice and patterns of insurance coverage. In addition, we did not collect information on socioeconomic status beyond insurance type, and this could be an important variable to consider in future studies, as Spanish-speaking populations may vary culturally and socioeconomically between locations. A larger sample size or alternate study format (eg, focus groups) might allow for additional analyses not conducted in our sample, such as a detailed investigation of reasons why children discontinued insulin pump use. A larger sample size would also be necessary to compare decision-making among Hispanic Spanish-language–preferring families versus Hispanic English-language–preferring families [9].

Additionally, it is possible that our questionnaire failed to capture some barriers to technology use in this patient population. We employed an experienced multidisciplinary diabetes team (including members with Spanish-language fluency and extensive experience working with the Spanish-speaking population) to collaborate in questionnaire design, but the questionnaire was not previously studied or validated for this clinical question and target population, so this remains a limitation. Finally, the study was conducted before the COVID-19 pandemic, and diabetes technology use has changed in several ways since the data were collected. In particular, CGM device use has increased substantially in our patient population due to expanded insurance coverage, particularly among those with public insurance. In addition, several new integrated pump-CGM systems providing automated insulin delivery have been released since our study concluded, and questions of access, use, and comfort with these new systems among Spanish-language–preferring children is an important area for future inquiry.

Conclusions

This study confirms that Spanish-language preference is associated with lower rates of insulin pump use in children with T1D, even after controlling for age, gender, age at diagnosis, and type of insurance. In addition, our analysis suggests that Spanish-language–preferring families experience higher rates of insulin pump discontinuation than their English-speaking non-Hispanic White counterparts. This finding has not previously been reported in the pediatric T1D literature. Finally, our study demonstrates that Spanish-language–preferring families are more likely than non-Hispanic White controls to report concerns over learning to use insulin pumps, highlighting the need for improved Spanish-language instructions about insulin pumps and increased support for Spanish-language–preferring families after pump technology has been adopted.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Questions and response options included in the questionnaire.
[DOCX File , 17 KB - diabetes_v8i1e45890_app1.docx]

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Abbreviations

CGM: continuous glucose monitoring
T1D: type 1 diabetes

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Review

Technology-Supported Integrated Care Innovations to Support Diabetes and Mental Health Care: Scoping Review

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Abstract

Background: For individuals living with diabetes and its psychosocial comorbidities (eg, depression, anxiety, and distress), there remains limited access to interprofessional, integrated care that includes mental health support, education, and follow-up. Health technology, broadly defined as the application of organized knowledge or skill as software, devices, and systems to solve health problems and improve quality of life, is emerging as a means of addressing these gaps. There is thus a need to understand how such technologies are being used to support, educate, and help individuals living with co-occurring diabetes and mental health distress or disorder.

Objective: The purpose of this scoping review was to (1) describe the literature on technology-enabled integrated interventions for diabetes and mental health; (2) apply frameworks from the Mental Health Commission of Canada and World Health Organization to elucidate the components, type, processes, and users of technology-enabled integrated interventions for diabetes and mental health; and (3) map the level of integration of interventions for diabetes and mental health.

Methods: We searched 6 databases from inception to February 2022 for English-language, peer-reviewed studies of any design or type that used technology to actively support both diabetes and any mental health distress or disorder in succession or concurrently among people with diabetes (type 1 diabetes, type 2 diabetes, and gestational diabetes). Reviewers screened citations and extracted data including study characteristics and details about the technology and integration used.

Results: We included 24 studies described in 38 publications. These studies were conducted in a range of settings and sites of care including both web-based and in-person settings. Studies were mostly website-based (n=13) and used technology for wellness and prevention (n=16) and intervention and treatment (n=15). The primary users of these technologies were clients and health

care providers. All the included intervention studies (n=20) used technology for clinical integration, but only 7 studies also used the technology for professional integration.

Conclusions: The findings of this scoping review suggest that there is a growing body of literature on integrated care for diabetes and mental health enabled by technology. However, gaps still exist with how to best equip health care professionals with the knowledge and skills to offer integrated care. Future research is needed to continue to explore the purpose, level, and breadth of technology-enabled integration to facilitate an approach to overcome or address care fragmentation for diabetes and mental health and to understand how health technology can further drive the scale-up of innovative integrated interventions.

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KEYWORDS

technology; mental health; type 2 diabetes; type 1 diabetes; virtual care; integrated care; scoping review; health information technology; digital health; support; psychosocial; education; application; distress; clinical integration; intervention

Introduction

Background

Every 1 in 10 globally and over 5 million Canadians are living with diagnosed diabetes today, including type 1 diabetes (T1D), type 2 diabetes (T2D), and gestational diabetes (GD); this number is steadily increasing worldwide [1]. Living with diabetes carries a heavy psychological burden [2] due to the constant need to adhere to regimented medication, diet, and exercise routines coupled with fear of diabetes complications, so much so that it has been said that diabetes is "one of the most psychologically demanding" chronic medical diseases [3]. Among individuals living with diabetes, the risk for developing mental illnesses such as depression and anxiety is greater than the general public [4]. Further, diabetes distress, defined as the negative emotions, despondency, and strain related to the burden of self-management, is increasingly prevalent [4-6]. The complexity of co-occurring mental and physical health challenges has contributed to increased calls for the integration of psychological care, such as cognitive behavioral therapy, into the care and management of diabetes [7-9]. However, despite this need, there remains limited access to interprofessional, integrated care that includes psychological support, education, and follow-up for individuals living with diabetes and associated comorbidities (eg, depression, anxiety, and distress).

Integrated care represents a solution to the fragmentation of care [10], such as the historically siloed physical and mental health care systems. Integrated care can take many forms, including the type of integration (eg, professional, clinical, or organizational), the level of integration (eg, macro-, meso-, or micro-), the breadth of integration (eg, a specific disease or a broader population group), and the intensity of integration (eg, informal linkages to aid in navigation or fully integrated whole systems) [10,11]. Although the literature examining integrated care as a concept continues to be developed and refined, there is a need to extend the use of the term to ultimately promote health and well-being and to support the development of enhanced skill and collaboration among health care providers. This includes understanding the ways that integrated care may address the adverse impacts of clinical complexity on individuals, their care experiences, and care outcomes, such as those found among individuals living with diabetes and mental health distress or disorder.

Emerging as a potential solution to this gap in clinical practice is the use of health technology as a means of offering person-centered, integrated diabetes and mental health care. Health technology is broadly defined as software, devices, and systems intended for the prevention, promotion, or rehabilitation of health, including those that assist, cure, or support [12]. These technologies are broad and include those categorized as eHealth or mobile health, wearable devices, and digital health. Although there is great variability in these technologies and how they are described, it is understood that these technologies should enable the processing and exchange of health information between end users such as patients and their care team using the internet [12]. Aligned with a rapid shift to remote care delivery in recent years, there is a need to understand how health technologies are being used to support, educate, and help manage individuals living with co-occurring diabetes and mental health distress or disorder.

Study Objectives

The purpose of this scoping review was to (1) describe the literature on technology-enabled integrated interventions for diabetes and mental health; (2) apply frameworks from the Mental Health Commission of Canada and World Health Organization to elucidate the components, types, processes, and users of technology-enabled integrated interventions for diabetes and mental health; and (3) map the level of integration of these interventions for diabetes and mental health.

Methods

Study Design

This scoping review was guided by the methodologies of Arksey and O'Malley [13], Munn et al [14], and Pollock et al [15] and adheres to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) extension for scoping reviews [16].

Search Strategy

The search terms, databases, and strategy were developed in consultation with a research librarian at McMaster University (Multimedia Appendix 1). We searched MEDLINE, Embase, Emcare, PsycINFO, Cochrane Database of Systematic Reviews, and Cochrane Central Register of Controlled Trials from inception to February 16, 2022. We manually searched reference lists of relevant reviews and included studies for citations that

were not captured in our search. Duplicates were removed and citations were uploaded to a secure web-based platform for screening (DistillerSR; Evidence Partners Inc).

Inclusion and Exclusion Criteria

Eligible studies of any design or type had to be published in English in a peer-reviewed journal and meet the following criteria: (1) report data on anyone with diabetes including T1D, T2D, and GD and (2) use technology (broadly defined, including the following: remote care, telephone, apps, SMS text messages, computer-based, or other e-technologies) to actively support both diabetes and any mental health distress or disorder in succession or concurrently. There were no criteria for the diagnosis of diabetes; however, studies with general adult populations or mixed populations, which provided subgroup analyses for participants with diabetes, were also considered for inclusion. We predefined that studies without subgroup analyses, but which had a mixed population, must have at least 80% of participants with our targeted condition to be included in our review. Participants did not need to have a mental health disorder at baseline for the study to be included provided the study aimed to address mental health concerns beyond merely as an outcome measurement. Outcomes were not used for inclusion or exclusion of studies. Studies were excluded if they (1) focused on either mental health or diabetes alone; (2) did not have explicit aims or components of the study that addressed both mental health and diabetes; (3) reported on data on those at-risk for, but not yet diagnosed with, diabetes; (4) were of diabetes-specific technology such as continuous blood glucose monitoring; and (5) were letters, commentaries, editorials, conference abstracts, or doctoral theses.

Data Extraction and Charting

A team of researchers conducted the screening and data extraction (MR, MJ, PA, DS, DF-L, CW). A minimum of 2 reviewers were required to screen titles and abstracts of all potentially eligible studies independently and in duplicate. Articles marked for inclusion by either team member went on to full-text screening, which was completed independently and in duplicate by 2 team members and required consensus for inclusion or exclusion. After confirmation of the included studies, we looked for related publications that met our search dates and inclusion criteria and grouped publications that were based on the same study and intervention. We developed forms that were housed in a web-based systematic review software program. All authors provided feedback and approved the components of these forms. For each primary study, 1 team member extracted study characteristics (including the aim of the study, sample size, methods, population demographics, delivery person, study outcome types and time points, study length, location, and setting) and details about the technology following categories suggested by the Mental Health Commission of Canada: "Mental Health, Technology, and You" [17]; the Valentijn 2015 framework [18] in combination with its adapted version by Kaehne and Nies [19]; and the World Health Organization's "Classification of Digital Health Interventions v1.0" [20]. Related or secondary publications were used to add details to the extracted data. Two team members independently verified all extracted data, and disagreements were resolved through discussion or third-party consultation. Conflicts were resolved by the lead researcher of this review (MR).

Data Extraction Frameworks

Three frameworks were applied to organize and structure review findings specific to the purpose of technology in the intervention, the targeted primary users of the technology, and the level of integration that the technology advanced.

The Mental Health Commission of Canada's "Mental Health, Technology, and You"

For each study, the purpose of using technologies was mapped against the definitions provided by the Mental Health Commission of Canada "Mental Health, Technology, and You" document [17]. This document contains 8 possible purposes of technology (wellness and prevention, coaching, peer-led support, intervention and treatment, web-based self-help, monitoring, crisis support, and recovery); we added a further two on the basis of the project team feedback (improve access to health care and digital literacy).

The World Health Organization's "Classification of Digital Health Interventions v1.0"

Digital health intervention classifications were gathered using the World Health Organization's "Classification of Digital Health Interventions v1.0" [20]. It provides groupings based on the targeted primary user. These groupings are as follows: (1) interventions for clients, (2) interventions for health care providers, (3) interventions for health system or resource managers, and (4) interventions for data services. Each grouping has subcomponents.

Valentijn 2015 Rainbow Model of Integrated Care

To describe the level of integration, we followed the Valentijn 2015 framework [18] in combination with its adapted version by Kaehne and Nies [19]. This framework introduces a taxonomy of integrated care, including 6 levels: clinical integration, professional integration, organizational integration, system integration, functional integration, and normative integration. For the purposes of this review, only clinical (ie, coordinating person-centered care across time, place, and discipline), professional (ie, interprofessional partnerships to deliver a continuum of care), organizational (ie, interorganizational relationships to deliver comprehensive services), and system integration (ie, coherent sets of rules and policies to facilitate both horizontal and vertical system integration) were explored.

Ethical Considerations

As this study was solely literature based and did not involve any research participants or subjects, no formal ethics approval from the McMaster Research Ethics Board was required.

Results

Study Selection

Our search yielded 4827 citations after duplicates were removed (see Figure 1). We assessed 69 full-text citations for eligibility

and excluded 45 of these studies mostly because they were not aimed to support both diabetes and mental health (either concurrently or in succession). The remaining 24 primary studies [21-44] described in 38 publications [45-58] were included in a qualitative synthesis for this scoping review (Figure 1). The included studies were mostly randomized controlled trials or controlled clinical trials (n=14; Tables 1-3). Other study designs included one-group pre-post studies (n=5) [23,31,32,41,44], systematic or literature reviews (n=3) [22,34,40], mixed methods (n=1) [33], and focus groups (n=1) [21].

Figure 1. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram. *Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers). **If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

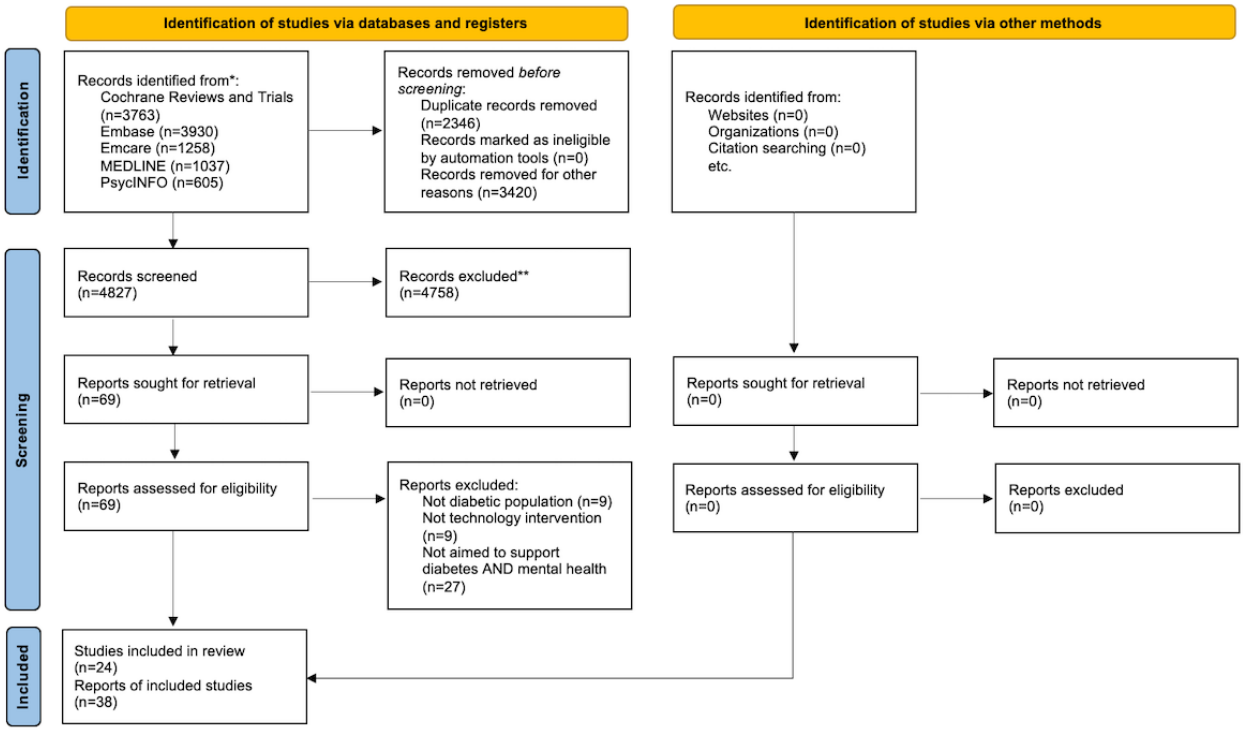


Table 1. Characteristics of included studies by a methodological approach: quantitative studies.

Author, year (ref)[a]	Study design	Sample size, n	Diabetes type	Focus of study	Length of study	Delivery person(s)	Site of care[b]	Outcomes measured[c]
Alessi et al [25], 2021	RCT[d]	91	T2D[e]	Mental health	16 weeks	Case manager	Clinic	Patient reported
Bakhach et al [28], 2019	CCT[f]	81	T1D[g]	Combined diabetes and mental health	12 months	Medical doctor or nurse practitioner	Clinic	Patient reported
Bendig et al [24], 2021	RCT	42	T1D and T2D	Combined diabetes and mental health	8 weeks	Psychologist	Primary care	Patient reported, process
Bond et al [37], 2010	RCT	62	N/R[h]	Combined diabetes and mental health	6 months	Nurse, social worker, or a PhD psychologist	Web-based	Patient reported
Clarke et al [41], 2016	One group pre-post design	91	T1D and T2D	Mental health	7 weeks	N/A[i] (self-guided)	Web-based	Patient reported
Clarke et al [27,47,48], 2019	RCT	780	T2D	Mental health	8 weeks	N/A (self-guided)	Web-based	Patient reported, health, process, other (health service use, days out of role)
Cohn et al [43], 2014	RCT	53	T2D	Mental health	5 weeks	N/A (self-guided)	Diabetes clinic	Patient reported, Process
Crawford et al [39], 2019	RCT	88	T1D and T2D	Mental health	3 days	N/A	Web-based	Patient reported, process, other (health care use)
DuBois et al [32], 2016	One group pre-post design	15	T2D	Mental health	12 weeks	Study trainer	Hospital and clinic	Patient reported, process
Magee et al [23], 2021	One group pre-post design	18	T2D	Combined diabetes and mental health	12 weeks	Social worker	Hospital	Patient reported, health, process
Mochari-Greenberger et al [31], 2016	One group pre-post design	466	T1D and T2D	Mental health	8 weeks	Social worker and behavioral coach	Web-based	Patient reported, health
Murray et al [29], 2017	RCT	374	T2D	Combined diabetes and mental health	12 months	Nurse facilitated but self-guided	Clinic	Patient reported, health, process
Naik et al [44], 2012	One group pre-post design	8	T2D	Mental health	12 weeks	Clinical psychologist, a developmental psychology postdoctoral fellow, doctoral student, and psychology student	Telephone	Patient reported, health
Naik et al [26,45,46], 2019	RCT	225	N/R	Combined diabetes and mental health	12 months	Psychologists, nurses, pharmacists, and social workers	MEDVAC clinic and telephone	Patient reported, health, other (health care use)
Newby et al [38,55], 2017	RCT	91	T1D and T2D	Mental health	10 weeks	N/A (self-guided)	Web-based	Patient reported, process
Nobis et al [30,49-51], 2015	RCT	260	T1D and T2D	Combined diabetes and mental health	8 weeks	Coaches	Web-based	Patient reported, health, process, other (cost)

Author, year (ref)[a]	Study design	Sample size, n	Diabetes type	Focus of study	Length of study	Delivery person(s)	Site of care[b]	Outcomes measured[c]
Orman et al [33], 2016	Pre-post mixed method	35	T1D and T2D	Mental health	4 weeks	N/A (self-guided)	Web-based	Patient reported, health, process
Piette et al [35,52], 2011	RCT	291	T2D	Combined diabetes and mental health	12 months	Registered nurse	Telephone	Patient reported, health
van Bastelaar et al [36,53,54], 2011	RCT	255	T1D and T2D	Mental health	N/R	Certified health psychologists	Web-based	Patient reported, health
Wu et al [42,56-58], 2018	CCT	1406	T2D	Mental health	12 months	Nurse care managers, nurse practitioners, physician, and social worker	Clinic	Patient reported, health, process, other (cost)

[a]References for primary papers and any related publications.

[b]Site of care for any intervention components beyond the technology.

[c]Outcome types: “process” includes study feasibility and adherence; “patient reported” includes quality of life, distress, anxiety, depression, and knowledge; “health” includes glucose measures, body composition, and cardiometabolic outcomes; and “other” is as described in the table including cost, provider experience, and health service use.

[d]RCT: randomized controlled trial.

[e]T2D: type 2 diabetes.

[f]CCT: controlled clinical trial.

[g]T1D: type 1 diabetes.

[h]N/R: not reported.

[i]N/A: not applicable.

Table 2. Characteristics of included studies by a methodological approach: qualitative studies.

Author, year (ref)[a]	Study design	Sample size, n	Diabetes type	Focus of study	Length of study	Delivery person(s)	Site of care[b]	Outcomes measured
Boggiss et al [21], 2021	Qualitative focus groups	16	T1D[c]	Mental health	3 months	Health psychology PhD candidate and registered health psychologist	Web-based	N/A[d]

[a]References for primary papers and any related publications.

[b]Site of care for any intervention components beyond the technology.

[c]T1D: type 1 diabetes.

[d]N/A: not applicable.

Table 3. Characteristics of included studies by a methodological approach: reviews.

Author, year (ref)[a]	Study design	Number of studies	Diabetes type	Aim of review	Inclusion criteria	Exclusion criteria	Main finding	Outcomes measured[b]
Franco et al [40], 2018	Review	5	T1D[c] and T2D[d]	Describe web-based interventions for depression in individuals with diabetes and to discuss these studies' procedures and findings in light of evidence from a wider range of interventions for depression and diabetes	Inclusion: published in English or Spanish in a peer-reviewed journal between 1990 and 2017, participants (18 years or older) with a primary diagnosis of diabetes and comorbid depression, program content multimedia; provision of web-based activities; and a guided or unguided self-help approach, target depression symptomatology with the specific intent of producing emotional, behavioral, and cognitive change, studies with repeated measure designs	—[e]	4 studies found a significant reduction in depression scores and diabetes distress in the intervention condition compared with control	Patient reported, health
van der Feltz-Cornelis [34], 2013	Literature Review	N/R[f]	N/R	What treatments of comorbid depression in diabetes mellitus can positively impact diabetes disease control, and what evidence for this view has emerged since 2010, with a focus on psychotherapeutic and pharmacotherapeutic versus eHealth or mHealth[g] interventions?	N/R	N/R	Face-to-face treatment appears to remain the treatment mode of choice, be it psychotherapy or pharmacotherapy. CBT[h], as well as pharmacotherapy, is effective in terms of depression outcomes. Results of eHealth and mHealth show that the improvement of glycemic control was small, both in patients with diabetes with and without depression. Interventions specifically aimed at improving glycemic control by eHealth or mHealth only show limited results	Patient reported, health
Yap et al [22], 2021	Systematic review and meta-analysis	20	T2D	Synthesized the best available evidence concerning the effectiveness of TBPIs[i] on diabetes distress, self-efficacy, HRQoL[j], and HbA_{1c}[k] level among adults with T2D	At least 18 years old and with the diagnosis of T2D; tested TBPIs (such as motivational interviewing, behavioral therapy, and CBT); compared TBPIs with usual care, enhanced usual care, waiting list, and attentional control groups; measured at least one of these outcomes: DD[l], self-efficacy, HRQoL or HbA_{1c} levels with validated measuring tools; used randomized controlled trials that were reported in English from 2010 to 2020; interventions delivered by health care providers and comprised more than 50% in-person sessions	Studies with self-help groups, peer-delivered interventions or general education	All outcomes except HRQoL were statistically significant with a small effect size	Patient reported, health

[a]References for primary papers and any related publications.

[b]Outcome types: "patient reported" includes quality of life, distress, anxiety, depression, and knowledge; and "health" includes glucose measures, body

composition, and cardiometabolic outcomes.

[c]T1D: type 1 diabetes.

[d]T2D: type 2 diabetes.

[e]Not available.

[f]N/R: not reported.

[g]mHealth: mobile health.

[h]CBT: cognitive behavioral therapy.

[i]TBPI: technology-based psychosocial intervention.

[j]HRQol: health-related quality of life.

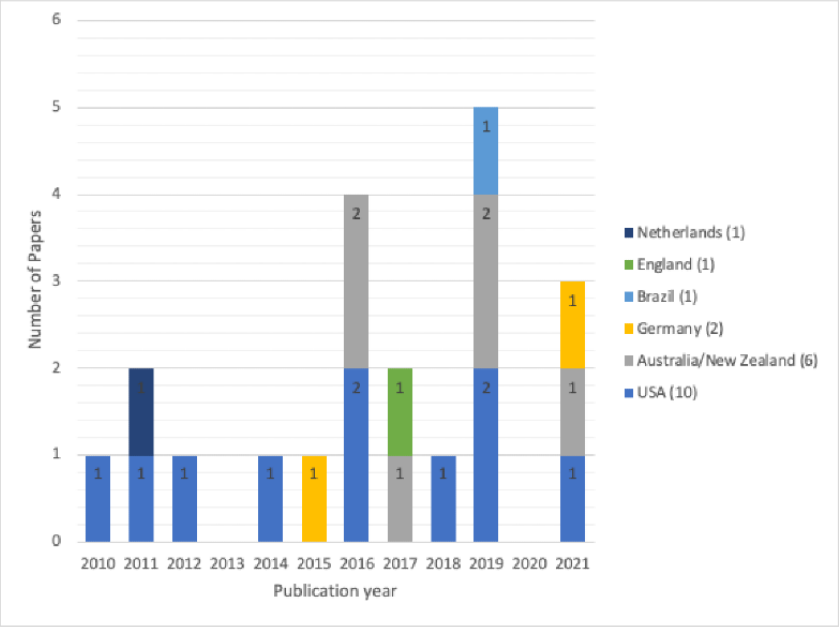
[k]HbA_{1c}: hemoglobin A_{1c}.

[l]DD: diabetes distress.

Study Characteristics

The characteristics of the primary papers can be found in Tables 1-3, and the full characteristics of the individual primary papers can be found in Multimedia Appendix 2. A total sample of 4748 adults with diabetes were included in this review. Studies included mostly participants with T2D (n=10) or mixed diabetes populations (n=9). Only 2 studies were conducted with participants with T1D (one qualitative focus group study [21] and the other a controlled clinical trial diabetes and mental health intervention [28] representing a total sample of 97 adults with T1D specifically), whereas in a further 3 studies, the diabetes population was unclear [26,34,37]. None of the included studies specifically reported including participants with GD. The publication years of the included studies suggest an increasing trend as 14 of the studies were published in the last 5 years and most of the publications were within the last 3 years of the review period (Figure 2). The papers originated from the USA (n=10), Australia (n=5), Germany (n=2), and 1 paper each from the following countries: Brazil, England, Netherlands, and New Zealand. Studies were generally of short duration with half the studies (n=12) being ≤12 weeks long, 2 between 13 and 26 weeks in duration, and 5 were 12 months long. Eight studies had a follow-up outcome measurement beyond the end of the study time point. Of the 20 intervention studies, 12 focused on addressing mental health in people living with diabetes [25,27,31-33,36,38,39,41-44] and 8 addressed both diabetes and mental health conditions concurrently [23,24,26,28-30,35,37].

Figure 2. Number of included papers by year and country. Note: 3 reviews are not included in this figure.

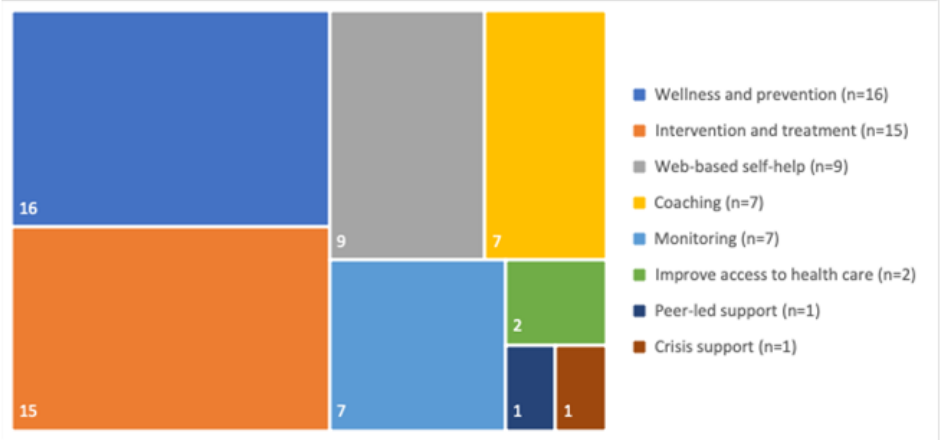


Technology-Enabled Integrated Interventions for Diabetes and Mental Health

Purpose of Use

Of the 10 purposes of technology described in the Mental Health Commission of Canada framework, 8 were found in our included studies (Figure 3; Multimedia Appendix 3). The overwhelming majority of the included studies used technology for wellness and prevention (n=16; ie, practicing healthy habits to maintain or improve health) and intervention and treatment (n=15; ie, specialist consultation, assessment, or follow-up). The other 2 most common purposes were web-based self-help (n=9; ie, accessing resources) and coaching (n=7; ie, working with a trained professional). Very few studies used the technology to improve access to health care (n=2) [29,33], to provide peer-led support (n=1) [37], or to provide crisis support (n=1) [42].

Figure 3. Tree map of the purpose of technology used in included studies as reported in 20 studies. Note: as per the definitions from the Mental Health Commission of Canada "Mental Health, Technology, and You," 3 systematic reviews and 1 focus group study are not part of the data extraction to construct this figure.



Context of Use

Studies were conducted in a range of settings and sites of care (Tables 1-3), and some included both web-based and in-person settings. Over half the studies (n=13) were delivered primarily through web-based platforms, websites, apps, or phone calls, and about one-third (n=9) of the studies included primary care settings such as doctor's offices, hospitals, or clinic visits. A variety of health care professionals and staff were used to help deliver the services and technologies to participants (Tables 1-3). Although 6 studies were entirely automated or self-directed by the participants, with no involvement by any health care professionals or staff, the remaining studies used 1 or more of the following: psychologist (n=6), nurse (n=6), social worker (n=5), graduate student (masters or doctoral level) or postdoctoral fellow (n=3), medical doctor or physician (n=2), and 1 study each for case manager, pharmacist, and behavior coach. Their involvement ranged from supervising, training, and overseeing the implementation of the research project, to directly supporting the implementation of the technology component of the study (phone calls, emails, telemedicine, remote feedback, and support through direct or instant SMS text messaging and video), to leading separate and additional components of the study outside of the technology (facilitating discussion groups and one-on-one meetings). Their involvement varied greatly in terms of structured and scripted feedback compared with more personalized and individualized coaching. Both synchronous and asynchronous deliveries were used.

Type of Technology Used in the Interventions

We extracted the details of the technology from the included studies that actively evaluated or tested a digital health technology (n=20 intervention studies). The 3 reviews and 1 focus group study were not included in this extraction of data as the general nature of the reviews and investigative purpose of the focus groups did not lend themselves to such specific categorization. Full data extraction on the components of the digital health technologies of the individual primary papers can be found in Multimedia Appendix 3.

Half of the studies (n=13) used computerized treatments, resources, and mobile apps. These were mostly website-based, accessible from many types of devices, and none of these mobile apps were mobile health. These websites served a variety of purposes and included many different features ranging from educational materials to interactive learning modules and discussion boards (Textbox 1). Telehealth or telemedicine was used in 9 of the included studies, some of which also used computerized treatments or apps. Only 1 study used social media or peer support platforms (MSN Messenger) [37], and 1 study used artificial intelligence [42].

Textbox 1. Website components offering diabetes and mental health from included studies.

- Resources and educational materials with articles and sites on diabetes and other health-related topics
- Interactive learning modules and topics related to diabetes self-care and management and behavior change
- Tracking of personal health data, physical activity and diet records, and participant logbooks and diaries
- Stories from peers or similar target audience, success stories, and emotional well-being support
- Activities and questionnaires
- Discussion boards and moderated forums, with or without involvement from intervention delivery persons
- Receiving advice, instruction, and action plans
- Setting frequency and type of text messaging and daily reminders
- Frequently asked questions

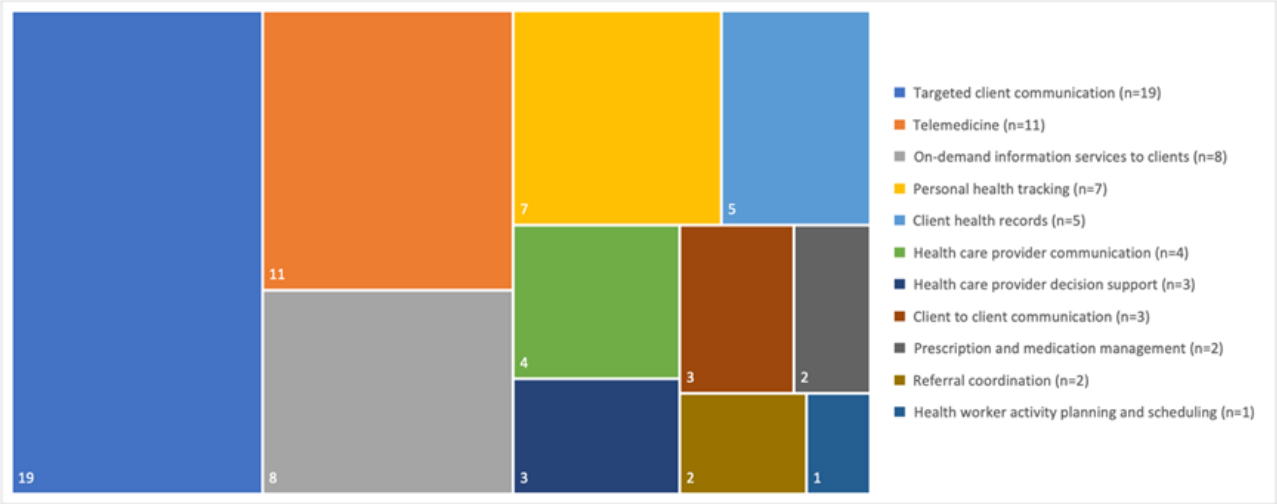
Primary Users

Applying the World Health Organization's "Classification of Digital Health Interventions v1.0" framework, primary users of interventions may be categorized as those specific to clients, health care providers, health systems, or data services. In this review, primary users included clients and health care providers, with none of the included studies describing interventions for health systems or data services.

Interventions for Clients

Interventions for clients encompassed 4 of the 7 subgroups (Figure 4): targeted client communication (such as telehealth, phone calls, emails, or SMS text messaging with a provider; n=19), on-demand information services to clients (mostly through access to websites or provision of information through pamphlets and handouts; n=8), personal health tracking (through websites; n=7), and client-to-client communication (such as discussion boards or peer-to-peer messaging systems; n=3) [28,29,37].

Figure 4. Tree map of the digital health intervention classifications as reported in 20 studies. Note: as per the World Health Organization's "Classification of Digital Health Interventions v1.0," 3 systematic reviews and 1 focus group study are not part of the data extraction to construct this figure.



Interventions for Health Care Providers

Seven of the 10 subgroups were covered by included studies (Figure 4). These were telemedicine (n=11), client health records (n=5) [25,28,31,37,42], health care provider communication (n=4) [25,26,42,44], health care provider decision support (n=3) [35,42,44], referral coordination (n=2) [23,42], prescription and medication management (n=2) [23,42], and health worker activity planning and schedule (n=1) [44]. These intervention components were mostly related to the professional integration of the study.

Level of Integration of Technology-Enabled Diabetes and Mental Health Support

Included studies only reported interventions operating at 2 of the levels of integration. All the included intervention studies (n=20) used technology for clinical integration, and approximately one-third (n=7) also used the technology for professional integration. Professional integration supports the communication and interaction between colleagues from different disciplines across different organizations [19]. In our included studies, the provision of information and data into the study technology allowed for better coordination, communication, and interaction of health care providers through sharing client records with specialists and other health care professionals, supporting health care decision-making, enabling communication between health care providers, coordination of referrals, and better prescription and medication management. For many studies, professional integration allowed the participants and the delivery persons (including health care providers) to set coordinated clinical care goals and action plans. Wu et al [42] used clinical decision support software as part of their technology intervention. This software automatically generated task reminders and alerts based on the data of patient records that were directed to specific providers.

Discussion

Principal Findings

People living with diabetes and mental health challenges may find it difficult to balance self-care demands (eg, maintaining a healthy diet, exercising, or taking medication) [4-6]. Integrated diabetes and mental health care delivery models can help overcome the historically fragmented and siloed care that people living with diabetes and mental health challenges currently must navigate [10]. Health technology, including innovative interventions such as those described in this review, may further drive the scale-up of these integrated solutions. Our review sought to describe technology-enabled integrated interventions for diabetes and mental health and to describe how these interventions are or may be integrated into clinical care.

Our review found that much of the evidence for integrated technology for diabetes and mental health support was derived from clinical controlled trials and pre-post studies. Similar to a previous review by Franco et al [40], we found that our included studies were heterogeneous in terms of whether they focused their intervention to support combined diabetes interventions with mental health components versus mental health–specific interventions in people living with diabetes. This is consistent

with prior research trends for both face-to-face and digital health interventions [40]. Moreover, about a quarter of the identified studies did not specifically discuss the mental health intervention components, aims, and goals, and it was unclear what constructs of psychological well-being were targeted (eg, distress, depression, or self-efficacy). This is despite high levels of evidence to suggest that individuals with diabetes value psychoeducation that is illness-specific such as interventions targeting depression [40]. Additional studies that provide a greater detail on the psychological constructs targeted are therefore needed. Similar behavioral treatment strategies and approaches can be used to address both mental health challenges and diabetes, which may contribute to better integration and improved overall health outcomes.

Most of the included studies used web-based technologies, and the majority targeted either mental health wellness and prevention or intervention and treatment support. Several studies identified their purpose as providing web-based self-help and health coaching, and only 2 studies used technology to improve access to health care [29,33]. Specifically, there was evidence of clinical integration (access to diabetes and mental health support); however, only 2 studies described health professional integration across diabetes and mental health care providers [23,42]. This finding highlights the state of integrated care, where clinical integration of diabetes care and mental health support exists but does not quite reach integration of health care professionals at the organization and system level. To that end, of the 7 studies that comprised diabetes and mental health combined interventions, only 3 included professional integration [23,26,35], suggesting that more work needs to be done to prepare health care professionals and organizations for the delivery of integrated care.

Recognizing the impact of COVID-19 and the push for technology-based solutions to deliver care, an abundance of recent papers spoke to the rapid uptake and evolution of technology-based interventions; however, only one of these studies met our inclusion criteria for technology-enabled integrated care [25]. Moreover, the pandemic has highlighted the need for careful consideration as to how technology may further restrict access to care, integration or coordination of care, and ultimately disadvantage some individuals, particularly those who are underserviced or underrepresented in diabetes and mental health care. For example, for those living with mental health challenges, the added time or cognitive investment inherent to some of these interventions may contribute additional burden, disempowerment, and ultimately lead to not seeking help—further reinforcing not only digital inequities but other social and health inequities too [59].

Future Research

We are consistently moving toward digital systems where interactions and services that were traditionally in-person, by phone, and paper are now only offered via a web platform or virtually. This includes health and social services. In this regard, digital equity is essential for universal access to these services, especially by underserved, marginalized communities. Barriers to digital equity, such as inadequate infrastructure in rural and remote communities, lack of affordable options for high-speed broadband internet, digital literacy, or digital poverty, must be considered as more technology-based health care services emerge. With an emphasis on equity, diversity, and inclusion, future research should carefully consider a staggered but not exclusive approach for offering self-management solutions to integrated clinical health care provider and organizational models of technology-enabled care. Further, the development of these interventions must be done in tandem with measurement-based approaches to digital health equity [59]. In particular with Indigenous populations, integration of mental health and physical health is important culturally in the development of effective health care interventions and services.

Strengths and Limitations

Our review has several strengths. First, we used a rigorous process to search, screen, and select on-topic literature, following best-practice methodologies [16,60]. Our search is current and includes papers as recent as February 2022 from multiple databases. Finally, we used several theoretical frameworks to dissect key concepts about technology-enabled diabetes and mental health integrated care including frameworks to understand key concepts such as the intervention, the purpose of the technology, and the intent of the integration. Although our review did not critically appraise the literature or perform a meta-analysis, our methods align with the aims and purpose of a scoping review [14,61]. By only including studies written in English, we may have missed important papers written in other languages.

Conclusions

Despite the growing need for diabetes and mental health support, there remains limited access to interprofessional, integrated care that includes psychological support, education, and follow-up for individuals living with diabetes and their comorbidities (eg, depression, anxiety, or distress). The findings of this scoping review suggest that there is an emergence of literature pertaining to health technology for diabetes and mental health integrated care. Future research is needed to continue to explore the purpose, level, and breadth of technology-enabled integration to facilitate an approach to overcome or address care fragmentation for diabetes and mental health.

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Data Availability

The main study data are the data extraction materials and quality ratings of included papers, most of which are included in the manuscript tables. Any other supporting data relating to this review are available by request from the authors.

Authors' Contributions

All authors were involved in conception and design of the study and approved the protocol. MR and DS were responsible for overseeing the search of databases and literature. MR handled the management of database and deduplication or records. MR, CW, MJ, PA, DF-L, and DS were involved in the screening of citations. MR and CW were responsible for data extraction. MR, CW, and DS were responsible for data verification and analysis of data. MR, DS, RD, OCM, FN, DC, JAC, VV, SR, AC, GS, P Senior, and P Selby were involved in interpretation of data. All authors supported in the drafting of the manuscript, which was led by MR, and all authors supported in revising and formatting of the manuscript. All authors have provided final approval of the version of the manuscript submitted for publication, and all authors agree to be accountable for all aspects of the work.

Conflicts of Interest

P Selby reports receiving grants and/or research support from CIHR, New Frontiers in Research Fund, Canadian Cancer Society, National Research Council of Canada, and the Ontario Ministry of Health. Through an open tender process Johnson & Johnson, Novartis, and Pfizer Inc. are vendors of record for providing smoking cessation pharmacotherapy, free or discounted, for research studies in which P Selby is the principal investigator or co-investigator. He is also supported by the Giblon Professorship held at the University of Toronto and research stipends from CAMH as well as the Department of Family and Community Medicine, Temerty Faculty of Medicine, University of Toronto. The authors have no further interests to declare.

Multimedia Appendix 1
Search strategy.
[DOCX File , 25 KB - diabetes_v8i1e44652_app1.docx]

Multimedia Appendix 2
Characteristics of included studies.
[DOCX File , 85 KB - diabetes_v8i1e44652_app2.docx]

Multimedia Appendix 3
Overview of digital health technology.
[XLSX File (Microsoft Excel File), 22 KB - diabetes_v8i1e44652_app3.xlsx]

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Abbreviations

GD: gestational diabetes
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
T1D: type 1 diabetes
T2D: type 2 diabetes

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Original Paper

Toward Diabetes Device Development That Is Mindful to the Needs of Young People Living With Type 1 Diabetes: A Data- and Theory-Driven Qualitative Study

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Abstract

Background: An important strategy to understand young people's needs regarding technologies for type 1 diabetes mellitus (T1DM) management is to examine their day-to-day experiences with these technologies.

Objective: This study aimed to examine young people's and their caregivers' experiences with diabetes technologies in an exploratory way and relate the findings to the existing technology acceptance and technology design theories. On the basis of this procedure, we aimed to develop device characteristics that meet young people's needs.

Methods: Overall, 16 in-person and web-based face-to-face interviews were conducted with 7 female and 9 male young people with T1DM (aged between 12 and 17 years) and their parents between December 2019 and July 2020. The participants were recruited through a pediatric diabetes clinic based at Canberra Hospital. Data-driven thematic analysis was performed before theory-driven analysis to incorporate empirical data results into the unified theory of acceptance and use of technology (UTAUT) and value-sensitive design (VSD). We used the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist for reporting our research procedure and findings. In this paper, we summarize the key device characteristics that meet young people's needs.

Results: Summarized interview themes from the data-driven analysis included aspects of self-management, device use, technological characteristics, and feelings associated with device types. In the subsequent theory-driven analysis, the interview themes aligned with all UTAUT and VSD factors except for one (privacy). Privacy concerns or related aspects were not reported throughout the interviews, and none of the participants made any mention of data privacy. Discussions around ideal device

characteristics focused on reliability, flexibility, and automated closed loop systems that enable young people with T1DM to lead an independent life and alleviate parental anxiety. However, in line with a previous systematic review by Brew-Sam et al, the analysis showed that reality deviated from these expectations, with inaccuracy problems reported in continuous glucose monitoring devices and technical failures occurring in both continuous glucose monitoring devices and insulin pumps.

Conclusions: Our research highlights the benefits of the transdisciplinary use of exploratory and theory-informed methods for designing improved technologies. Technologies for diabetes self-management require continual advancement to meet the needs and expectations of young people with T1DM and their caregivers. The UTAUT and VSD approaches were found useful as a combined foundation for structuring the findings of our study.

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KEYWORDS

type 1 diabetes mellitus; unified theory of acceptance and use of technology; UTAUT; value-sensitive design; young people; data- and theory-driven analysis; improved device design

Introduction

Background

Type 1 diabetes mellitus (T1DM) is an autoimmune condition often diagnosed in children and adolescents [1]. It requires lifelong self-management, including blood glucose monitoring; adherence to insulin regimens; lifestyle adjustments, including diet and exercise; and, for many, the management of psychological health [2]. Advanced diabetes technologies, such as insulin pumps, continuous glucose monitors (CGMs), and closed loop systems, have been found to improve self-management and quality of life among young people with diabetes [3]. Moreover, the use of such technologies can help reduce the risk of acute and long-term diabetes complications [4].

An important strategy to understand young people's needs and preferences regarding technologies for T1DM management is the examination of their day-to-day experiences with these technologies. The analysis of their experiences with technologies also serves to identify their specific perceptions, decisions, and behaviors regarding technology use [5,6]. Co-design research is enriched through feedback on experiences with technology use [7]. The experiences of young people with T1DM with diabetes technologies have been studied mainly using exploratory research designs [8,9].

Exploratory (qualitative) research (eg, into user experiences) is distinguished by the absence of a priori theory in social sciences; it is an inductive process that is used to generate knowledge or theory [10]. By contrast, technology adoption and use are predicted and explained using sociotechnical theories in social sciences and computer science (such as technology acceptance models), which informs technology design decisions. Research on both user experience and technology acceptance ultimately aims to understand the mechanisms that shape the uptake and use of technology [11]. It is only recently that the merit of combining both approaches has been recognized, for example, by investigating how user experiences can inform technology acceptance models [12] or how knowledge from technology acceptance models can advance or structure user experience research [13]. The latter can be implemented using a transdisciplinary theory-driven analysis of exploratory qualitative empirical data [13]. A stronger focus on theory can strengthen and advance the translational outcomes of research [14,15], whereas a greater focus on exploratory inductive research can deepen the validity and applicability of findings. In the case of user experience research, technology acceptance and technology design theories provide the opportunity to align a data-driven approach with a theory-driven analysis. Incorporating the theoretical framework of technology acceptance and technology design knowledge into the study of the experiences and preferences of young people regarding diabetes technologies can promote a well-grounded foundation for future research in this area and can inform the development of improved diabetes technologies for young people on a sound basis.

Study Aim

Our study had 3 aims. The first aim was to examine young people's and their caregivers' experiences and preferences regarding insulin pumps, sensor technologies, and diabetes communication technologies in an exploratory manner. The second aim was to relate the findings to selected technology acceptance and technology design theories. The third aim was to develop, based on the outcomes of the second aim, device characteristics that would meet the needs of young people. Thus, we aimed to highlight the benefits of incorporating validated theory into empirical user experience research for designing new and improved technologies.

Methods

Overview

We conducted 16 interviews with young people with T1DM and their parents about their use of diabetes technologies. The interviews were conducted face to face, either in person or on the web, by female academic health experience researchers (AP, JD, MC, and NB-S; PhD or MPH degree; Health Experience Team of *Our Health in Our Hands* at the Australian National University) with experience in conducting qualitative research. Interviews were held between December 2019 and July 2020 (12 in-person interviews and 4 web-based video calls owing to the onset of COVID-19) until data saturation was reached. The participants were recruited through a pediatric diabetes clinic based at Canberra Hospital. The first contact was established either at appointments at the clinic through invitation from pediatric endocrinologists, or in response to a study flyer in the

waiting room, or through invitations sent via email by the study coordinator. There was no prior relationship between the participants and the interviewers. The interviews lasted between 20 and 30 minutes. In-person face-to-face interviews were conducted at the National Center for Epidemiology and Population Health at the Australian National University. After 16 interviews, preliminary data analysis showed that we had reached thematic saturation. The sample size was similar in magnitude to the qualitative studies included in a previous review on the experiences of young people and their caregivers with diabetes technology use [8], although the length of the interviews in our study was shorter (an average of 20 to 30 minutes) than that in the studies in the review (20 minutes to 2 hours). The interview protocol was carefully designed to elicit the desired information. Although some participants were less talkative than others, overall, we were able to gain sufficient data to inform the study. No major differences were noted between the in-person and web-based interviews.

The interview protocol focused on exploratory data collection for a data-driven analysis, which was the first step, without the influence of preexisting categories, whereas, as the second step, a theory-driven analysis was performed to enable the alignment of the interview themes with the categories from the selected theories. To achieve this, the interview protocol was kept as open-ended and short as possible, with general probing questions to initiate conversation about experiences with diabetes technologies and related preferences. It contained questions about managing diabetes with technological devices, the types of devices used and preferred, experiences with these devices, decision-making, and the challenges encountered. The interview protocol was developed in collaboration with 3 young people with T1DM who were members of our research team (EB, KH, and LP). The interview probes (questions) were first drafted by the researchers, then discussed with the young people (EB, KH, and LP) and other research partners (pretest), and, finally, revised to make them more concise and clearer for the participants. All the interviews were audio recorded and professionally transcribed.

Ethics Approval

Ethics approval was obtained from the Australian National University's Human Ethics Committee and the Australian Capital Territory Health Human Research Ethics Committee in October 2019 (2019.ETH.00143 and 2019/ETH121700). In addition, an ethics protocol variation for web-based interviews was approved by the same committees in April 2020. All the interviews were conducted with informed consent.

Data Analysis

For data analysis, we used a combination of data-driven thematic analysis (stage 1) and theory-driven analysis (stage 2) to pay respect to rich data generated from both the interviews and the existing literature. Conducting our data-driven analysis before the theory-driven analysis enabled the identification of themes without the influence of theoretical factors, ensuring that the analysis was not limited to theoretical factors.

Stage 1 followed a qualitative data-driven thematic analysis approach based on Braun and Clarke [16]—data familiarization and coding, generation of themes, thematic review, definition of themes, and reporting—to identify themes arising from the 16 interviews. Transcripts were uploaded to the NVivo (version 12, QSR International) data management software. Two researchers (MC and NB-S) familiarized themselves with the data via multiple readings; then, codes were identified from the keywords and phrases of interest and compared and combined to form the coding schema for the data-driven analysis (Multimedia Appendix 1). Ongoing discussions between the 4 researchers (AP, JD, MC, and NB-S) were held throughout the data analysis process to ensure construct validity. We did not perform an internal comparison of different emerging themes in relation to their frequency of endorsement. Our goal was not such a quantitative weighing of themes but an inclusive search for thematic breadth from the interviews.

In the second stage, the same researchers analyzed the initial themes from the interviews using selected relevant theories on (1) technology acceptance and use and (2) technology design by classifying and sorting the interview themes and results into theoretical factors. We collected all the interview themes and excerpts that represented, for example, *accessibility issues* and reported them alongside the technology design factor *accessibility* (refer to the selected theories and factors in Tables 1 and 2).

Table 1. Explanation of the unified theory of acceptance and use of technology (UTAUT) factors [17] and their alignment with interview data and systematic review [8].

Model, category, and factor	Factor explanation or definition [17]	Interview data theme	Relevant interview data excerpt	Relevant systematic review theme [8]
UTAUT				
Core determinant				
Effort expectancy	The ease of the technology use	Ease of and effort needed for use (CGM[a], FGM[b], and pump)	IP[c]4: "you just wipe it [FGM] and you get the number"	Discussed as a part of impact on blood glucose control
Facilitating conditions	Infrastructure (eg, organizational or technical) supporting the technology use	HCP[d] support, support at school and at home, customer service of technology, and programs and funding (CGM and pump)	IP4: "we can call them [health care team] at any time of the day"	Impact on independence and relationships
Performance expectancy	The extent to which the user and nonuser believes that using the technology will improve their performance	Expectations regarding self-management with technology: device expectation, success in self-management, and preferences (CGM and pump)	IP1: "satisfaction of seeing it [blood glucose management] successful"	Impact on blood glucose control and satisfaction with technologies
Social influence	The degree to which someone thinks that it is important others believe that they should (not) use the technology	Influence on technology use (parents, peers, and HCPs), technology suggested by physician, and child's or parents' decision to use technology (age dependent)	IP1P: "[physician name] sort of seems to be quite keen on devices and quite keen on pumps"	Impact on independence and relationships
Moderator				
Gender and age	The user and nonuser's gender and age	Gender and age differences	IP1: "all the kids have Dexcom [CGM], my age"	Experiences with alarms, satisfaction with the technologies, and age (groups) as a general background variable
Use experience	Previous experience with the technology	Length of disease and length of technology use	IP3P: "now that it's part of our lives [diabetes], I'm very grateful for my experiences"	Across all themes
Voluntariness of use	The degree to which it is perceived that the technology is used out of free will	Influence on technology use (parents, peers, and HCPs), technology suggested by physician, and child's or parents' decision to use technology (age dependent)	IP16P: "I don't want to force [child] [to use technology] since it's [child's] body"	Impact on independence and relationships

[a]CGM: continuous glucose monitor.

[b]FGM: flash glucose monitor.

[c]IP: interview participant identifiers for young people (eg, IP1) and their parents (eg, IP1P).

[d]HCP: health care professional.

Table 2. Explanation of value-sensitive design (VSD) factors [18] and their alignment with interview data and systematic review [8].

Model, category, and factor	Factor explanation or definition [18]	Interview data theme	Relevant interview data excerpt	Relevant systematic review theme [8]
VSD				
System feature				
Connectivity	Features that allow the user to interact with the devices and share information with others	Connectivity among CGM[a], pump, watch, and apps; data sharing and access (HCPs[b] and family); and downloading before sharing	IP[c]14P: the "devices [CGM, pump, apps, etc]...talk to each other"	• Impact on independence and relationships: data sharing • Device design and features: connectivity and calibration
Data analysis	Features that allow the user to make sense of data over time	Data trends and graphical outputs (display; CGM and pump)	IP14P: "not always a hundred percent accurate" (using CGM data to calculate HbA1c[d])	• Device design and features: data trends
Data retrieval and storage	Features that allow the user to access and store data	Apps and web-based sources for information, cloud storage, and storage in devices (blood glucose meter and pump)	IP6: "and the pump...it stores all the information that you have"	• Data access discussed in terms of its impact on sleep and overnight experiences (eg, sensors)
Value				
Accessibility	The system's availability, adaptability, and portability	Technology adaption to new situations and conditions (eg, travel, sports, camp, sleepover, and night; regarding alarms, tape, size etc) and data accessibility in these situations (CGM and pump)	IP1P: "having it [CGM] meant [child] could go to school camp"	• Impact on sleep and overnight experiences • Experiences with alarms • Device design and features: discomfort
Accountability and autonomy	Self-responsibility for habits and care performance, with independent behavior and decision-making	Increased self-responsibility, independence from parents, sense of control, and interference of parents (CGM, FGM[e], and pump)	IP3P: "[child] doesn't really want to have [child's] parents knowing what [child is] doing all the time"	• Impact on independence and relationships
Compliance	Adherence, following the diabetes care plan	Self-management compliance (style of management, including blood glucose testing, medication, etc)	IP1 or IP1P: "tend to over worry, and overly focus [on diabetes care]"	• Impact on blood glucose levels (better management decisions with technology) • Impact on sleep and overnight experiences (improved management at night) • Experiences with alarms (affect compliance at school)
Dignity	Sense of pride and self-respect (impacted by negative outcomes or unfair treatment for performance)	Dignity: discrimination and unfair treatment (school)	IP3P: "you sort of feel like there's this constant discrimination for something that [child] has no control over" (diabetes)	• Impact on independence and relationships • Experiences with alarms (school)
Empathy	Desire to be understood by others	Empathy: shown by friends, family, and HCPs	IP5P: "they [siblings] were all lining up for finger pricks" (empathy)	• Impact on independence and relationships
Feedback	Responses from others or technology	Feedback: from HCPs and parents (CGM and pump)	IP15P: "it [CGM] just constantly alarmed for everything"	• Impact on independence and relationships • Experiences with alarms

Model, category, and factor	Factor explanation or definition [18]	Interview data theme	Relevant interview data excerpt	Relevant systematic review theme [8]
Hope and joy	Motivation to meet future-oriented expectations and personally valued goals, including joy in life	Hope to meet the self-management goals with technology and increasing joy with technology, for example, through anxiety alleviation (CGM and pump)	IP15P: "sometimes [child] likes to have a break" (hope for normality and enabling joy)	• Expectations before technology use
Privacy	Information protection when sharing sensitive (health) data	Not mentioned in interviews	Not mentioned in interviews	• Not part of the themes
Sense making	Ability to give meaning to data	Sense making of data and understanding data based on diabetes education; graphical outputs were helpful	IP16P: "we were learning so much about diabetes"	• Device design and features: trends and graphs
Trust	Trust in technology, oneself, and others	Trust in body (confidence in self and hypo awareness) versus technology (accuracy, technology failures, time lag, and reliability; CGM and pump), and trust in HCP team	IP14: "sometimes it [CGM] gets very inaccurate"	• Device design and features: data lag

[a]CGM: continuous glucose monitor.

[b]HCP: health care professional.

[c]IP: interview participant identifiers for young people (eg, IP1) and for parents (eg, IP1P).

[d]HbA1c: hemoglobin A1c.

[e]FGM: flash glucose monitor.

Both technology acceptance and technology design theories are highly relevant as a foundation for analyzing experiences with diabetes technologies to develop device characteristics that meet the needs of users. Technology acceptance and use approaches posit factors that attempt to explain or predict use intentions and decisions, whereas technology design approaches posit factors for improved technology design. In our study, these theoretical branches tackled different sides of the same coin (improving technology and its uptake) and were able to complement each other to provide a broader picture. Thus, an integration of knowledge from both approaches offered comprehensive guidance for our analysis of diabetes technology user experiences. In the following sections, we further explain which specific theories we selected and how they complemented each other.

Theoretical Foundations for Theory-Driven Analysis

Technology acceptance models offer a sound framework for examining decisions and behaviors regarding health technology use. The unified theory of acceptance and use of technology (UTAUT) comprises elements from 8 previously well-established models [17] and has been applied in recent studies examining the acceptance of information and communication technologies by patients with diabetes [19,20] and health care professionals [21]. The UTAUT summarizes 8 factors that directly or indirectly influence technology use intention or use behaviors [17]. It comprises 4 core determinants of technology use intention and actual use—performance expectancy, effort expectancy, social influence, and facilitating conditions—and 4 additional factors—gender, age, use experience, and voluntariness of use—that act as moderators. For example, previous experiences with technologies moderate associations between other antecedent factors and use intention [17] or technology use [22] and influence technology uptake [23,24]. For a full description of these factors, refer to Table 1.

However, technology acceptance models such as UTAUT are subject to certain limitations owing to their binary logic of technology acceptance (acceptance or rejection) [25] and their assumption of the underlying rational behavior [26], which are at odds with the principles of a complex self-managing ecosystem in which users with varying needs, desires, and interests make decisions and act within a sociocultural context [18]. This is where our selected technology design approach can fill a gap and complement UTAUT for developing device characteristics that meet young people's needs.

Value-sensitive design (VSD) offers a holistic methodological framework that integrates users' values and life circumstances into the examination of their interaction with technologies [27]. It is underpinned by an integrative and iterative methodology that consists of 3 interrelated yet distinct investigations: technical investigations that focus on the technology, empirical investigations that gather the responses of individuals or groups affected by the technology, and conceptual investigations that examine the values of key stakeholders [27]. VSD is used to identify and conceptualize users' values and to design technologies in accordance with these values [18]. For example, technically viable implantable medical devices can be undesirable for some patients and not align with their values [28]. In their study of adults with type 1 or type 2 diabetes,

Dadgar and Joshi [18] used a VSD lens to identify system features and values that are important to people with diabetes to complement the usual functionalist approach to usability. They summarized 4 system features—connectivity, data analysis, data retrieval, and storage—and 12 values—accessibility, accountability and autonomy, compliance, dignity, empathy, feedback, hope and joy, privacy, sense making, and trust (extended to include technology)—relevant to the design of diabetes technologies. For a complete description of these features and values, refer to Table 2.

For example, Dadgar and Joshi [18] found that *trust* in technologies affects their use by patients, with a lack of trust in the devices leading to technology resistance and masking the advantage of the respective technology. The value *trust* also includes trust in others who use technologies to provide care. The authors acknowledge that patients' technology use is embedded in self-management activities and relationships with family, friends, and health care providers. As self-management is integral to the well-being of people with diabetes and technology is rapidly developing in this space, marrying the needs of users with technology design is essential. Although VSD has been applied to the design of technologies for children and youth [29], a specific summary of values and system features focusing on young people with diabetes could not be found, and the work of Dadgar and Joshi [18] provided a useful foundation on which to build.

Using both theoretical approaches in the second part of our data analysis, we assessed the alignment of our initial themes with key factors from UTAUT and VSD. There was little overlap between the factors in the UTAUT and the selected VSD approach because of the different focuses of the theories, and thus, all factors from both theories could be used to guide the analysis. In Tables 1 and 2, we provide definitions of the respective factors and the alignment of the data with the theoretical factors. Multimedia Appendix 2 [18,27,30-33] provides a working example of how the VSD factors were adapted from the work of Friedman et al [27] and Dadgar and Joshi [18], and Multimedia Appendix 3 [17,18] presents data excerpt examples.

Summary of Device Characteristics Meeting Young People's Needs

On the basis of the analysis, the device characteristics that meet the needs of young people with T1DM were summarized. Key points and major themes from the data-driven analysis were collected alongside the theoretical factors to describe expectations, preferences, and needs, as articulated in the interviews. We did not focus on a quantitative summary but rather on important and highlighted aspects that emerged throughout the interviews regarding the device characteristics. For example, the interview participants (IPs) highlighted the importance of device accuracy and reported problems with time lags and technical failures, which affected their trust in the devices. Thus, the accuracy and reliability of the devices were summarized as important device characteristics aligned with the VSD factor *trust*.

Throughout the reporting of our study methods and results, we used the COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist, as presented in Multimedia Appendix 4. The study results were presented to and discussed with the Health Experience Team of *Our Health in Our Hands* at the Australian National University, which included young people with T1DM and medical researchers.

Results

Study Sample and Devices Used

The sample included 16 young people with T1DM (female: n=7, 44%; male: n=9, 56%) aged between 12 and 17 years and accompanied by a parent (mother: n=11, 69%; father: n=4, 25%; both: n=1, 6%). We focused on this age group because of 3 reasons. First, government subsidies are limited to those aged <21 years [34]. Second, younger individuals have been reported to be "more exposed to new technologies and easier to absorb the new technological advancements with minimum effort" [35]. Third, adolescence—with a transition from childhood to adulthood—is accompanied by general life challenges affecting diabetes management [36,37]. The young people in our study had been diagnosed with T1DM between 1 and 14 years before this study.

Overall, 81% (13/16) of participants used an insulin pump (t:slim [Tandem Diabetes Care Inc]: n=3, 23%; Medtronic: n=10, 77%), 88% (14/16) used a CGM (Dexcom: n=11, 79%; Guardian [Medtronic plc]: n=3, 21%), and 6% (1/16) used a flash glucose monitor (FGM; FreeStyle Libre [Abbott Laboratories]). The participants used an insulin pump (2/16, 12%), a CGM (3/16, 19%), or a combination of both (11/16, 69%). In one case the FGM system was used in addition to the pump. Additional devices used included the Apple watch (Apple Inc; previously used: 2/16, 12%; currently using: 1/16, 6%; planned to use: 1/16, 6%), diabetes apps on smartphone or smart devices (various), and glucose and ketone meters (16/16, 100%). An overview of the study sample is presented in Table 3.

Table 3. Study sample overview[a].

IP[b]	Mode	Sex	Year of diagnosis (range)	CGM[c]	Insulin pump	Other technology
1	Face to face	Male	2016-2020	Dexcom	No pump	—[d]
2	Face to face	Female	2011-2015	Dexcom	t:slim (Tandem Diabetes Care Inc)	Previously, Apple watch (Apple Inc)
3	Face to face	Male	2011-2015	No CGM and previously, Dexcom	Medtronic	—
4	Face to face	Male	2016-2020	Dexcom	t:slim	FreeStyle Libre (Abbott Laboratories) and thinking about Apple watch
5	Face to face	Male	2006-2010	Dexcom	Medtronic	—
6	Face to face	Male	2006-2010	Dexcom	Medtronic	Apple watch
7	Face to face	Female	2006-2010	Dexcom	Medtronic	—
8	Face to face	Female	2016-2020	No CGM	Medtronic	—
9	Face to face	Male	2006-2010	Medtronic (Guardian, Medtronic plc)	Medtronic	—
10	Face to face	Female	2006-2010	Dexcom	Medtronic	—
11	Face to face	Male	2011-2015	Dexcom	Medtronic	—
12	Face to face	Female	2016-2020	Dexcom	t:slim	—
13	Zoom (Zoom Video Communications)	Male	2011-2015	Medtronic (Guardian)	Medtronic	Previously, Dexcom and Apple watch
14	Zoom	Female	2016-2020	Dexcom	No pump yet; t:slim planned	—
15	Zoom	Male	2006-2010	Medtronic (Guardian)	Medtronic	—
16	Zoom	Female	2016-2020	Dexcom	No pump	—

[a]The participants were aged between 12 and 17 years; each young participant was accompanied by a parent or parents.

[b]IP: interview participant identifier for young people (eg, IP1).

[c]CGM: continuous glucose monitor.

[d]Not available.

Interview Themes and Alignment With Theoretical Factors

Initial themes (Multimedia Appendix 1) identified from the interview data included information related to (1) sociodemographic characteristics, (2) medical diabetes and diabetes self-management (eg, diagnosis, family members with diabetes, diabetes education, hypoglycemic or hyperglycemic awareness and events, and style of self-management), (3) device use (eg, types of devices used, length and frequency of use, and preferences), and (4) specific device type–related technological characteristics and feelings associated with the specific device type used (CGM, insulin pump, or FGM). Themes were mostly related to the use of CGM, insulin pump, or a combination of both. Cases where the themes were related to the use of FGM or other devices have been specifically mentioned in the result section on UTAUT factors or VSD factors. Tables 1 and 2 also specifically mention the device types that the themes are related to.

In the following sections, the findings focus on the alignment of the initial themes with the UTAUT and VSD key factors (Tables 1 and 2) and are reported in accordance with these factors (data excerpts in Multimedia Appendix 3). The participants' statements are cited with interview participant identifiers IP (eg, young interview participant 1 has been referred to as IP1), and their parents' statements are indicated with an additional *P* following the number (eg, the parent of the young IP1 has been referred to as IP1P).

UTAUT Factors

Performance Expectancy

The participants described how CGM and pump technologies contributed to their success in T1DM self-management and how the use of the devices made self-management easier. CGM improved and facilitated blood glucose tracking (IP14 and IP16), allowed the young people to take breaks from diabetes management (IP13P), and led to the "satisfaction of seeing it [blood glucose management] successful" (IP1). The direct

connection of CGMs to phones was considered a major benefit (IP7). The insulin pump assisted in stabilizing blood glucose levels (IP14 and IP15), reduced the use of needles (IP2 and IP6), allowed flexible eating (IP2, IP6, and IP15), and was viewed as convenient and a device that enables a normal life (IP5P). The reduction in the use of injections by using a pump was perceived as a major advantage for small children (IP5P). Avoiding calculations was considered another benefit of the insulin pump (IP12P). Most young people expressed appreciation for having the devices, and this was also highlighted by one of the parents (IP6P).

Effort Expectancy

CGM was perceived as easy to use and put on (IP16). It did not require constant "fiddling" (IP13) and saved time (IP1 and IP5). The phone could be quickly checked instead of using finger pricks (IP2, IP6, IP7, IP11, and IP12). In addition, FGM was perceived as easy to use because "you just swipe it and you get the number" (IP4), as was the insulin pump (IP8P). The participants mentioned that they had to "calculate the carbs" for calculating the insulin dose delivered through the pump (IP3, IP4P, and IP8P). "When you just click that, so you can bolus there, put a basal on, like all that cool stuff" (IP7). The pump was considered easier to handle than insulin pens (IP5P, IP6, and IP9), owing to data storage options (IP6) and "pre-programmed" calculations (IP3):

> *I think the biggest thing when [name] got the pump for us as a family, it has made it much easier because...on a long car journey, we've got two older children, so they'd be constantly "can we have some food?" And I'd be like "no, because [name] has got to have another injection." So once he got the pump, "yeah, sure you can have some. Just dial up some more insulin, [name]."* [IP6P]

Difficulties in charging devices in some situations were mentioned (IP6P), which led to the use of insulin pens in certain circumstances (IP6P). However, in most situations, the pump could be used (refer to *Accessibility*).

Social Influence and Voluntariness of Use

Physicians recommended CGMs (IP6 and IP14) and insulin pumps (IP1P, IP2P, and IP16P), whereas people with T1DM paid particular attention to the devices used by their peers with T1DM (IP14). This helped them make decisions regarding their own devices (IP16):

> *I ask them about their pumps, because they've all got the same pump...so I talk to them about it and try and get, like, what they think about it.* [IP14]

Social influence on device decisions was closely related to the voluntariness of use, reflecting the degree to which technology use was perceived to be volitional [17]. Device decisions were taken by parents for very young children (IP10P), whereas adolescents reported that they made informed decisions on their own or together with their parents (IP3P). The parents of all the participants were closely involved in diabetes management, as the participants were all minors. Nevertheless, some young people decided against insulin pumps (IP1 and IP16) even though their physicians had recommended them, and their parents accepted these decisions (IP16P; also refer to *Accountability*).

Use Experience

The participants reported that the period when they were diagnosed with diabetes was stressful, especially the early days after diagnosis, and that they had tried to learn about the disease and how to operate the devices (IP3P, IP4P, and IP5P). Subsequently, a self-management routine was established, and self-management became easier, especially for the participants who had used devices for longer or had been living with diabetes for an extended period (IP3P and IP6P):

> *She was only a baby...with rotavirus...that was the trigger...Took her to the doctors, he said "oh look...it could be diabetes"...I had no idea what he was talking about...He phoned me that night and he said "we need you down the hospital straight away." And at that point, my life changed.* [IP10P]

The participants also reported trialing multiple devices until the best self-management solution was found to maintain blood glucose level in the ideal range (IP13 and IP15):

> *Before that he tried the Dexcom CGM, and before that he tried the...Medtronic Guardian one...it didn't really work...so that's why we went to the Dexcom, and then since he's been on this new pump, then we went back to the Medtronic one.* [IP15P]

Facilitating Conditions

Health insurance and subsidy schemes were reported to impact device use and choice; there were waiting periods for chronic conditions and device replacements (IP2P, IP3P, IP7P, IP8P, IP13P, IP14P, IP15P and IP16P) and delays in technology release processes (IP5P, IP12P, and IP14P). The release of new pump features was welcome; however, at the same time, the parents expressed concerns about the effects of new features on self-management, such as those overriding basal adjustment (IP10P). There was a desire for improved funding options to pay for devices (IP5P). The high cost of devices—especially the insulin pump—was criticized by several participants (IP2P, IP4, IP5P, and IP7), which led to the fear of device breakage (IP5P) or attempts to extend a device's life span (IP2P):

> *We had to wait until our health insurance covered it. Because they're expensive. And so now we're waiting to get the Medtronic sensor, because it's covered with one of the rebates or whatever that the government do for people under 21, but it's not covered for my older [child]...It's very expensive, it's thousands of dollars a year.* [IP7P]

Moreover, 12% (2/16) of participants mentioned problems with customer service, provided through a company hotline, for both CGM devices (IP2P) and insulin pumps (IP13P). In contrast to some difficulties with device customer service, most participants mentioned good hospital infrastructure with ongoing support provided by the diabetes health care team, including training on how to use an insulin pump (IP14):

> *That's the staff at the Canberra Hospital, they're brilliant...There's the paediatric diabetes team at the*

> *Canberra Hospital...the diabetic educators. They're great.* [IP13P]

A hospital hotline was available for the families, connecting them to diabetes educators or on-call registrars (IP4 and IP14P), as well as email contact with doctors, educators, and dietitians (IP14 and IP14P, IP15P and IP16P). Mobile numbers of endocrinologists were also provided (IP14P), and phone consultations in addition to face-to-face consultations were made possible during the COVID-19 pandemic (IP14P). The parents valued face-to-face support from the health care team (IP15P and IP16P). For some participants who had been treated in both rural and urban clinics, the rural clinics were reported to deliver less efficient consultations than urban clinics (IP2P and IP15P), and communication among the health care teams in a rural setting was criticized by one of the participants (IP15P). The interview data pointed to the possibility that the quality of diabetes support might also vary between general practitioners or pediatricians and diabetes specialists (IP13P and IP15P).

In addition to health care support, Facebook (Meta Platforms) groups for parents of children with T1DM (or other social media) were used for nonmedical queries (IP13P). Support from school personnel, such as teachers, was described as being important for safe diabetes management outside home. Most of the young participants with T1DM reported that their teachers were supportive of their device use and diabetes management in class (IP5, IP6P, IP7, IP8P, IP9P, IP13, IP13P, IP14, IP15, and IP16P); however, some highlighted problems with relief teachers (IP2 and IP4) or inappropriate behaviors by uninformed teachers or the school (IP3):

> *There was one time where a teacher asked to take the pump...well, one of my diabetic friends that goes to that school, he got his pump off him for the day, which probably wasn't good.* [IP4]

School management plans regarding device use in school were agreed on together with the health care team (IP3P and IP14) in close cooperation with parents (IP6P). CGMs were perceived as particularly helpful in the school environment (IP16P).

VSD Factors—System Features

Connectivity

Although the pump could not be directly connected to a phone for easier operation (IP14) and direct data sharing from the pump was not possible (IP2), most participants used a CGM to make the "devices...talk to each other" (IP14P; also reported by IP2, IP3P, IP4, and IP12). They tried to achieve a closed loop system, with partial success (IP7P), connecting the phone, CGM, and pump (IP2), whereas some used an Apple watch in addition (previous use: IP13 and IP13P; current use: IP6 and IP2). The Medtronic system (CGM plus pump) had the "suspend when low" function (IP2P and IP5P) but did not allow data sharing; by contrast, the Dexcom and pump combination allowed data to be shared with several other devices (IP7) but did not provide the suspend function (IP1 and IP5P). A combination of both was wished for by the participants (IP1P, IP5P, and IP9P). It was perceived as difficult to choose 1 pump or CGM system, as "they all have their pros and cons. A bit like Ford and Holden [cars]" (IP2P). Depending on the chosen system, patient data could be automatically accessed by the health care team for some patients, for example, through the Dexcom Clarity (IP4, IP13P, IP14, and IP16P), whereas others had to upload their data to a cloud system to share them with the health care team (eg, Medtronic CareLink, IP15P). Apart from the health care team, Dexcom data were mostly shared within the family (IP1P, IP4P, IP5P, IP7, IP12P, IP13, and IP14), particularly those of younger children (IP15P). The parents especially valued the sharing option (including alarms) as a "safety net" (IP1P, IP7P, IP9P, and IP16P). This option also made Dexcom the most popular CGM in the study sample (IP1).

Data Analysis, Retrieval, and Storage

The participants reported that their endocrinologists used the transmitted CGM data to calculate an average value resembling their hemoglobin A1c (HbA1c) level, especially when HbA1c testing was not possible (IP16P). However, this was described as "not always a hundred percent accurate" (IP14P). Moreover, the participants valued weekly summaries (IP4, IP7P, and IP14), data trends (IP1P and IP14), and other graphical output or visualization options of the CGM (IP5P).

To access or retrieve diabetes information, the parents used diabetes information websites (IP13P), Facebook groups for people with T1DM (IP1P and IP13P), and Google (IP4P). To access blood glucose data or information about food, young people used glucose tracking apps and food database apps (IP4):

> *So when I'm on my phone...I'll quickly switch to that [app] and check it. So then when I turn on the phone, I just glance at it and do my business before I turn it off, I just check it again.* [IP1]

Data storage was reported as a feature of insulin pumps and blood glucose meters (IP6).

VSD Factors—Values

Accessibility

Accessibility—the system's availability, adaptability, and portability—was mentioned when the young people and their parents described situations in which technology required flexibility. This included diabetes management at night, during sports, at school, or when participating in sleepovers or camps. Devices facilitated attendance at camps or sleepovers (IP1P and IP15P), with CGM and its data sharing options being more useful than the pump (IP6P and IP9). Some young people kept their CGMs on their bodies during sports and swimming (IP7, IP12, and IP16), whereas some took it off only during swimming (IP6). Water resistance of the pump was mentioned by one of the participants (IP4). The device tapes came off at times (IP1, IP2P, IP5, IP7-8, and IP13-14), so better adhesives (IP1, IP3, and IP14P), as well as reduced device sizes to facilitate physical activity (CGM: IP1 and IP3; pump: IP6-7 "bulky"), were requested. The participants expressed a desire for devices that were small but still effective (IP4) and for fewer devices that a person is required to carry with them (IP1P and IP5P):

> *What is needed is an all in one device (CGM, insulin pump and control system) that doesn't require tubes and can be controlled via an app with an algorithm*

> *that constantly regulates blood sugars that can operate as a closed loop system.* [IP14P]

Taking the pump off during swimming (IP11 and IP13) or sports (IP10 and IP15) initiated a "panic mode" that "you need to put it on silent otherwise your bag...is making all sorts of wonderful noises" (IP13P). Device alarms were reported to be challenging in various situations (IP9 and IP15P), such as when interfering with sleep (IP1P, IP2P, IP3P, IP12, and IP13P) or activities in school. Alarms were perceived as embarrassing in school (IP1, IP3, IP4, and IP15), which led to ignoring (IP2P, IP6P, and IP9) or limiting them (IP7 and IP15P) or turning the vibration or silent mode on (IP2-4 and IP15). Some parents tried to teach their children not to be ashamed of their devices. (IP2P). However, at night, alarms created a feeling of safety (IP1, IP3P, IP4P, and IP14), especially for the parents when the young people would sleep through them (IP1P, IP2, IP4, IP5P, IP6, IP7, IP8P, IP9, IP14P, and IP16P). However, alarms could be customized for different situations (IP1).

Accountability and Autonomy

At night, most parents reported taking care of their children's diabetes management (IP2P, IP5P, IP7, IP8P, IP10P, IP13P, and IP16P), which is related to perceptions of accountability and autonomy [18]. One of the participants stated that responsibility lay with their parents at night (IP1). Commonly, the parents transferred part of the responsibility to their children when they became teenagers (IP2P and IP15P), assisting them when needed (IP2P and IP16P). At that stage, the adolescents preferred some independence from their parents and the freedom to make their own decisions (IP23P, IP3, IP5, IP9, and IP10P), as they felt more confident and in control of their diabetes devices (IP14):

> *I feel like you reach a point where we kind of know a bit more [than the doctor]...because we're the ones experiencing it kind of every day.* [IP14]

Some adolescents felt like role models for younger children with T1DM (IP4P). In contrast to young people, some parents had problems letting go of the responsibility, wishing to continue data sharing (IP15P), which was at times perceived as intrusive by the young people (IP2), as they reported being fine without CGM data sharing (IP15). However, CGM data sharing also facilitated independence in some young people and reduced anxiety in parents when their control over the children was reduced (IP16P).

Trust

Independent management was associated with trust in the devices, which was affected by accuracy and device failures (IP8P). CGM technology was reported to be inaccurate at times (IP1, IP2, IP3P, IP8, IP14, IP14P, and IP16P), for example, when "it...wears down" (IP16P; similar: IP11) and when time lags occur (IP1, IP3P, IP10, IP11, IP12P, IP13P, and IP16P), whereas the pump was mostly accurate and reliable (IP3, IP8, and IP15). Technical device failures, such as blocked insulin tubing, were reported for both the pump (IP4, IP6, IP9, and IP15) and CGM (IP1-2, IP8P, IP10, and IP13). Most participants used finger pricking as a backup option when they were uncertain about the device accuracy or when recalibrating the device (IP1-6, IP8P, IP10, IP12, IP13P, IP14-15, and IP16P). They also considered other measures to improve the safety net, such as a diabetes assistance dog (IP1P). Device calibration was perceived as difficult at times; for example, taking paracetamol affected blood glucose readings and respective calibration (IP1-2 and IP14). Several participants mentioned that they trusted their bodies and the blood glucose meter more than the CGM devices (IP1, IP5, IP8, and IP14-15), for knowing when hyperevents or hypoevents are occurring (IP3, IP10, IP12, and IP13P). Trust in the health care team was equally relevant, as this gave the participants a feeling of safety in case they needed medical support. This was reported by almost all the participants (refer to *Facilitating Conditions*).

Sense Making

The participants stated that their ability to make sense of the data and give meaning to them increased with advancing age, disease duration, and independence. Diabetes education and device training played a crucial role in understanding data and managing diabetes independently (IP14 and IP16P). It was described as a gradual and individual process of learning how to best deal with the disease, its management, and device use (IP13). Graphical device outputs facilitated the sense making of numerical values (refer to *Data Analysis*). Management approaches were individual, and solutions had to be adapted to each patient, with no one-size-fits-all solution available (IP14 and IP15P). Some participants preferred multiple daily injections over an insulin pump (IP1 and IP16) or vice versa (IP6 and IP8), whereas others preferred the pump more than CGM (IP15), with CGM not working for some (IP3 and IP8).

Compliance

The degree of independence partly depended on the overall style of self-management between the parents and their children and the compliance with the care regimen. Some young people reported overmanagement (IP1 and IP1P, IP5), whereas others were not following care recommendations strictly (IP2). The omnipresence of the disease and the devices was reported as overwhelming by some participants who were strict in their management (IP5P); the participants reported that especially during puberty, it was difficult to control blood glucose levels (IP14, IP15P, and IP16P) and that they made use of the devices to improve self-care (IP14).

Dignity, Empathy, and Feedback

Negative self-management outcomes impacted the participants' dignity related to their sense of pride and self-respect, for example, receiving unfair treatment because of diabetes. Some participants reported a sense of discrimination because of being unfairly treated at school (IP14P):

> *I was forced to go back in sickbay which I didn't...want to go there because the stomach bug was there and that's really bad for diabetics to get a stomach bug. So we had to actually go to the hospital and change my claim...that I am allowed to inject in class.* [IP14]

One of the parents said that "we had to go through a lot of steps [to use the CGM in class]...you sort of feel like there's this constant discrimination for something that he has no control

over...and [there are] safety concerns" (IP3P). In another situation "they sort of buddied them up for the first school camp...but I think they don't have to be coupled just because they've got type 1 diabetes" (IP13P); especially young people's dignity could be impacted because of such treatments. Despite these challenges, empathy was reported—most young people explained that their friends, peers, and family members accepted their medical condition and were very supportive (IP1, IP5P, and IP13). Empathy was also expressed by the health care team when feedback and support were reported (refer to *Facilitating Conditions*). Parents or the health care team provided feedback based on data sharing, as well as devices in the form of automated feedback.

Hope and Joy

Overall, most participants hoped for and expected improvement in their self-management with the devices and tried to achieve normality in life, being able to enjoy life rather than being burdened by the omnipresence of the disease (IP5P, IP15P, and IP16P). Diabetes burnout was mentioned as a challenge with the omnipresence of diabetes technologies, including constant messages (IP4P) and the burden of wearing the pump all the time (IP5P). The participants reported high psychological pressure related to diabetes management, including anxiety (IP1, IP2P, IP4, IP8P, and IP14). The use of devices helped alleviate this anxiety, especially for parents (IP1P, IP2P, IP7, IP12P, and IP16P). Moreover, the participants tried to manage negative feelings such as discomfort, annoyance, and frustration related to device insertion and site changes (IP2, IP14, and IP16), carrying several devices (IP3, IP14P, and IP16), and operating the devices (IP3). In particular, pump tubing was mentioned as cumbersome (IP1, IP4, IP7, and IP9). Breath devices, such as breath ketone sensors, were considered a potentially interesting noninvasive alternative to reduce pain related to needles and finger pricking (IP1). New CGM and pump models were expected to solve these challenges (IP14), for example, with fewer calibration requirements (IP2P) or easier insertion expected in the new CGM models (IP16). Overall, the participants perceived that "benefits outweigh the negatives" (IP3P) regarding diabetes technologies.

Privacy

Surprisingly, privacy concerns or related aspects were not reported throughout the interviews, and none of the participants made any mention of data privacy.

Overall, the expectations of what devices should look like were mentioned throughout the interviews and were in accordance with all the theoretical factors from the models. Summarizing these expectations resulted in a list of device characteristics that meet young people's needs (mainly related to CGM and insulin pump use), including specific features and designs, as presented in Table 4. These included, for example, improved reliability and accessibility of diabetes technologies, facilitated device interconnectivity, data sharing and fully automated closed loop systems, improved device algorithms, device noninvasiveness, and reduced device sizes and the number of devices to be carried.

Table 4. Device characteristics reflecting young people's needs—derived from the interview findings and structured along theoretical factors.

Model, category, and factor	Device characteristics
UTAUT[a] core determinants	
Effort expectancy	• Improved ease of use of devices • Reducing effort to use technology • Facilitated integration in everyday life
Facilitating conditions	• Improved device infrastructure: easy to access customer service, reduced device cost or improved funding or subsidies, and quicker release of new technology and improved access to this advanced technology (shorter waiting periods) • Improved training related to device use in school and family environments • Facilitated cooperation with the health care team
Performance expectancy	• Features to make technology-supported self-management easier • Facilitated decision-making to select devices (eg, pump brands) • Taking preferences and expectations into account through personalization features • Increased communication of success in self-management (eg, positive feedback and rewards)
Social influence	• Improved education on device selection
UTAUT moderators	
Gender and age	• Devices taking the age of patients into consideration (the needs of young children are different from those of adolescents, eg, regarding autonomy in self-management)
Use experience	• Technology features adaptable to the needs of patients who were newly diagnosed versus patients with long disease management experience • Personalization
Voluntariness of use	• Features related to the accountability or autonomy of young person with diabetes • Avoiding extreme controlling mechanisms and offering some flexibility for the individual in data sharing setups, etc
VSD[b] system features	
Connectivity	• Improved connectivity among CGM[c], pump, and phones (closed loop), especially connecting pump directly to phone (without the need of CGM) • Fully automatized system • Improved data sharing possibilities, including no need to download data before sharing, and quick data access for HCPs[d] and caregivers (with opportunities for independence in adolescents; refer to the Accountability/autonomy category) • Combination of data sharing and automatized device cutoff mechanisms when blood glucose level is low • Improved connectivity with other devices (eg, smart watches) • Personalized regulation of device feedback (alarms and notifications)
Data analysis	• Improved algorithms and result display of insulin pumps • Improved visualization of results • Data prediction
Data retrieval and storage	• Facilitated data retrieval (eg, nutritional information included in device platform) and data storage (automatic storage of data, eg, regarding physical exercise) • Facilitated interconnection to other apps and websites
VSD values	
Accessibility	• Devices automatically adapting to new situations and conditions (eg, travel, sports, camp, sleepover, and night) • Facilitated data accessibility in these situations, including reduced device size, improved charging possibilities, robust devices, waterproof devices, improved device adhesives, and improved alarm settings (personalization and reducing faulty and excessive alarms) • Facilitated data sharing • Improved cutting off when blood sugar level is low

Model, category, and factor	Device characteristics
Accountability and autonomy	• Features supporting increased self-responsibility and independence in adolescents, with options for facilitated data sharing with HCPs and caregivers (potentially giving youth the opportunity to decide when data are not to be shared) • Facilitated diabetes management at night (number of alarms, etc) • Improved parent-child dynamics
Compliance	• Features that improve compliance with care regimen and reduce overmanagement at the same time
Dignity	• Features that reduce discrimination or unfair treatment, devices improved for use in public or at school (alarms, injection in class, etc)
Empathy	• Features to share empathy • Improved communication features
Feedback	• Facilitated feedback from HCPs and caregivers through the devices • Improved automated and personalized feedback (without increasing the number of messages and input, which might lead to diabetes burnout, for example, by providing personalization options for notifications)
Hope and joy	• Features that enable normality in life, reduce the omnipresence of disease and device overload, and reduce anxiety (feeling of safety) • Reduced alarms and messages to prevent diabetes burnout (personalization) • Reduced discomfort with devices, for example, reduced number of devices to be carried, reduced insertion discomfort, noninvasiveness, improved tapes, and no use of tubes and wires (pump)
Privacy	• Data privacy of sensitive health data
Sense making	• Data that can be easily understood and interpreted, including by youths • Graphical outputs for fast interpretation
Trust	• Accuracy and reliability of devices without time lags, mirroring hypoglycemia and hyperglycemia awareness, reduced technological failures, and facilitated calibration or lack of need for calibration (increasing trust)

[a]UTAUT: unified theory of acceptance and use of technology.

[b]VSD: value-sensitive design.

[c]CGM: continuous glucose monitor.

[d]HCP: health care professional.

Discussion

Principal Findings

All the factors in the UTAUT and VSD theories, except for one (privacy), aligned with the themes independently identified through data-driven user experience analysis, indicating that these theories have value in structuring the data analysis and empirical findings. This also demonstrates the alignment of the empirical interview data with both the existing theoretical models. Multimedia Appendix 3 summarizes the alignment of the initial themes with the theoretical factors and provides exemplary data excerpts.

We were intrigued that the participants in our study did not raise issues of privacy, as this was considered to be of great importance in previous research examining the VSD of technologies [27]. Britton and Britton-Colonnese [38], for example, highlighted the data privacy and security risks associated with CGMs, such as the lack of possibilities to control how patient data are collected, stored, and used. Young people are more likely to be concerned about privacy on the internet than older people, recognizing the compromises that they must make to their own privacy to use embedded web-based networks [39]. It is possible that CGM data do not strike young people as compromising privacy as clearly as social media does. Future user experience research should focus specifically on privacy aspects to elucidate potential concerns of young people and their parents regarding diabetes technologies—such as if CGM data are regarded as risky for privacy—and how these concerns might be important for device design.

We compared this study's findings with a previous systematic integrative review of 17 studies on the experiences of young people living with T1DM and their caregivers with using technologies to manage T1DM [8]. The review identified eight themes: (1) expectations of the technologies before use, (2) perceived impact of technology use on sleep and overnight experiences, (3) experiences with alarms, (4) impact of technology use on independence and relationships, (5) perceived impact of technology use on blood glucose control, (6) device design and features, (7) financial cost, and (8) user satisfaction. Despite the independent analysis of both studies, there was a major overlap between the review themes and our UTAUT- and VSD-aligned interview study findings (Tables 1 and 2). Our results confirmed the results of previous studies, which we see as an important research strategy to validate empirical results.

Messer [40] argued that with new technological advancements, expectations among some individuals regarding new diabetes

technologies are high at first (idealism) but then fall when reality does not match these expectations. The systematic review [8] reported that some of these expectations are related to the self-sufficiency of these technologies, resembling an actual artificial pancreas system that can make life easier and enable normality, reducing the burden of the disease. Similar wishes and expectations were expressed in the interviews, for example, related to fully automatized systems (factor *Connectivity*). In line with the systematic review [8], the participants in our study indicated that reality diverted from these expectations, with inaccuracy problems reported in CGMs (time lag in interstitial fluid measurements) and technical failures occurring in both CGMs and insulin pumps. When reality does not match initial expectations, it can lead to a risk of nonadherence and discontinuation of therapy due to frustration [40]. By contrast, not all users initially set their expectations high, as shown in another study by Quintal et al [41], with some people expecting inconveniences regarding technical limitations, cost, wearability, or similar aspects before using the technologies [41]. Overall, accuracy and reliability were highlighted as the most important technological criteria in our study, in line with other studies [8,42].

Apart from expectations before use, diabetes management at night and device alarms, as found among the review themes [8], were major concerns for the participants in our study (factor *Accessibility*), whereas independence was a topic especially raised by adolescents or teenagers (factor *Accountability/autonomy*) in both our study and the review. Similarly, Babler and Strickland [43] found that adolescents experienced challenges with independent care and conflicts with their parents. Diabetes-related distress, family conflict, and depressive symptoms were reported as barriers toward using diabetes technologies [44]. Previous research described a learning curve traversed by individuals newly diagnosed with T1DM as they gradually learn how to self-manage T1DM with devices and in cooperation with important others such as the health care team and parents [45]. Distress was mentioned in our study as being particularly high in the early days after the diagnosis. Both the review [8] and our study reported that diabetes technologies were able to alleviate psychological challenges such as anxiety to some extent.

The outcomes of technology use for self-management and overall satisfaction with the devices were discussed as part of the UTAUT factors *Performance and Effort Expectancies* and VSD values in our study, with most participants acknowledging the benefits of the devices. A previous study on CGM and insulin pump use in the United States and Germany [46] stated that 47% of pump users were very satisfied with the pump and 98% would recommend the pump to others, whereas only 84% would recommend CGM to others. Apart from device failures and in line with the review [8], the participants in our study reported that cost and funding were major barriers to device accessibility.

Finally, our study participants highlighted certain aspects that expanded the themes of the systematic review [8]. These included perceived discrimination towards having a chronic disease such as T1DM. This was a good fit for the VSD factor *Dignity*. In contrast to a previous study showing difficulties in integrating technologies into clinical workflows [42], most participants in our study reported the process of sharing their diabetes data with the health care team and integration of these data into a consultation to be smooth. According to Vrijhoef et al [47], integrated care pathways could be used for mutual decision-making between patients and health care professionals, supported by information technologies that facilitate patient empowerment and improve monitoring and management [47]. Overall, one particular strength of our study was the combination of data-driven and theory-driven analyses. None of the 17 studies included in the systematic review [8] used a theoretical foundation to underpin their examination of experiences, despite the proven benefit of using theory in research [15]. Incorporating knowledge from 2 different theoretical approaches (technology acceptance and technology design) into our study design enabled us to produce research aligned with a theoretical foundation and add new (knowledge from) empirical data to the existing theories. This has resulted in a piece of research that supports the use of theory in user experience research, suggesting that such an approach is fruitful for the future; this is because theory can inform our user experience data analysis, and new empirical data can be provided to support or expand the existing theoretical foundations. In our study, all the interview themes could be aligned with the theoretical factors from UTAUT and VSD, suggesting that the 2 theories provide a comprehensive foundation (using UTAUT alone would have made it difficult to align emotional themes such as discrimination, as they do not align with UTAUT factors). The combination of UTAUT with VSD allowed us to combine 2 theoretical approaches examining technology and its uptake from different angles. This has the potential to expand the focus of research on one topic, by taking 2 lenses into consideration. Similar approaches for combining theories can be found in recent literature on various health topics [48,49]. The minimal overlap of factors in our 2 selected approaches, the difference in focus on technology and its uptake, and the possibility to fill the theoretical limitations of one theory with the other, as described above, means that the 2 approaches complement each other very well. Thus, a sound foundation is available for understanding user experiences to advance diabetes technologies. Further research is needed on such a hybrid approach to further evaluate and substantiate the use of theory combinations in empirical research. This will ultimately inform the design of new technologies and addresses a general lack of theoretical underpinnings in studies on diabetes and other health technologies [14].

Study Limitations

Our findings were based on the self-reports of young people with T1DM and their caregivers. Additional perspectives of health care professionals would also provide valuable insights into this topic. A degree of self-selection of the participants was unavoidable because of the voluntary nature of study participation. This might have led to an overrepresentation of young people with T1DM who managed their disease well. Perspectives might differ in people with T1DM who struggle with its management or who do not follow their care regimen. However, we did not have access to the participants' clinical results, such as HbA1c, to confirm how well their diabetes was managed. We did not aim to quantify the results; thus, the results

are not generalizable and specifically correspond to young people in the respective setting. However, we found a large overlap of our study findings with other studies' results, as shown in the comparison with a recent systematic review [8]. To quantify the results or eliminate differing technical properties of the various insulin pumps or CGMs, a study with a larger sample would be required.

Conclusions

Our study indicates that technologies for diabetes self-management require continual advancement to meet the needs and expectations of young people with T1DM. Understanding their experiences and challenges with using devices enabled us to identify a variety of device characteristics that reflect the needs of the young people interviewed. The identified characteristics can be useful in designing and developing improved technologies, ideally including participatory design approaches. Our research highlights the benefits of the transdisciplinary use of exploratory and theory-informed methods for designing improved technologies. In our study, theoretical technology acceptance and VSD approaches proved useful as a combined foundation for structuring the study findings regarding technological experiences. Our results confirmed the results of previous studies and that the combination of theory and empirical results can offer greater surety. In addition to clinical or regulatory guidelines, the use of theories is important to integrate new empirical findings into the existing theoretical knowledge and expand and further develop theoretical knowledge to advance the rigorous and informed design of diabetes technologies.

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Data Availability

Further information about the study can be provided upon request (corresponding author).

Authors' Contributions

NB-S, AP, JD, and MC had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All the authors were involved in the study concept and design. HS and AH guided the development of the theoretical foundation of this study. MC and NB-S conducted the initial analysis. The findings were discussed with AP. MC, NB-S, AP, and JD were involved in the subsequent analysis and interpretation of the data. NB-S drafted the manuscript, and all the authors were involved in the revision. JD and HS supervised the study.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Initial themes derived from the interviews (coding schema).
[DOCX File , 20 KB - diabetes_v8i1e43377_app1.docx]

Multimedia Appendix 2
Additional value-sensitive design factor explanations.
[DOCX File , 20 KB - diabetes_v8i1e43377_app2.docx]

Multimedia Appendix 3
Alignment of the initial themes with theoretical factors and relevant data excerpts.
[DOCX File , 24 KB - diabetes_v8i1e43377_app3.docx]

Multimedia Appendix 4
COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist.
[PDF File (Adobe PDF File), 1289 KB - diabetes_v8i1e43377_app4.pdf]

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Abbreviations

CGM: continuous glucose monitor
COREQ: Consolidated Criteria for Reporting Qualitative Research
FGM: flash glucose monitor
HbA1c: hemoglobin A1c
IP: interview participant
T1DM: type 1 diabetes mellitus
UTAUT: unified theory of acceptance and use of technology
VSD: value-sensitive design

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Original Paper

Experiences and Perceptions of Telehealth Visits in Diabetes Care During and After the COVID-19 Pandemic Among Adults With Type 2 Diabetes and Their Providers: Qualitative Study

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Abstract

Background: Since the COVID-19 pandemic, telehealth has been widely adopted in outpatient settings in the United States. Although telehealth visits are publicly accepted in different settings, little is known about the situation after the wide adoption of telehealth from the perspectives of adults with type 2 diabetes mellitus (T2D) and their providers.

Objective: This study aims to identify barriers and facilitators of maintaining continuity of care using telehealth for patients with T2D in a diabetes specialty clinic.

Methods: As the second phase of a multimethod study to understand missed appointments among adults with T2D, we conducted semistructured, individual, in-depth phone or Zoom interviews with 23 adults with T2D (14/23, 61% women; mean age 55.1, SD 14.4, range 35-77 years) and 10 providers from diabetes clinics in a tertiary academic medical center in Maryland. Interviews were audio-recorded, transcribed, and analyzed using thematic content analysis by the research team.

Results: Adults with T2D and their providers generally reported positive experiences with telehealth visits for diabetes care with some technical challenges resulting in the need for in-person visits. We identified the following 3 themes: (1) "perceived benefits of telehealth visits," such as convenience, time and financial efficiencies, and independence from caregivers, benefits shared by both patients and providers; (2) "perceived technological challenges of telehealth visits," such as disparities in digital health literacy, frustration caused by unstable internet connection, and difficulty sharing glucose data, challenges shared by both patients and providers; and (3) "impact of telehealth visits on the quality of diabetes care," including lack of diabetes quality measures and needs and preferences for in-person visits, shared mainly from providers' perspectives with some patient input.

Conclusions: Telehealth is generally received positively in diabetes care with some persistent challenges that might compromise the quality of diabetes care. Telehealth technology and glucose data platforms must incorporate user experience and user-centered design to optimize telehealth use in diabetes care. Clinical practices need to consider new workflows for telehealth visits to facilitate easier follow-up scheduling and lab completion. Future research to investigate the ideal balance between in-person and telehealth visits in diabetes care is warranted to enhance the quality of diabetes care and to optimize diabetes outcomes. Policy flexibilities should also be considered to broaden access to diabetes care for all patients with T2D.

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KEYWORDS

telehealth; type 2 diabetes mellitus; adults; user experience; care continuity

Introduction

It is estimated that there are more than 37 million people in the United States with diabetes mellitus, and 90% to 95% of those cases are type 2 diabetes mellitus (T2D) [1]. Working with health care professionals is essential for diabetes management [2,3], but 12% to 36% of people with diabetes did not attend their regular medical appointments before the COVID-19 pandemic [4,5].

Telehealth, the use of telecommunication technologies to provide health care remotely [6], has been widely adopted in the United States in outpatient settings since the COVID-19 pandemic began in 2020, to mitigate the spread of COVID-19 [7]. Telehealth visits reduced people's travel time and expenses, limiting COVID-19 exposure, and enabled clinicians to view a person's lifestyle and environment [8-10]. Telehealth has been publicly accepted as a form of consultation and perceived positively by patients, caregivers, and providers in cancer, nephrology, and primary care settings [8-14]. The limitations cited by both patients and providers included technological challenges and the inability to perform a physical exam [8,10,12].

Specific to diabetes care, the transformation from in-person to telehealth visits has the potential to democratize routine diabetes care provision, such as providing care to those with limited transportation who otherwise could not be at the clinic regularly [15,16]. A previous study found that telehealth visits reduced the odds of missed appointments by more than 50% among adults with T2D, compared with in-person visits [17]. Telehealth visits also addressed some barriers (eg, better access to appointments, shorter travel time) of in-person visits in a group of veterans with T2D living in rural areas before COVID-19 [18]. Since the COVID-19 outbreak, many people with T2D have tried telehealth for the first time, with positive perceptions because no in-person care was provided during stay-at-home orders and insurance coverage expanded [19,20]. Promisingly, the reduction of in-person visits and increase of telehealth visits during the COVID-19 pandemic did not result in compromised glycemic control among adults with T2D with commercial or Medicare Advantage health plans [21].

However, some endocrinologists believed telehealth visits were more helpful for people with type 1 diabetes mellitus (T1D) compared with those with T2D because people with T1D are more closely monitored by continuous glucose monitoring (CGM) and insulin pumps [22]. Additionally, some patients with T2D and providers had concerns related to confidentiality and the quality of physical exams during a telehealth visit [20]. A systematic review of 20 articles on telehealth and telemonitoring in diabetes care found scant evidence examining the preferences and satisfaction of people with T2D in using telehealth [23]. Given that little is known regarding the impact of telehealth on T2D care from both patients' and providers' perspectives after the wide adoption of telehealth visits during the pandemic, the purpose of this study was to identify barriers and facilitators of maintaining continuity of care using telehealth for patients with T2D in a diabetes specialty clinic.

Methods

Study Setting

This qualitative narrative study took place in the Johns Hopkins Diabetes Center, a multidisciplinary team (physicians, endocrinology fellows, nurse practitioners [NPs], registered dietitians, and certified diabetes care and education specialists) providing comprehensive diabetes care across multiple locations in the greater Baltimore area affiliated with a tertiary academic medical center in Maryland. There were no telehealth (video or phone) visits before the COVID-19 pandemic. During COVID-19, appointments at the Johns Hopkins Diabetes Center were transferred to telehealth visits on March 23, 2020, after the expansion of coverage by the Centers for Medicare & Medicaid Services [24]. The clinics started scheduling both in-person and telehealth visits based on patients' preferences and their COVID-19 risk around September 2020. Around the time of the interview, the clinicians would have at least one session (4-hour block) for telehealth visits per week.

In normal circumstances, the telehealth visits at Johns Hopkins are through MyChart (Webex by Cisco). A medical assistant usually calls a day before the appointment to verify patients' physical locations to meet individual state regulations. On the day of the appointment, vital signs and medical history are verified again through a phone call after a patient completes the electronic check-in through MyChart. Before the scheduled appointment time, the link to "start your video visit" appears to initiate the visit. The link for the video visit can be sent via text message if a patient does not use MyChart. A simple phone call may be used if the patient does not have devices with video capabilities [25].

Recruitment and Study Participants

The findings for this manuscript were the second part of a multimethod study focusing on missed appointments among adults with T2D. In short, the first part of the study used electronic health records (EHRs) to examine if predictors of missed appointments differ (1) between pre-COVID-19 (January 2019 to March 2020) and COVID-19 (March 2020 to December 2020) periods and (2) by health care delivery modes (in-person or telehealth visits) during COVID-19 among adults with T2D; more information is described elsewhere [17].

Based on the results of the first phase, the eligibility criteria for this qualitative study included a diagnosis of T2D, age greater than 18 years, residence in the state of Maryland, and at least one appointment with either a physician or an NP marked as a no-show in the EHR in the past year at the time of recruitment (February 2022 to July 2022). Adults who met the inclusion criteria were identified from the EHR and then were contacted via emails, phone calls, or text messages. We used purposive sampling with maximum variation to include adults from different physicians and NPs with diverse characteristics (eg,

age [<60 years old, 61-75 years old, >75 years old], sex [female, male], race/ethnicity [Black, White, other], health care delivery modes [in-person or telehealth visits]) based on our quantitative results [17].

Potential provider participants were invited through a study presentation by one of the authors (CAS) at the monthly diabetes center meeting. CAS then emailed the study information to all potential provider participants. All physicians and NPs working at the Johns Hopkins Diabetes Center were eligible to participate.

Ethical Considerations

The Johns Hopkins Medicine Institutional Review Board (IRB; #IRB00231790) approved the study design and procedures. Verbal consent was obtained from each participant.

Data Collection

The study team developed a semistructured interview guide to explore perceptions among people with T2D and their providers regarding the barriers and facilitators of keeping appointments for both in-person and telehealth visits, with a focus on interpersonal relationships. The initial interview guide drafted by CAS was based on the findings of our previous quantitative study on missed appointments during the COVID-19 pandemic [17] and previous literature on user perceptions of telehealth [18-20,22]. Interview questions were revised and discussed among team members after the first 3 interviews with patients and providers. Example questions and probes to patient participants included the following: “Can you describe your experience doing a telehealth/video visit with your diabetes providers?” “What do you like the most and why?” Example questions and probes to provider participants included the following: “What is your experience of telehealth visits?” “How do you like it?” “What are the differences between providing care via telehealth or in-person visits?” The final qualitative interview guides are included in Multimedia Appendix 1.

One-on-one 30-minute to 45-minute phone or Zoom interviews were conducted by 2 trained interviewers (CAS and ZS) from February 2022 to July 2022 until thematic saturation was reached. In total, we contacted 52 eligible people with T2D; 28 refused (ie, not interested in the study topics, no times to be interviewed, no replies after 3 calls or text messages), and 24 agreed to participate. Of those participants agreeing to participate, 23 completed the interview, and 1 participant was excluded due to a mislabeled T2D diagnosis on the EHR. Among 12 eligible providers, 10 (8 physicians and 2 NPs) agreed to participate and completed the interviews. All phone interviews were audio-recorded; all Zoom interviews were recorded using Zoom’s recording features. Only audio recordings were saved and sent to a professional transcription vendor approved by the Johns Hopkins IRB for verbatim transcription. After verifying the accuracy and removing identifiable information, transcripts were imported into f4analyse for coding and analysis.

Data Analysis

The analysis began after the transcription of the first interview and continued throughout data collection. We conducted a thematic content analysis of the interview transcripts, a common method of analysis when coding categories are derived directly from data [26,27]. Each transcript was read and coded independently by at least 2 of the 3 coders (CAS, ZS, and SZ). The study team identified codes for patients and providers separately. Any discrepancies in the codes were resolved through discussions referring to the transcripts until at least 2 study members reached a consensus to ensure coding consistency. Each coder then grouped similar codes into emerging themes by patients and providers. The study team discussed all emerging themes and finalized themes and subthemes. During the ongoing discussions, the study team realized some themes were similar across patient and provider participants and, thus, decided to further merge the themes as one.

Rigor

Reflexivity was achieved through discussions between interviewers and written notes after the interview. Trustworthiness was maintained through team discussions and audit trail documentation; all documentation was kept using Microsoft Word. The transferability of the study was enhanced by providing a thorough description of the study method, study setting, and our processes of data collection [28].

Results

Participant Characteristics

Patient Characteristics

Details of characteristics of persons with T2D included in this study can be found in Table 1. Among 23 participants, >50% (14/23, 61%) were female, with an average age of 55.1 (SD 14.4) years. The majority of participants were Black, and all were non-Hispanic. Of the adult participants, 87% (20/23) had an active patient portal account, although 1 person had never logged in and 1 person had logged in more than a year ago at the time of the interview.

Table 1. Characteristics of persons with types 2 diabetes mellitus (T2D) at the time of the interview (n=23).

Characteristics	Results
Age (years), mean (SD; range)	55.1 (14.4; 35-77)
Sex, n (%)	
Female	14 (61)
Race, n (%)	
Black	12 (52)
White	10 (44)
Other	1 (4)
Insurance, n (%)	
Medicare	12 (52)
Medicaid	7 (30)
Commercial	4 (17)
Diabetes medications, n (%)	
Any insulin	16 (70)
Continuous glucose monitoring, n (%)	
Ever used	8 (35)
Patient portal account, n (%)	
Activated	20 (87)
Time of care initiation, n (%)	
Before March 2020	15 (65)
Health care delivery experience, n (%)	
In-person visits only	4 (17)
Both in-person and telehealth visits	19 (83)

Provider Characteristics

Among 10 provider participants (8 physicians, 2 NPs), there were 7 female and 3 male providers, with an average service time at the institution of 7.2 (SD 4.54, range 1-14) years.

Qualitative Findings

Overview

We identified 3 themes with 13 subthemes addressing patients' and providers' perspectives on telehealth visits in T2D care (see Table 2). Both patients and providers identified multiple benefits of telehealth visits in diabetes care but with certain technical challenges. Those challenges in telehealth visits resulted in negative clinical implications and called for the need for at least one annual in-person visit in diabetes care.

In the following sections, we first describe the first theme, "perceived benefits of telehealth visits," shared by both patients and providers, followed by the benefits noted by providers only. We then describe the second theme, "perceived technological challenges of telehealth visits," shared by both patients and providers. Finally, we describe the third theme, "impact of telehealth visits on the quality of diabetes care," as perceived by both patients and providers, though mainly from providers' perspectives with some patient input. Direct quotes are presented in the following sections.

Table 2. Themes and subthemes from patients' and providers' perspectives.

Themes	Provided quotes	
	Patients	Providers
Theme 1. Perceived benefits of telehealth visits in diabetes care		
Diabetes care "in the comfort of your home" at a time of one's convenience	Yes	Yes
Saving money and time due to no need for transportation	Yes	Yes
Relief from relying on one's caregiver and less "juggling to get it into our schedule"	Yes	Yes
Efficient visits, fewer delays, and more time with adults with T2D[a]	No	Yes
Theme 2. Perceived challenges related to telehealth visits		
Disparities in digital health literacy and lack of devices as barriers to telehealth visits	Yes	Yes
Frustration caused by unstable internet connection	Yes	Yes
Phone visits not encouraged	No	Yes
Difficulty sharing glucose data	Yes	Yes
Theme 3. Impact of telehealth visits on the quality of diabetes care		
A double-edged sword for care continuity	No	Yes
Perceived incomplete visits due to no diabetes quality measures	Yes	Yes
Compromised care quality due to unavailability of glucose data and/or unpreparedness of their patients	No	Yes
Needs for and preferences of in-person visits	Yes	Yes

[a]T2D: type 2 diabetes mellitus.

Theme 1. Perceived Benefits of Telehealth Visits in Diabetes Care

The majority of persons with T2D and provider participants described positive experiences with telehealth visits due to several benefits, mainly noting increased convenience and efficiency as compared with in-person visits. We identified the following 5 subthemes: (1) diabetes care "in the comfort of your home" at a time of one's convenience; (2) saving money and time due to no need for transportation; (3) relief from relying on one's caregiver and less "juggling to get it in our schedule"; (4) efficient visits, fewer delays, and more time with patients; and (5) a good fit for data-driven diabetes care.

Regarding the first subtheme (diabetes care "in the comfort of your home" at a time of one's convenience), many adults with T2D specifically cited the convenience of being able to conduct telehealth visits from their homes or at a private location conducive to their schedule. Similarly, from providers' perspectives, many providers acknowledged the added convenience of telehealth visits for their patients, citing reasons largely in alignment with what patient participants mentioned:

> *It's really convenient, I don't have to take off from work, I don't have to park. Based on the time of the day, any time prior to like 3 o'clock, the parking garage is pretty well filled up. So, it just really alleviates a lot of additional stress, and a lot of the times, I can either do it at work in a secluded area. I think it's just great, very convenient.* [Adult09]

> *I think the benefit of telehealth is patients who are not coming in because of either distance or they can't find the time to come in at least we have this as a resort to say, "Well, if you can take 20 minutes out of your workday even at work, we can at least still see you and try to do some management." I think it's useful in that sense.* [Provider09]

Regarding the second subtheme (saving money and time due to no need for transportation), people with T2D who drive to in-person visits expressed contentment about not having to pay for parking or gas. Adults who take public transportation to attend in-person visits were satisfied with telehealth visits due to saving money and decreased wait times for both transportation as well as in the provider's office. Many providers empathized with people's economic and time constraints that often hindered in-person visit attendance. The following quotes from a person with T2D and a provider reflect the mutual understanding of the perks of being able to conduct diabetes care visits irrespective of their physical locations:

> *Yeah, I do like the video visits. I mean, because it saves money. You know, you don't have to worry about transportation to and from. You know, you could be in the comfort of your own home.* [Adult18]

> *I think it (video visit) is a fantastic way to extend care to people who don't have to drive into our clinic, don't have to park, don't have to waste probably an hour to 2 hours of their day.* [Provider06]

Regarding the third subtheme (relief from relying on one's caregiver and less "juggling to get it into our schedule"), several people with T2D shared their emotional burden of having to rely on their caregivers (ie, family) to attend in-person visits for a variety of reasons. For them, sharing one vehicle meant that family members had to miss time from work or skip their own medical appointments to help people with T2D with transportation to in-person diabetes visits, or sometimes the adults with T2D would need to skip their visit in lieu of their caregivers. Hence, when telehealth visits were available, these adults with T2D felt content as they no longer needed to rely on others for in-person visits. This quote highlights the experience of 1 participant who had a right leg amputation:

> *To me, it's convenient that you don't always have to go into the hospital because my fiancée works 9 to 5, which is most of the time that appointments are, so she doesn't have to miss time from work to take me. Normally I could drive, but now with this amputation, I can't do that myself. So, they help a lot, that everything can be done right through a video call, don't actually have to be there.* [Adult10]

A provider also acknowledged the barriers of in-person visits, saying:

> *The patients, I think, though, have more of a struggle (doing in-person visits) than we do because of transportation and coming in. If they're older and they don't drive, and yet they need to be driven there, that kind of thing.* [Provider04]

The fourth subtheme (efficient visits, fewer delays, and more time with adults with T2D) was unique to providers. Providers described how telehealth visits can be conducted more efficiently than in-person visits, thereby reducing delays in their daily schedule and allowing them to maximize their time spent with each patient. One provider participant contrasted their use of time during in-person and telehealth visits and the beneficial impact on their daily workflow:

> *The person has to get transportation to (the clinic), and then maybe if they have a vehicle, they have to park it. There's the process of getting signed in, and my 1:00 patient who arrives a couple minutes after 1:00, and then the medical assistant is a little busy, may not get them in the room until 1:25, which can then set my schedule behind. Whereas on telemedicine, I'm running it, I can say to a patient, if we need to wrap-up, like "We only have 5 more minutes," and I know I'll have somebody coming into the queue, who will be ready to go ahead and have their appointment. It's easier to structure the patient to the amount of time you have and also make use of that full amount of appointment time, because you immediately sign onto them, so there's no delay at all.* [Provider04]

The fifth subtheme (good fit for data-driven diabetes care) was unique to providers. Most providers mentioned that diabetes care was suitable for telehealth visits as it focused more on the behavioral and cognitive perspectives. However, providers also specifically expressed the requirement of having home blood glucose data to provide optimal diabetes care and a treatment plan to their patients. This practice is particularly important in telehealth visits as most adults might not have an available glycated hemoglobin (HbA_{1c}) measurement for the telehealth visits as compared with in-person visits, where a point-of-care HbA_{1c} is taken. Advances in diabetes technology allow most people with diabetes to share their blood glucose data before telehealth visits.

> *Diabetes care, half the time, I don't even put my hands on a patient, other than to look at their toes and maybe recheck their blood pressure. It really is whatever they say, a cognitive specialty. If they (adults) can share their readings from home, it can be just as good and preferable from the patient's perspective.* [Provider02]

Theme 2. Perceived Challenges Related to Telehealth Visits

Despite the aforementioned benefits, patient and provider participants all faced some challenges related to technology during telehealth visits. To complete a successful telehealth visit in diabetes care, people with T2D needed to have a digital device, know how to get online, navigate the patient portal to the nested telehealth platform, upload their glucose data via a cloud or patient portal, and have familiarity with manipulating the video camera and volume. Any disruption could happen during this process, which could result in a suboptimal experience. We identified 3 subthemes related to technological challenges from both adults and providers and 1 subtheme unique to providers.

Regarding the first subtheme (disparities in digital health literacy and lack of devices as barriers to telehealth visits), when navigating technology aspects of telehealth (eg, using a digital device, patient portal, telehealth platform, uploading glucose data) throughout COVID-19, some people with T2D were proficient from the beginning, while others required additional support from staff at the diabetes clinics or other family members. For other patient participants, the repeated practices over time made them more comfortable with telehealth-related technology:

> *I've got a desktop that we've had for some time, and my wife is a technical genius in the house, she helped me get it set up three times now, I'm an old veteran; I could do it solo now.* [Adult04]

However, 2 people with T2D specifically cited computer illiteracy as the reason for not utilizing the patient portal (Adult06, Adult18). In this case, they would rely on providers to contact them using alternate video platforms (eg, Doximity, FaceTime) without going through the patient portal. All

providers acknowledged that the use of telehealth required digital health literacy and were prepared to use different ways to connect with their patients. A provider discussing the limitations of telehealth visits mentioned the following:

> *Not everybody has a computer at home, which is a problem. Or they don't have iPhones, so, we can't do a Facetime call with them. (...) Any of these technical issues mean that we can't cover as much in that half an hour as I would if I saw them in person because you don't have those limitations in person.* [Provider10]

Both people with T2D and providers acknowledged that the lack of digital devices was a barrier to telehealth visits. At the time of the interview, 3 adults did not have a digital device with a camera capacity (Adult02, Adult07, Adult15). Of these adults, 2 had only phone visits during the peak of COVID-19, while the other person had only in-person visits as he established care after in-person visits resumed. One person who only had experiences with phone visits stated the following:

> *No. I don't even know how to work that (video visit), uh-uh. I just have telephone calls. I don't know how to do none of that virtual stuff. (...) I just upgraded my phone, but I'm saying I still don't know how to work it real good.* [Adult07]

Regarding the second subtheme (frustration caused by unstable internet connection), once people with T2D and providers were connected, echoing in voices and delay in transmission due to unstable internet connection were other issues that undermined the quality of conversation and sometimes caused frustration for both parties involved. As most of the allotted time was spent on nonmedical issues (ie, trying to get connected with each other), people did not have enough time to ask questions, and providers were unable to properly deliver care. A provider provided the following quote when discussing the disadvantages of telehealth visits:

> *It really comes down to the connection and the person's savvy with it. I had a lady, lives in Virginia, and she's elderly, and a friend had to drive her over the line into Maryland. So, they were in the car trying to get a connection with me, and where they were, it wasn't good connection. So, I'm seeing her frozen face, she sees my frozen face, we halfway hear each other, and finally it had to degrade into a phone conversation.* [Provider04]

A person with T2D discussing this frustration in her previous telehealth experience mentioned the following:

> *It (video visit) didn't go through. We were talking and then it kept disconnecting. The call kept dropping, so we had to wind up just texting. So, 1 out of 5, I'd give it a 1. (...) I will not give it (the video visit) a try.* [Adult21]

The third subtheme (phone visits not encouraged) was unique to providers. At the time of the interview, phone visits were not encouraged due to the complexity of the reimbursement and compliance issues. Although phone visits were the least preferred method for providers to connect with their patients, it was a necessary backup when connection issues or the other abovementioned technical issues persisted.

> *You can't bill for phone visits. (...) Or you can bill for it, but you won't get reimbursed for it. So, then why did I go to all that trouble? Then, I can just have my secretary set up a phone call, and I can just have a phone call, which will work easier, instead of doing this thing of getting onto EPIC—it's a nightmare. Not good.* [Provider06]

Regarding the fourth subtheme (difficulty sharing glucose data), both people with T2D and providers mentioned the potential obstacles of sharing glucose data in telehealth visits. Depending on the devices (ie, CGM or glucometer) a person uses, sharing glucose data can be either easy or very troublesome. Patient participants with a CGM generally reported a smooth and easy process for sharing data compared with those with a traditional glucometer. However, not everyone with T2D was eligible for insurance coverage for a CGM, which is expensive for a person paying out of pocket. Many adult participants using a glucometer reported sending handwritten documents ahead of the telehealth visits or reading their daily glucose data in the past few weeks aloud during the telehealth visits. A person with T2D with experience using both glucose monitoring systems shared his experience:

> *Before, it (sharing glucose data) was really easy. Now that I've got different insurance, it's not as easy as it was before, because before I had a CGM and it could just upload the information. So, I just uploaded the information to my dock . Now I'm back to pricking my finger (glucometer), I can't (upload my data), it (the glucometer) didn't do the same. I've got to keep a record of it myself and share it with my doctors.* [Adult04]

Sometimes, if a person did not have their glucometer with them, a provider would rely on the person's memories of their glucose trends to decide on the treatment plan. Either way, this process took extra time for providers to make sense of the glucose data (eg, time in range, average, trends) before a clinical judgment was made. Those practices specific to telehealth visits either increased the time needed by providers or limited the length of a visit to address adults' questions and concerns:

> *I had to have them (during telehealth) grab their glucometer and scroll through the numbers and read to me what those were, but for a 20-minute visit, if they're doing that for more than 10 minutes, it really leaves us not much time to go over other things.* [Provider09]

Theme 3. Impact of Telehealth Visits on the Quality of Diabetes Care

The aforementioned benefits and challenges of telehealth had clinical implications for diabetes care. We identified 4 subthemes mainly from providers' perspectives with support from patient input, including "a double-edged sword for care continuity," "perceived incomplete visits due to no diabetes quality measures," "compromised care quality due to

unavailability of glucose data and/or unpreparedness of their patients," and "needs for and preferences of in-person visits."

The first subtheme (a double-edged sword for care continuity) was unique to providers. With all the needed information on hand, telehealth visits allowed providers to offer more frequent quality diabetes care to adults with T2D who traditionally could not attend in-person visits often due to geographic barriers or other transportation-related issues:

> *I think this model (telehealth setting) has some advantages in that way, I mean they can touch base more frequently, they might be shorter communications, but they're more frequent as opposed to spaced out longer in-person visits.* [Provider07]

Provider participants also noticed that telehealth visits decreased missed appointments, which increased care continuity. Adults with T2D scheduling a telehealth visit received at least one extra reminder because current regulatory requirements mandated the verification of a person's location before the visit. Additionally, due to the unpredictable nature of technical issues in telehealth visits, providers were more likely to outreach to adults despite an initial absence on the telehealth platforms. Most of their patients were able to remotely engage immediately in telehealth visits when prompted by a provider's phone or video call. A provider described missed appointments and provided the following quote:

> *I will say, with telemedicine, it's easier, because you can just call them and say "Hey, you have an appointment, let's just talk right now." A lot of people will say "Okay, that's fine."* [Provider03]

On the other hand, the current telehealth workflow in the diabetes clinics requires adults with T2D to take the initiative to schedule their next appointment after a telehealth visit, instead of scheduling the next appointment at the front desk on the way out of the office after an in-person visit. Although it did not bother people with T2D in this study, a person described how her other health conditions delayed her scheduling the next appointment:

> *I know I need to schedule an appointment. In fact, I was gonna call this week, but I'm getting a medical procedure, so Monday I was seeing other health care providers, so probably next week, I'll call the scheduling line and set up something or try and do it through MyChart to set up (the next appointment).* [Adult13]

The delay in scheduling the next appointment could sometimes lead to discontinuity in diabetes care because there was no follow-up mechanism at the time of the interview by the clinics after each visit. A provider discussing the impact of telehealth in diabetes care described this phenomenon:

> *Often, I will say they fall through the cracks, because we don't have the staff to follow-up on every patient and see if they scheduled a follow-up, and so it's sort of like I tell them "Please schedule a follow-up," and I put in the order so that they'll get a prompt in MyChart, but beyond that we're not following-up to see what happens, and so they may not schedule it themselves.* [Provider05]

Regarding the second subtheme, (perceived incomplete visits due to no diabetes quality measures), both people with T2D and providers viewed being unable to complete a thorough physical evaluation as a major limitation of telehealth visits. The American Diabetes Association recommends each person with T2D undergo a physical exam (eg, foot exam) and biofeedback (eg, BMI, blood pressure, HbA_{1c}, lipid panel, microalbumin) quarterly or annually [3]. Instead of getting their point-of-care HbA_{1c} or other biofeedback at their in-person visits (lab facilities are available in the same building for all diabetes clinics), the responsibility of completing the required lab work shifted to adults with T2D after a telehealth visit; they must remember to make an additional trip to a lab facility. Additionally, it is not feasible to assess diabetes-related complications and other physical exams via telehealth. A person weighing in on telehealth visits mentioned:

> *I mean, I think that's (video visits) good, but I can't come in getting my instant test, how "boom," they give you the A1c. It was awesome. I liked that.* [Adult22]

Providers admitted the same limitation, adding this additional effort sometimes led to incomplete diabetes quality measures. Without the information, providers might not be able to provide timely treatment recommendations, which could ultimately compromise their patients' health outcomes. When comparing in-person and telehealth visits, a provider provided the following quote:

> *We can't do a point-of-care A1c at those visits, and those are problems because we care about all of those and it impacts our decision making . (...) We try to reach out to patients who haven't had labs done in a while to try to get their labs before their (video) visit, but that's challenging because the point-of-care A1c makes it very (easy)—it's a 5-minute test result.* [Provider10]

The third subtheme (compromised care quality due to unavailability of glucose data and/or unpreparedness of their patients) was unique to providers. Although telehealth visits had the potential to enhance care continuity through proactive outreach from a provider, provider participants felt that sometimes their patient was distracted during a telehealth visit—they might be driving with an intermittent internet connection, walking down the street, or having other commitments—so it was difficult to assess their lifestyle management during that environment. In addition to the inattention, people with T2D might not have their glucose data ready to share, as mentioned previously. Therefore, provider participants sometimes felt that a telehealth visit could compromise the care quality. A provider discussing frustration in telehealth visits mentioned the following:

> *There are times when telehealth visits are not productive. It really, I think, depends on patient engagement. I certainly have had patients who are taking the call while they're driving, or they forgot that they had a visit with me. So, in some ways, people*

> *take the telehealth less seriously, in which case, it's a waste of their time and so they're not ready for the visit and so sometimes they don't have labs, no glucometer data (...).* [Provider09]

Regarding the fourth subtheme (needs and preferences for in-person visits), both patient and provider participants shared the need for in-person visits. Although people with T2D in this study generally perceived that the conversations and interpersonal relationships during both telehealth and in-person visits were similar, only 5 participants noted a preference for telehealth visits; more than one-half of the participants specifically noted a preference for in-person visits because of the challenges and clinical implications discussed above:

> *Personally, I like face-to-face with my doctors, a checkup to see how you're doing, with diabetes care. (...) It's not like I have any kind of feet issues or circulation issues, hopefully never, but it's good to go through that kind of stuff (check my feet) and just have them check that stuff, and it's hard to do that with a virtual visit.* [Adult20]

Similarly, provider participants also mentioned that adults with T2D should have an in-person visit at least once a year:

> *I do think that patients do have to be seen at least annually, in-person, for a comprehensive foot exam, and other parts of the exam that need to be done as well. (...) What I was finding with telemedicine is that a lot of time, though the visits were great and the recommended frequency would continue, often, the labs would lag behind. Patients wouldn't feel comfortable going to get their labs done.* [Provider08]

Discussion

Principal Findings

This qualitative study outlined the perspectives of both providers and patients with T2D on the benefits and challenges of telehealth in diabetes care. Although people with T2D and their providers acknowledged the convenience and efficiency of telehealth visits for promoting care continuity in diabetes care, telehealth also had challenges that could compromise the quality of diabetes care.

Consistent with previous literature [18], both adults with T2D and providers in this study acknowledged that telehealth visits addressed the barriers of transportation and work commitments with in-person visits. Beyond these benefits, providers in this study generally viewed intermittent telehealth visits as appropriate for diabetes care in the setting of a stable internet connection and the absence of technical issues. A cross-sectional study using national data and census data found that neighborhood broadband internet subscription was highly associated with the use of telehealth [29]. To mitigate widening disparities in access to care via telehealth services, state and federal governments should progressively invest in affordable household broadband internet infrastructure [30] and programs aiming to increase digital health literacy for all [31].

Given health care systems' rapid increase in telehealth capacities since the COVID-19 pandemic [32], it is key to address the digital divide to ensure health equity by examining individual digital health literacy and the usability of the telehealth platforms. In our study, many adults with T2D had problems navigating through their smart devices or patient portal due to limited digital health literacy, but they indicated a willingness to use telehealth services with additional support. Quality improvement efforts to evaluate the uptake of telehealth services and specific measures to bridge digital literacy gaps, particularly among populations with limited resources, should be undertaken. For example, clinical practices may implement validated satisfaction surveys to identify digital literacy shortfalls and inform the development of staff training to better support patients in navigating through the platform [33,34]. Additionally, telehealth or health information platforms should seek to simplify the navigation of their systems with end user experiences in mind (eg, fewer layers to get to the actual link for telehealth visits) [35]. Last, clinical practices should consider new workflows for telehealth visits to facilitate easier follow-up scheduling and lab completion that include the perspectives of adults with T2D [36].

Several temporary policy flexibilities broadened access to diabetes care during the COVID-19 pandemic [15,16], including the coverage of audio-only visits [37] and the suspension of geographic requirements for patients [38]. However, with those flexibilities being phased out [39,40], telehealth care will be more limited, particularly to underserved populations. Currently, people living in rural areas across state lines must be present in the same state as their clinics' locations to access care, further burdening those with limited resources. Additionally, we found that audio-only visits in diabetes care became necessary when technical issues arose, even though phone visits were not encouraged at the time of the interview due to reimbursement and compliance issues. Eliminating audio-only visits disproportionately affects certain populations, such as racial minority populations, those with public insurance, and older adults [41,42]. To ensure equitable access to diabetes care, new legislation and licensure registration should provide more flexibility in telehealth delivery [38].

Our study revealed concerns about glucose data availability impacting the quality of diabetes care in telehealth visits. Of the patients in this study, 70% (16/23) used insulin at the time of their interview, and glucose monitoring is integral to guiding individualized treatment plans in this population [43]. Sharing data, particularly from a glucometer, has been troublesome in telehealth visits as it requires extra steps and additional technological familiarity for people with T2D. Most participants (15/23, 65%) used a glucometer (finger sticks) for their daily glucose monitoring at the time of the interview, and none of them uploaded the data to the suggested platform (ie, Glooko). To enhance the quality of diabetes care and minimize burden, user experience and user-centered design should be considered in redesigning glucose-sharing platforms to minimize challenges faced by adults with T2D [44]. CGM, which is increasing in use for T2D, could also provide a convenient way to share glucose data in telehealth visits [45], but coverage for people with T2D remains limited [46]. With the potential to reduce inequality in diabetes burden and relevant complications [1], future research is warranted to investigate the benefits of CGM

among individuals with non-insulin-dependent T2D. Insurance policies should also consider expanding CGM coverage to people using any insulin or oral medications with a higher risk of hypoglycemia (ie, sulfonylureas) and adults with physical, cognitive, or emotional barriers to finger sticks [47]. Additionally, although data platforms such as Glooko have been developed to address interoperability, none of the platforms can synchronize with all the commercially available diabetes devices (glucometers or CGMs). Moreover, diabetes data are not currently integrated in EHRs. More discussion on interoperability, integration, and patient privacy should be undertaken to enhance diabetes care for both clinicians and patients [48].

Both patient and provider participants in this study acknowledged that telehealth visits promote care continuity because of convenience and efficiency, but both indicated the need for in-person visits in T2D care. Attending in-person visits allows people with T2D to check diabetes quality measures (ie, foot exam, BMI, blood pressure, HbA_{1c}, lipid panel, microalbumin [3]) within the same trip. During the COVID-19 pandemic, diabetes-related HbA_{1c} and nephropathy monitoring declined and did not recover to the prepandemic volume in the primary care setting [49]. A gap in timing between HbA_{1c} measurements was also a risk factor for missed appointments in the diabetes-specific setting [17]. To ensure care continuity and promote better outcomes, future research is warranted to investigate the ideal balance between in-person and telehealth visits in diabetes care.

Limitations

This study has a few limitations. All participants were from diabetes clinics within a large urban academic medical center in the mid-Atlantic region of the United States. Additionally, the study was designed to focus on missed appointments and interpersonal relationships, and thus, themes presented in this study might not apply to the people with T2D who do not miss appointments. Last, this study collected data from participants who spoke English and responded to our phone calls, text messages, or emails. Although we maximized variations in recruiting participants (eg, based on age, race, and lengths of provider-patient relationship), the themes derived may not apply to people lacking a working phone number or who do not speak English.

Conclusion

In summary, telehealth implementation during the COVID-19 pandemic has expanded access to diabetes care. Adults with T2D and providers generally reported positive experiences with telehealth visits, although some definite technical challenges exist. To ensure equitable access to diabetes care, legislation should provide more flexibility regarding geographic boundaries and telehealth delivery modes (audio-only versus video-audio visits). Telehealth-related technology design also needs to consider user experience and user-centered design to optimize the use of telehealth; a person-oriented telehealth workflow has the potential to address concerns about the negative effects of telehealth visits on the quality of diabetes. Future research to investigate the ideal balance between in-person and telehealth visits in diabetes care is warranted to enhance the quality of diabetes care to optimize diabetes outcomes.

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Authors' Contributions

CAS, SR, NM, NP, SL, and HRH conceptualized the study, and CAS and HRH designed the interview guides. CAS, ZS, HRH, and SZ performed the formal analysis. CAS, ZS, and SZ wrote the original manuscript draft, and CAS, ZS, SR, NM, NP, SL, and HRH reviewed and edited the manuscript.

Conflicts of Interest

SL is an employee of Beckman Coulter, a company that develops clinical diagnostics and clinical decision support solutions.

Multimedia Appendix 1
Interview guides.
[DOCX File , 19 KB - diabetes_v8i1e44283_app1.docx]

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Abbreviations

CGM: continuous glucose monitoring
EHR: electronic health record
HbA_{1c}: hemoglobin A_{1c}
IRB: institutional review board
NP: nurse practitioner
T2D: type 2 diabetes mellitus

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Original Paper

Prediction of Weight Loss to Decrease the Risk for Type 2 Diabetes Using Multidimensional Data in Filipino Americans: Secondary Analysis

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Abstract

Background: Type 2 diabetes (T2D) has an immense disease burden, affecting millions of people worldwide and costing billions of dollars in treatment. As T2D is a multifactorial disease with both genetic and nongenetic influences, accurate risk assessments for patients are difficult to perform. Machine learning has served as a useful tool in T2D risk prediction, as it can analyze and detect patterns in large and complex data sets like that of RNA sequencing. However, before machine learning can be implemented, feature selection is a necessary step to reduce the dimensionality in high-dimensional data and optimize modeling results. Different combinations of feature selection methods and machine learning models have been used in studies reporting disease predictions and classifications with high accuracy.

Objective: The purpose of this study was to assess the use of feature selection and classification approaches that integrate different data types to predict weight loss for the prevention of T2D.

Methods: The data of 56 participants (ie, demographic and clinical factors, dietary scores, step counts, and transcriptomics) were obtained from a previously completed randomized clinical trial adaptation of the Diabetes Prevention Program study. Feature selection methods were used to select for subsets of transcripts to be used in the selected classification approaches: support vector machine, logistic regression, decision trees, random forest, and extremely randomized decision trees (extra-trees). Data types were included in different classification approaches in an additive manner to assess model performance for the prediction of weight loss.

Results: Average waist and hip circumference were found to be different between those who exhibited weight loss and those who did not exhibit weight loss (P=.02 and P=.04, respectively). The incorporation of dietary and step count data did not improve modeling performance compared to classifiers that included only demographic and clinical data. Optimal subsets of transcripts identified through feature selection yielded higher prediction accuracy than when all available transcripts were included. After comparison of different feature selection methods and classifiers, DESeq2 as a feature selection method and an extra-trees classifier with and without ensemble learning provided the most optimal results, as defined by differences in training and testing accuracy, cross-validated area under the curve, and other factors. We identified 5 genes in two or more of the feature selection subsets (ie,

CDP-diacylglycerol-inositol 3-phosphatidyltransferase [*CDIPT*], mannose receptor C type 2 [*MRC2*], PAT1 homolog 2 [*PATL2*], regulatory factor X-associated ankyrin containing protein [*RFXANK*], and small ubiquitin like modifier 3 [*SUMO3*]).

Conclusions: Our results suggest that the inclusion of transcriptomic data in classification approaches for prediction has the potential to improve weight loss prediction models. Identification of which individuals are likely to respond to interventions for weight loss may help to prevent incident T2D. Out of the 5 genes identified as optimal predictors, 3 (ie, *CDIPT*, *MRC2*, and *SUMO3*) have been previously shown to be associated with T2D or obesity.

Trial Registration: ClinicalTrials.gov NCT02278939; https://clinicaltrials.gov/ct2/show/NCT02278939

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KEYWORDS

type 2 diabetes; obesity; weight loss; feature selection; classification; transcriptomics

Introduction

Background

Type 2 diabetes (T2D) is a metabolic disorder characterized by high blood glucose levels due to impaired insulin secretion or insulin resistance. T2D is one of three types of diabetes, which also includes gestational diabetes and type 1 diabetes; however, T2D accounts for 90%-95% of diabetes cases in the United States [1]. According to the Centers for Disease Control and Prevention, an estimated 88 million Americans have prediabetes and more than 34 million Americans have T2D [2]. In 2017, the United States spent US $327 billion on diabetes, with US $9601 spent on each individual with T2D [3]. The number of diabetes cases continues to increase and is expected to reach 693 million worldwide by the year 2045 [4].

A number of behavioral factors can alter the risk of developing T2D. Obesity is one of the leading T2D risk factors, as increased adipose tissue mass can lead to impaired insulin secretion or insulin resistance [5]. Diets high in saturated fats, refined grains, and sugar-sweetened beverages increase the risks of obesity and T2D [6]. Cultural and societal influences on diet may put certain populations and groups at higher risk of T2D. For example, certain racial and ethnic groups, including Filipino Americans, have been found to be more susceptible to developing T2D, with an estimated 2.5-fold higher T2D incidence compared to White adults [7]. Filipino American diets include a mix of carbohydrates and proteins like rice, vegetables, and meat [7]. These diets are associated with an overall increase in caloric and fat intake compared to the historical diets of Filipinos living in the Philippines [7]. In addition to the direct impact of evolving dietary patterns and cultural and social influences, evidence suggests there could be interactions with underlying ancestral genetic characteristics that interact with behavioral factors to increase risk [8].

Tools to screen for the risk of T2D have been created by the American Diabetes Association [9-11]. These tools consider common demographic and clinical risk factors like obesity and family history of diabetes. Risk prediction models can incorporate multiple variables relevant to T2D, but current models exhibit unreliable risk prediction [12]. Accurate assessment of behavioral data related to obesity and risk for T2D (ie, physical activity and diet) is challenging and can result in highly dimensional data sets that are difficult to analyze and interpret. Genome-wide association studies have identified a number of genes and single nucleotide polymorphisms that are significantly associated with T2D. Polygenic risk scores that include genetic variants known to be associated with T2D have been developed. However, the addition of these risk scores to models that include demographic (eg, family history) and clinical (eg, obesity) characteristics fails to provide a sufficiently accurate prediction of risk [13].

Interactions between the behavioral and genetic factors that contribute to the etiology of T2D make it a difficult condition to prevent and treat. In contrast to genetic information, assessment of the transcriptome, or the full set of expressed genes at a given moment in time within a specific tissue type from an individual, may provide insights about how an individual is responding to behavioral factors in the context of their underlying genetic characteristics. Transcriptome profiles change over time, including in response to changes in behavioral patterns. Because of this dynamic activity, the transcriptome may be a more useful means of assessing the combined impact of behavioral and genetic risk factors. However, as with physical activity and dietary data, transcriptomic data sets are highly dimensional and can be challenging to analyze and interpret.

Prior Work

To address the challenge of complex and high-dimensional data sets, methods for optimal feature selection and machine learning algorithms have been developed [14]. Feature selection is a method that is employed to reduce the dimensionality of large data sets like transcriptomic data in order to capture the most relevant variables for outcome prediction. Machine learning algorithms include different types of classification approaches that use automated processes to discover patterns within large complex data sets to predict clinical outcomes [14]. Previous studies employed different classifiers in the prediction of the risk for T2D, using factors like BMI, blood pressure, age, and expression of long noncoding ribonucleic acid (lncRNA) [15]. When assessing lncRNA expression, the authors found that logistic regression and support vector machine (SVM) had the highest accuracy for predicting T2D [15]. Moreover, some classifiers performed better on specific data sets than others in a study that included 58 predictor variables to predict the outcome of fasting blood glucose [16]. The model that performed the best was also dependent on the observed metric score and the amount of available data [16]. The limitations of both studies were a small sample size, which may prevent accurate representation of the population, and limited

generalizability, given the study sample characteristics. Additional studies that include individuals at the greatest risk for T2D based on social and biological characteristics are needed.

Goal of This Study

The group of Filipino Americans is an example of an ethnic group at high risk for T2D, which has not been previously well represented in clinical research studies. The purpose of this study was to evaluate weight loss in response to a behavioral intervention tested in a previously completed clinical trial that included Filipino Americans. We integrated demographic and clinical data with behavioral and transcriptomic data to evaluate whether we could optimize the prediction of weight loss. We also identified the optimal transcriptomic features and determined their potential for mechanistic relationships with weight loss and the risk for T2D.

Methods

Study Participants

The data used in this secondary analysis were obtained from the Fit and Trim (F&T) Diabetes Prevention Program (DPP) study (ClinicalTrials.gov NCT02278939). This randomized, waitlisted, controlled trial was designed to assess the feasibility and acceptability of a DPP-based intervention in overweight Filipino Americans at risk for T2D. The goal of the intervention was to achieve 5% weight loss over 3 months. A total of 67 participants were recruited in the San Francisco area. The inclusion criteria were as follows: (1) self-identifying as Filipino American, (2) BMI >23 kg/m^2, (3) age >24 years, (4) diabetes risk test score >5 points [17], (5) fasting plasma glucose level of 100-125 mg/dL, (6) hemoglobin A_{1c} (HbA_{1c}) >5.6% or oral glucose tolerance test (OGTT) result of 140-200 mg/dL, (7) considered physically inactive based on the Brief Physical Activity Recall Questionnaire [18], (8) no cognitive impairment based on the Mini-Cog test [19], and (9) able to speak English. The exclusion criteria were as follows: (1) fasting blood glucose level >126 mg/dL, (2) OGTT result >200 mg/dL, (3) HbA_{1c} >7.0%, (4) glucose metabolism–associated disease, (5) thyroid disease that has been suboptimally treated, (6) special exercise program requirements, (7) current participation in a lifestyle modification program, (8) traveling outside the United States during the study period, (9) known eating disorders, (10) plans to have a gastric bypass surgery, (11) current pregnancy or delivery 6 months prior, (12) severe hearing or speech problems, and (13) use of antibiotics, antituberculosis agents (except tuberculosis prophylaxis), or prescription weight-loss drugs.

Demographic data were collected using a standardized questionnaire by trained study personnel. Blood pressure, waist and hip circumference, height, and weight were also collected by trained study personnel at each study visit. Blood was collected by venipuncture by trained study personnel at the enrollment visit following a 12-hour fast.

Ethics Approval

This study was approved by the University of California, San Francisco Institutional Review Board (approval number: 19-29707), and participant consent was obtained before the start of the study.

Behavioral Data

At enrollment, the Beverage Intake Questionnaire (BEVQ-15) and Fat-Related Diet Habit Questionnaire were used to assess dietary habits [20,21]. Participants were asked to wear a Fitbit Zip activity tracker for at least 10 hours per day to measure step count. The average daily step count over the last 4 weeks of the intervention period was used to characterize physical activity in prediction models.

Study Design

Participants were randomized into one of two groups, which determined when they received the intervention. Regardless of which group they were placed in, all participants wore a Fitbit Zip device for the entire 6-month duration of the study to track and record daily step count. Those in the immediate group received a culturally tailored intervention and had access to a Facebook support group during the first 3 months (months 0-3) of the study. Those in the waitlist group received the intervention and had access to the support group during the last 3 months (months 3-6) of the study. For the study described in this manuscript, the 2 groups were “stacked” such that all data were analyzed simultaneously, with month 0 considered as baseline for the immediate group and month 3 considered as baseline for the waitlist group. Month 3 was considered as the final timepoint for weight loss in the immediate group, and month 6 was considered as the final timepoint for weight loss in the waitlist group.

Molecular Data Collection

Blood was collected in PAXgene vacutainers (Qiagen) containing reagents to lyse cells and stabilize RNA molecules according to the standard protocol. Vacutainers were stored at −80 °C until RNA isolation was completed using the PAXgene blood RNAeasy kit (Qiagen) according to the standard protocol.

Library preparation and sequencing were performed by the University of California, Davis DNA Technologies and Expression Analysis Core Laboratory. Barcoded 3′-Tag-Seq libraries were prepared using the QuantSeq FWD kit (Lexogen) for multiplexed sequencing according to the recommendations of the manufacturer. The fragment size distribution of the libraries was verified via microcapillary gel electrophoresis on a Bioanalyzer 2100 system (Agilent). The libraries were quantified by fluorometry on a Qubit instrument (LifeTechnologies) and pooled in equimolar ratios. A total of 48 libraries were sequenced per lane on a HiSeq 4000 sequencer (Illumina) with single-end 100 base-pair reads.

Data Preprocessing

Of the 67 participants in the parent trial, 11 were excluded for this analysis due to missing transcriptomic or step count data. Two of the remaining 56 participants had missing clinical data (ie, glucose, total cholesterol, triglycerides, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol), which were imputed using the mice package from R [22]. The parameter “pmm” or predictive mean matching was recommended and selected for imputation of continuous data.

Sugar-sweetened beverage scores (calories and grams) were calculated based on a scoring guide, which included totaling up scores from sweetened fruit beverages, soft drinks, sweetened tea, tea or coffee with cream or sugar, and energy drinks [21]. The calculated fat score was the average of 5 factors (substitution, modify meat, avoid frying, replacement, and avoid fat) [20]. Changes in fat scores and sugar-sweetened beverage scores were then calculated between baseline and the end of the intervention for all participants. The average step count of the 4 weeks prior to completion of the intervention for each participant was used as a predictor variable. Due to the small sample size, 1 participant who had missing step count data for the previous 4 weeks was imputed with a mean of means involving all participants' average step counts for the previous 4 weeks. Weight loss was defined as having a change in weight over 3 months of ≥5% of the baseline weight. Weight loss was then coded as "1" if there was ≥5% weight change and "0" otherwise for the outcome variable. The gene transcripts from the RNA-seq data were first filtered so that only those that appeared in 90% (51/56) of the samples and had ≥10 counts were retained. EdgeR was used to normalize the read counts for use in the feature selection methods, except the DESeq2 method [23,24].

Statistical Analysis

Descriptive statistics were calculated for demographic and clinical characteristics overall and stratified by weight loss group, using the tableone package in Python [25]. The mean and SD were reported for continuous variables when the normality assumption held. Counts and percentages were reported for categorical variables. Two-group *t* tests were used to compare continuous variables between weight loss groups when the normality assumption held; otherwise, Wilcoxon rank sum tests were used. Chi-square tests were used for categorical variables. In addition to age, gender, and baseline weight, clinical and demographic variables with a *P* value <.05 based on a 2-sample *t* test were included in models that predicted weight loss. Statistical significance was declared based on a *P* value <.05. Through tableone default, Bonferroni correction was computed to account for multiple testing in Python.

Feature Selection

For the transcriptomic data, the following 4 feature selection methods were evaluated: (1) Kolmogorov-Smirnov (K-S) test and correlation feature selection (CFS) [26], (2) correlation-based feature subset selection (CfsSubsetEval and BestFirst) [27], (3) differential gene expression using DESeq2 [23], and (4) modified Linear Forward Search & Maximum Relevance-Minimum Redundancy [28]. GreedyStepwise was applied as the search method for the K-S test and CFS method [26]. In addition, Maximum Relevance-Minimum Redundancy was modified to CfsSubsetEval, SubsetSizeForwardSelection, and Mutual Information and evaluated [28]. A combination of R, Python [29], and Waikato Environment for Knowledge Analysis (WEKA) [30], a data mining tool, was used to implement the feature selection methods.

The SVM classifier was used to determine the accuracy of the top 10, 9, 8, etc transcripts of each feature-selected subset. The accuracy of each size subset was compared for all the feature selection methods, and the top 5 transcripts had an optimal accuracy score. The top 5 transcripts of each feature selection method were then selected as predictors for the classifiers in the prediction of weight loss.

Classifiers for Prediction

The Python library scikit-learn was used to run the following 5 supervised learning classification algorithms: (1) SVM, (2) logistic regression, (3) decision trees, (4) random forest, and (5) extremely randomized decision trees (extra-trees) [31]. Stratified 5-fold cross-validation was performed. Models were run with increasing complexity, starting with demographic and clinical characteristics and then adding behavioral characteristics, with the final addition of transcriptomic variables. After every model, parameter tuning was carried out. Parameter tuning was performed to select the optimal parameters for each algorithm, and then, each model was run again with the new set of parameters. Training and testing accuracy, cross-validated (CV) accuracy, area under the curve (AUC), CV AUC, precision, recall, and F1-scores were applied to assess and compare model performance.

Final risk models were run after incorporating all of the selected and statistically significant features from the different types of data available (ie, demographic, clinical, behavioral, and transcriptomic). These models were based on an ensemble method that used a bagging classifier to reduce variance by fitting classifiers on randomly generated subsets from the original data set and aggregating their individual predictions to form a final prediction [31]. SVM, logistic regression, decision trees, random forest, and extra-trees were all run with and without the bagging classifier. The same model performance metrics were applied to these final models.

Results

Among the 56 participants, hip and waist circumference were found to be significantly different between the >5% weight loss and no weight loss groups, using a 2-sample *t* test (*P*=.02 and *P*=.04, respectively) (Table 1). The group that exhibited weight loss at the end of the intervention (n=25) had a smaller hip and waist circumference at baseline (Table 1). There was no difference between the immediate and waitlist groups at baseline (Table 1). More than half of the sample (31/56, 55%) identified as female (Table 1). The overall sample had a mean age of 43 (SD 13) years and was obese (mean BMI 30.1, SD 4.2 kg/m^2) (Table 1).

The inclusion of all available transcripts that were normalized using edgeR (n=6088) in the SVM classifier resulted in overfitting, with a training accuracy and testing accuracy of 100% and 71%, respectively (Multimedia Appendix 1). Identification of the optimal subsets of transcripts using the 4-feature selection methods and filter criteria yielded varying numbers of transcripts and metric scores Multimedia Appendices 1-3). Overall, CV accuracy was higher when a feature selection method was applied than when using all 6088 transcripts. Using SVM, we determined that 5 was the optimal number of transcript features (Multimedia Appendix 1 and 2). On evaluating each of the subsets of 5 transcripts derived by different feature

selection methods, DESeq2 had the smallest difference between the training and testing accuracy of 3%, with both an average CV accuracy and CV AUC of 83% (Multimedia Appendix 3). CfsSubsetEval, BestFirst, and Random Forest Ranker, and K-S test, CfsSubsetEval, and GreedyStepwise reported both an average CV accuracy and CV AUC of ≥90% and a training and testing accuracy difference of ≥21% (Multimedia Appendix 1 and 2). CfsSubsetEval, SubsetForwardSelection, and Mutual Information also had an average CV accuracy and CV AUC of >80%, while there was a 14% difference between the training and testing accuracy (Multimedia Appendix 1).

To assess how different types of data perform in different classifiers, SVM, logistic regression, decision trees, random forest, and extra-trees were run with data types in an additive manner (Multimedia Appendix 4). When using the extra-trees algorithm, demographic and clinical data only (ie, age, gender, baseline weight [pounds], and waist and hip circumference [cm]) yielded model scores of 50%-60% for testing accuracy, average cross-validation, AUC, and CV AUC (Table 2). Testing accuracy did not improve with the addition of the dietary behavior scores, while the average CV accuracy and CV AUC scores increased slightly (Table 2). When step count data were included, the testing accuracy and AUC scores dropped to 41%, while the average CV accuracy and CV AUC scores rose to approximately 80% (Table 2).

The final risk prediction models included the demographic and clinical data, dietary scores, step counts, and transcript subsets selected by feature selection methods with and without an ensemble approach (Table 3; Multimedia Appendices 5-7). Feature selection using DESeq2 and an extra-trees model yielded the best results (Table 3). When considering all the model metric scores collectively, the extra-trees model both with and without an ensemble approach had the smallest difference between the training and testing accuracy of 14% and 3%, respectively (Table 3). The CV AUC scores for both approaches were greater than 90% (Table 3).

Five transcripts were selected as the optimal predictors using each feature selection approach (Figure 1). Five transcripts were found to overlap in at least two of the feature selection approaches (Figure 1), including mannose receptor C type 2 (*MRC2*), CDP-diacylglycerol-inositol 3-phosphatidyltransferase (*CDIPT*), regulatory factor X-associated ankyrin containing protein (*RFXANK*), small ubiquitin like modifier 3 (*SUMO3*), and PAT1 homolog 2 (*PATL2*).

Table 1. Demographic and clinical characteristics.

Variable	Overall (N=56)	No weight loss group (n=31)	>5% weight loss group (n=25)	*P* value
Group, n (%)				.40
Immediate (0-3 months)	27 (48.2)	17 (54.8)	10 (40.0)	
Waitlist (3-6 months)	29 (51.8)	14 (45.2)	15 (60.0)	
Gender, n (%)				.85
Male	25 (44.6)	13 (41.9)	12 (48.0)	
Female	31 (55.4)	18 (58.1)	13 (52.0)	
Age (years), mean (SD)	43 (13)	42 (12)	44 (13)	.58
BMI (kg/m^2), mean (SD)	30.1 (4.2)	31.0 (5.0)	29.0 (2.6)	.06
Glucose level (mg/dL), mean (SD)	92 (10)	94 (10)	90 (9)	.17
Glucose change (mg/dL), mean (SD)	−2 (8)	−1 (8)	−3 (9)	.25
Total cholesterol level (mg/dL), mean (SD)	194 (31)	196 (33)	191 (30)	.52
Total cholesterol change (mg/dL), mean (SD)	−3 (25)	1 (22)	−8 (28)	.18
LDL[a] cholesterol level (mg/dL), mean (SD)	115 (26)	118 (25)	112 (28)	.36
HDL[b] cholesterol level (mg/dL), mean (SD)	52 (14)	52 (16)	54 (14)	.57
Weight (kg), mean (SD)	79.4 (15.4)	82.6 (17.2)	75.7 (12.2)	.07
Waist circumference (cm), mean (SD)	98 (10)	100 (11)	95 (7)	.04
Hip circumference (cm), mean (SD)	104 (9)	106 (11)	101 (5)	.02
Systolic blood pressure (mmHg), mean (SD)	126 (12)	128 (11)	125 (13)	.34
Diastolic blood pressure (mmHg), mean (SD)	78 (11)	79 (11)	76 (10)	.33

[a]LDL: low-density lipoprotein.

[b]HDL: high-density lipoprotein.

Table 2. Evaluation of extra-trees models.

Scoring metric	Model 1[a]	Model 2[b]	Model 3[c]	Model 4[d]	
				No ensemble	Ensemble
Training accuracy	0.85	0.97	0.97	0.85	0.90
Testing accuracy	0.59	0.53	0.41	0.82	0.76
Average CV[e]	0.56	0.61	0.85	0.83	0.77
AUC[f]	0.65	0.57	0.43	0.75	0.76
CV AUC	0.55	0.60	0.82	0.90	0.91
Precision	0.75	0.60	0.44	0.80	0.73
Recall	0.33	0.33	0.44	0.89	0.89
F1-score	0.46	0.43	0.44	0.84	0.80

[a]Model 1 included demographic (age and gender) and clinical (average waist and hip circumference, and baseline weight) characteristics.

[b]Model 2 included variables in Model 1 and dietary factors (fat-related diet habits summary score, and sugar-sweetened beverage average daily calorie and gram scores).

[c]Model 3 included variables in Model 2 and step count (average over the last 4 weeks).

[d]Model 4 included variables in Model 3 and the 5 most optimal transcripts selected by DESeq2.

[e]CV: cross-validated.

[f]AUC: area under the curve.

Table 3. Comparison of classifier results using all selected features.

Classifier and ensemble[a]	Training accuracy	Testing accuracy	Average CV[b]	AUC[c]	CV AUC	Precision[d]	Recall[d]	F1-score[d]
SVM[e]								
Ensemble	0.79	0.47	0.80	0.50	0.92	0.50	0.56	0.53
No ensemble	0.79	0.53	0.77	0.61	0.81	0.55	0.67	0.60
Logistic regression								
Ensemble	0.90	0.41	0.85	0.46	0.85	0.44	0.44	0.44
No ensemble	0.90	0.41	0.90	0.47	0.86	0.44	0.44	0.44
Decision trees								
Ensemble	0.95	0.59	0.80	0.70	0.85	0.60	0.67	0.63
No ensemble	0.95	0.53	0.85	0.65	0.84	0.60	0.33	0.43
Random forest								
Ensemble	0.92	0.71	0.82	0.74	0.90	0.70	0.78	0.74
No ensemble	0.95	0.71	0.82	0.72	0.87	0.70	0.78	0.74
Extra-trees								
Ensemble	0.90	0.76	0.77	0.76	0.91	0.73	0.89	0.80
No ensemble	0.85	0.82	0.83	0.75	0.90	0.80	0.89	0.84

[a]All models included demographic (age and gender), clinical (baseline weight, and waist and hip circumference), behavioral (dietary factors and step count), and transcript (5 most optimal predictors identified by DESeq2) features. An ensemble approach using a bagging classifier was assessed for each classifier.

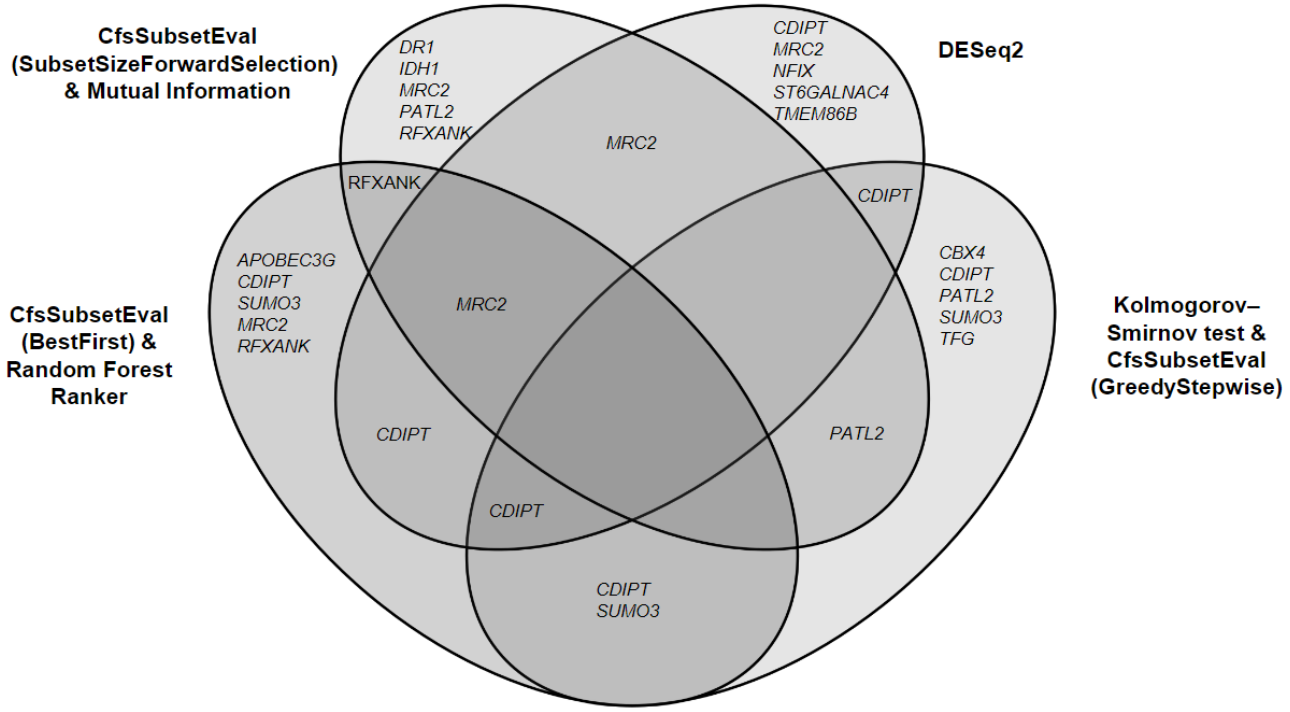
[b]CV: cross-validated.

[c]AUC: area under the curve.

[d]Precision, recall, and F1-score for no weight loss (weight loss band=0).

[e]SVM: support vector machine.

Figure 1. Venn diagram of overlapping and unique transcripts identified using 4 different feature selection methods. APOBEC3G: Apolipoprotein B MRNA Editing Enzyme Catalytic Subunit 3G; CBX4: Chromobox 4; CDIPT: CDP-Diacylglycerol-Inositol 3-Phosphatidyltransferase; CFS: correlation feature selection; DR1: Down-Regulator Of Transcription 1; IDH1: Isocitrate Dehydrogenase (NADP(+)) 1; MRC2: Mannose Receptor C Type 2; NFIX: Nuclear Factor I X; PATL2: PAT1 Homolog 2; RFXANK: Regulatory Factor X Associated Ankyrin Containing Protein; ST6GALNAC4: ST6 N-Acetylgalactosaminide Alpha-2,6-Sialyltransferase 4; SUMO3: Small Ubiquitin Like Modifier 3; TFG: Trafficking From ER To Golgi Regulator; TMEM86B: Transmembrane Protein 86B.



Discussion

Summary of the Results

Analytic methods that incorporate both genetic and environmental factors to describe the risk for complex diseases like T2D may improve risk prediction. In this study, the use of demographic, clinical, and behavioral data did not result in highly accurate prediction of weight loss for the prevention of T2D. Although there are well known associations of dietary components and physical activity with weight and risk for T2D, in our models, these variables did not improve risk prediction (Table 2). The F&T trial was a feasibility study, and it is possible that the dose of the intervention was not sufficient to achieve a significant association with weight loss or that the specific measures of dietary factors and physical activity were not optimal for the weight loss outcome. Another explanation could be that in this study sample of people who identified as Filipino, the impact of genetic risk was greater than the impact of behavioral factors. The addition of gene transcripts into the models improved the prediction accuracy, but only when a subset of transcripts identified by feature selection was applied. Feature selection using DESeq2 reported the most optimal results when applied to an extra-trees model. A bagging classifier, the selected ensemble learning approach, also improved the AUC and CV AUC scores.

DESeq2 Applied to Studies of T2D

Based on metrics for model performance, DESeq2 was found to be the best feature selection method for the data set in this study when the features were analyzed using an extra-trees model [23]. The training and testing accuracy had the smallest difference compared to all models, suggesting overfitting of the data was minimized. In contrast, a perfect (100%) training accuracy or a large difference in training and testing accuracy indicated possible overfitting in some of the observed models. DESeq2 is a popular R package available for differential gene expression that considers fold changes and dispersion rates by estimating shrinkage and is a conservative approach to control for false positives [23]. Most studies that focused on associations between the transcriptome and T2D used DESeq2 to identify differentially expressed genes that may be dysregulated or potentially involved in the pathogenesis of T2D and related complications [32,33]. Saxena et al [33] applied DESeq2 to identify 2752 differentially expressed genes (P<.01; log fold change ±2) using RNA expression data obtained from femoral subcutaneous adipose tissue in Asian Indians with and without diabetes. Another study identified 184 differentially expressed genes (adjusted P<.05; fold change ±2) from a total of 58,037 transcribed genes from the skin of individuals with and without T2D [23]. As a feature selection method, DESeq2 has been used to identify genes associated with small-cell lung cancer and integrated with other feature selection methods like EdgeR and Limma + voom to identify a smaller subset of overlapping genes [34]. Although DESeq2 has not appeared in studies as a feature selection method on its own, it offers the potential to select for a smaller more relevant subset of genes for risk predictions.

Ensemble Learning in Studies of T2D

The 2 best approaches in this analysis included a model that used a bagging classifier for the ensemble learning approach

and a model that did not. In addition to bagging, other ensemble learning approaches have been used to predict the risk for T2D [35], including stacking and boosting, which have the goal to improve modeling and make more accurate predictions [35]. Kumari et al [36] found that the soft voting classifier produced the highest scores with a prediction accuracy of 79.05% in a study of diabetes in Pima Indians. In the same sample, another study reported the highest prediction accuracy of 93.1% using a stacking classifier [35]. Within the same data set, the stacking classifier outperformed the soft voting classifier in not only accuracy but also precision, recall, and F1-scores [35,36]. However, both studies had relatively higher scores when using ensemble learning algorithms compared to models without these [35,36]. Similarly, in another study focused on the prediction of diabetic retinopathy, high accuracy was observed when a previously developed feature selection method and an original stacking-based ensemble learning technique (XGBIBS and Sel-Stacking, respectively) were used [37]. Jian et al [38] also compared different classification approaches and ensemble methods to predict the risk factors for T2D. Although XGBoost had the best performance, other models like logistic regression and random forest had higher metric scores when classifying metabolic syndrome and hypertension, respectively [38]. In the study described in this paper, the ensemble learning approach had higher AUC and CV AUC scores, but the model without the ensemble approach had higher testing and average CV accuracy. Although studies that focused on the prediction of the risk for T2D reported improved results with the inclusion of ensemble learning methods, our results suggest that ensemble learning will not always yield higher metric scores [39].

Gene Functions/Pathways

Feature selection methods identified several genes that were found to be relevant to the weight loss outcome. In the subsets of 5 genes identified by feature selection, *CDIPT*, *MRC2*, *PATL2*, *RFXANK*, and *SUMO3* were found to overlap in at least two subsets. Some of these genes have known associations with the risk for T2D or obesity, while the function of others is less clear. Below is a review of evidence for associations between these genes and obesity or related risk factors.

Located on chromosome 16, *CDIPT* encodes for an enzyme that produces phospholipid phosphatidylinositol, which is a signaling molecule in lipid synthesis [40]. Previous studies linked abnormal *CDIPT* function to diseases like oral cancer or hepatic steatosis in zebrafish [40,41]. A *CDIPT* variant (hi559) was identified in zebrafish liver with upregulated endoplasmic reticulum stress markers [41]. This stress may be associated with insulin resistance in metabolic disorders like T2D and obesity [41]. Copy number variations (CNVs) in *CDIPT* have also been described in individuals with obesity or neurological disorders [42].

MRC2 encodes for a receptor involved in extracellular matrix remodeling, cell migration, and invasion [43]. Upregulated *MRC2* expression has been detected in cancer tissues as well as in the peripheral blood of patients with diabetic nephropathy [43]. A simulation conducted to mimic glucose levels in T2D detected *MRC2* at high levels in mouse mesangial cells with high levels of glucose [43]. The study also found that knocking down *MRC2* using short interfering RNA (siRNA) affected the cell cycle and proliferation of mouse mesangial cells [43].

PATL2 encodes for proteins that are predominantly expressed in oocytes and is responsible for inhibiting processes after transcription and translation [44]. *PATL2* mutations have mainly been associated with oocyte maturation and female infertility [45,46]. However, a study that looked at whole-genome expression found *PATL2* to be differentially expressed in obese and normal weight individuals with asthma compared to controls [47].

RFXANK encodes for a protein subunit of a larger complex that binds to major histocompatibility complex class II (MHCII) genes [48,49]. MHCII components are required for the adaptive immune response in which dysfunctions are associated with immunodeficiency disorders [49]. *RFXANK* mutations are prevalent in bare lymphocyte syndrome (BLS) group B, an immunodeficiency disorder affecting CD4+ T and B cells [50]. However, *RFXANK* has not been associated with obesity or T2D in previous studies, though MHCII has been found to play a role in obesity [51], and our own prior studies have identified pathways related to inflammation and immunity as common themes in individuals at risk for T2D [52]. Deng et al [51] analyzed *RFXANK* between 7 obese women and 7 lean postmenopausal women but did not find the expression to be significantly different.

SUMO3 is involved in the posttranslation modification of target proteins known as sumoylation [53]. *SUMO3* has been found to be involved in disorders like obesity and neurodegenerative disorders like Parkinson disease and amyotrophic lateral sclerosis [53-55]. In a study that looked at obese and normal weight participants, proteomic analysis identified *SUMO3* to be one of the top 10 differentially expressed genes between the 2 groups [55]. Using microarray-based comparative genomic hybridization, another study found deleted *SUMO3* in an identified CNV in a child with syndromic obesity [56].

Additional studies are needed to determine the potential functional implications of the identified genes for T2D and obesity. *CDIPT* and *SUMO3* have been found to be differentially expressed in obese individuals; however, the exact mechanisms are not known. Upregulation of *MRC2* has been observed in people with T2D, and further studies are needed to determine whether these genes may be potential therapeutic targets.

Limitations

Some limitations of this study were the modest sample size and missing data for some of the participants, requiring imputation. We were not able to exactly replicate feature selection methods from previous studies that required specific software and coding packages. We did not identify an external data set for validation that contained the necessary combination of variables (ie, dietary, step count, and transcriptomic). Future studies with larger sample sizes may also need to implement recent technological advances in methods for the collection of dietary and physical activity data. Some of the genes identified in this study are not known to be associated with obesity or the risk for T2D, and further assessment of potential functional relationships is needed.

Conclusion

This study assessed multiple domains of individual characteristics for the prediction of weight loss in Filipinos at risk for T2D. This is one of the only studies to integrate transcriptomic data with behavioral data, and to our knowledge, this is the only study to apply this approach in the high-risk Filipino population. We identified optimal tools for feature selection and classification approaches for risk prediction, with an accuracy as high as 90% in the prediction of weight loss. Five genes were identified by multiple feature selection methods, including those known to be associated with conditions related to the risk for T2D and T2D complications.

Authors' Contributions

LC performed data analysis and drafted the manuscript. YF was the primary investigator of the Fit & Trim trial, contributed to the study design, and approved the final manuscript. BEA contributed to the study design and approved the final manuscript. LZ contributed to the study design and approved the final manuscript. EF was responsible for the overall study design, molecular data collection, data analysis plan, and final approval of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Support vector machine modeling scores for transcripts selected by CfsSubsetEval, BestFirst, and Random Forest Ranker.
[DOCX File , 14 KB - diabetes_v8i1e44018_app1.docx]

Multimedia Appendix 2
Support vector machine modeling scores for transcripts selected by the Kolmogorov-Smirnov test, CfsSubsetEval, and GreedyStepwise.
[DOCX File , 14 KB - diabetes_v8i1e44018_app2.docx]

Multimedia Appendix 3
Support vector machine modeling scores for transcripts selected by DESeq2.
[DOCX File , 14 KB - diabetes_v8i1e44018_app3.docx]

Multimedia Appendix 4
Classifier metric scores for different models.
[DOCX File , 16 KB - diabetes_v8i1e44018_app4.docx]

Multimedia Appendix 5
Classification results for all data (demographic, clinical, behavioral, and transcriptomic data) using CfsSubsetEval, BestFirst (bidirectional search), and Random Forest Ranker with and without an ensemble approach.
[DOCX File , 15 KB - diabetes_v8i1e44018_app5.docx]

Multimedia Appendix 6
Classification results for all data (demographic, clinical, behavioral, and transcriptomic data) using SubsetSizeForwardSelection, CfsSubsetEval, and Mutual Information with and without an ensemble approach.
[DOCX File , 15 KB - diabetes_v8i1e44018_app6.docx]

Multimedia Appendix 7
Classification results for all data (demographic, clinical, behavioral, and transcriptomic data) using the Kolmogorov-Smirnov test, CfsSubsetEval, and GreedyStepwise with and without an ensemble approach.
[DOCX File , 15 KB - diabetes_v8i1e44018_app7.docx]

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Abbreviations

AUC: area under the curve
CDIPT: CDP-diacylglycerol-inositol 3-phosphatidyltransferase
CFS: correlation feature selection
CNV: copy number variation
CV: cross-validated
DPP: Diabetes Prevention Program
K-S: Kolmogorov-Smirnov
lncRNA: long noncoding ribonucleic acid
MHCII: major histocompatibility complex class II
MRC2: mannose receptor C type 2
OGTT: oral glucose tolerance test
PATL2: PAT1 homolog 2
RFXANK: regulatory factor X-associated ankyrin containing protein
SUMO3: small ubiquitin like modifier 3
SVM: support vector machine
T2D: type 2 diabetes

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Original Paper

An “All-Data-on-Hand” Deep Learning Model to Predict Hospitalization for Diabetic Ketoacidosis in Youth With Type 1 Diabetes: Development and Validation Study

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Abstract

Background: Although prior research has identified multiple risk factors for diabetic ketoacidosis (DKA), clinicians continue to lack clinic-ready models to predict dangerous and costly episodes of DKA. We asked whether we could apply deep learning, specifically the use of a long short-term memory (LSTM) model, to accurately predict the 180-day risk of DKA-related hospitalization for youth with type 1 diabetes (T1D).

Objective: We aimed to describe the development of an LSTM model to predict the 180-day risk of DKA-related hospitalization for youth with T1D.

Methods: We used 17 consecutive calendar quarters of clinical data (January 10, 2016, to March 18, 2020) for 1745 youths aged 8 to 18 years with T1D from a pediatric diabetes clinic network in the Midwestern United States. The input data included demographics, discrete clinical observations (laboratory results, vital signs, anthropometric measures, diagnosis, and procedure codes), medications, visit counts by type of encounter, number of historic DKA episodes, number of days since last DKA admission, patient-reported outcomes (answers to clinic intake questions), and data features derived from diabetes- and nondiabetes-related clinical notes via natural language processing. We trained the model using input data from quarters 1 to 7 (n=1377), validated it using input from quarters 3 to 9 in a partial out-of-sample (OOS-P; n=1505) cohort, and further validated it in a full out-of-sample (OOS-F; n=354) cohort with input from quarters 10 to 15.

Results: DKA admissions occurred at a rate of 5% per 180-days in both out-of-sample cohorts. In the OOS-P and OOS-F cohorts, the median age was 13.7 (IQR 11.3-15.8) years and 13.1 (IQR 10.7-15.5) years; median glycated hemoglobin levels at enrollment were 8.6% (IQR 7.6%-9.8%) and 8.1% (IQR 6.9%-9.5%); recall was 33% (26/80) and 50% (9/18) for the top-ranked 5% of youth with T1D; and 14.15% (213/1505) and 12.7% (45/354) had prior DKA admissions (after the T1D diagnosis), respectively. For lists rank ordered by the probability of hospitalization, precision increased from 33% to 56% to 100% for

positions 1 to 80, 1 to 25, and 1 to 10 in the OOS-P cohort and from 50% to 60% to 80% for positions 1 to 18, 1 to 10, and 1 to 5 in the OOS-F cohort, respectively.

Conclusions: The proposed LSTM model for predicting 180-day DKA-related hospitalization was valid in this sample. Future research should evaluate model validity in multiple populations and settings to account for health inequities that may be present in different segments of the population (eg, racially or socioeconomically diverse cohorts). Rank ordering youth by probability of DKA-related hospitalization will allow clinics to identify the most at-risk youth. The clinical implication of this is that clinics may then create and evaluate novel preventive interventions based on available resources.

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KEYWORDS

type 1 diabetes; T1D; diabetic ketoacidosis; DKA; machine learning; deep learning; artificial intelligence; AI; recurrent neural network; RNN; long short-term memory; LSTM; natural language processing; NLP

Introduction

Background

Despite advances in technologies and insulin analogs used to treat type 1 diabetes (T1D), 7% to 10% of youth and young adults with preexisting T1D in the United States still experience preventable hospital admissions for diabetic ketoacidosis (DKA) annually; this rate is increasing [1-3]. DKA is a severe metabolic decompensation caused by absolute insulin deficiency. DKA is also a leading cause of morbidity and mortality in youth with T1D, accounting for approximately 50% of all deaths in this population. Episodes can lead to dangerous complications such as long-term neurocognitive impairment, cerebral edema, coma, or even death [4-6]. In 2014, the mean hospital charge was US $26,566 per DKA admission, with the aggregate US national charges for DKA being US $5.1 billion [3]. Most studies pertaining to DKA risk prediction in youth have relied on a limited number of discrete variables available in the electronic health record (EHR) and on conventional statistical models, such as logistic regression, which do not consider changes in predictors or recurrence of discrete events over time [7-9].

Prior research has applied machine learning and deep learning to EHR data to forecast health outcomes but not yet to predict DKA among children with T1D [10]. The ability to accurately predict and effectively intervene to prevent hospital admissions for DKA would support the achievement of the quadruple aim of improving population health, reducing the cost of care, improving patient experience, and improving the work-life balance of health providers [11]. Many clinics providing care for individuals with T1D seek to improve the quality of health of their clinic populations by using population data housed in EHRs, enterprise data warehouses, or data repositories governed by learning health networks. Forecasting with such data may allow for earlier intervention before an adverse health outcome occurs [12].

Objective

We constructed a predictive model using a recurrent neural network–based approach suited to processing time series and other sequential data [13]. We specifically developed and evaluated the performance characteristics of a long short-term memory (LSTM) model to predict the 180-day risk of DKA-related hospitalization among youth with T1D [14].

Methods

Study Design

We developed a model to predict DKA-related hospitalizations within the T1D population of diabetes centers. We considered youth with the appropriate International Classification of Diseases, Ninth and Tenth Revisions, codes to have T1D. Autoantibody and C-peptide laboratory results and expert chart review were used to confirm the diagnosis. We chose to develop the model for youth aged 8 to 18 years, as this age range represents most of the hospital admissions for DKA at the institution.

Source Data

The source data were derived from the Cerner Millennium Electronic Medical Record System. Data used for model development and validation included demographic data, discrete clinical observations (laboratory results, vital signs, anthropometric measures, diagnosis, and procedure codes), medications, visit counts by type of encounter, number of historic DKA episodes, number of days since last DKA admission, patient-reported outcomes (answers to clinic intake questions), and data features derived from diabetes- and nondiabetes-related clinical notes via natural language processing (NLP). Demographic data included sex (female or male), age (in years), ethnicity (non-Hispanic or Hispanic), race (Asian, Black or African American, White, other, or unknown), and insurance type (public=Medicaid, other, government, or competitive medical plan and private=commercial, Blue Cross, or self-pay). For periods leading up to the prediction period, the counts of each clinical note type and the total words for each note type for the 20 most common note types were recorded. The counts for the 100 most common words and the 100 most common 2-word phrases were recorded as data features.

Feature Generation for the LSTM Model

The handling of data features varied by feature type. Structured clinical data, comprising Current Procedural Terminology codes, diagnosis codes (International Classification of Diseases, Ninth and Tenth Revisions), and Systematized Nomenclature of Medicine Clinical Terms codes, were included in the model development. When an individual had multiple encounters on the same day, the corresponding Concept Unique Identifier (CUI) codes were grouped together, with each CUI code recorded only once. The counts per period for the 200 most

common CUI codes were recorded. For most measures, we calculated summary metrics for all observations quarterly (eg, participant 1 as of April 8, 2016; July 7, 2016; and October 5, 2016).

The goal of this work was not to identify explanatory variables for DKA risk but to develop a high-performing predictive model that is feasible for clinical implementation. Clinical implementation of a predictive model requires a data pipeline and analytic approach that can manage the biased *missingness* that characterizes data in EHR systems (ie, some important observations are recorded infrequently and only on individuals who are sick or who access care within an observation window). We used a simple imputation approach to solve this problem. We assumed that to meet our objective, absent observations in the EHR for any data feature in any quarter could be adequately represented by an individual's most recent value carried forward or by the population average for that feature when a particular variable had never been measured in the individual. When a youth did not have a certain laboratory result or vital sign recorded during a quarter, for example, the value for that quarter was imputed using the last recorded value carried forward. When no prior measurement for a laboratory or vital sign was available, we set the imputed value to the population average for that variable. On average, results for approximately 4.28% (58,897/1,377,000) of all available laboratory tests performed on the cohort during the total observation period were present during any given quarter (ie, 1,318,103/1,377,000, 95.72% of laboratory values were imputed per quarter). A total of 10.61% (146,053/1,377,000) of laboratory values were imputed using an earlier value and 85.12% (1,172,050/1,377,000) were imputed using the population average. For vital signs, on average, approximately 44.66% (49,197/110,160) were present during a given quarter, 15.48% (17,053/110,160) were imputed using an earlier value, and 39.86% (43,910/110,160) were imputed using the population average.

We used counts to represent certain data types. The counts per quarter for the 50 most common medications, counts of all medical visits, and counts by type of visit (daytime, ambulatory, emergency, inpatient, outpatient, and other) were recorded. We also included the number of previous DKA admissions and the number of days since the last DKA admission, which was capped at 365 days for those who did not experience DKA during the previous year. For the training, partial out-of-sample (OOS-P), and full out-of-sample (OOS-F) cohorts, the number of previous DKA admissions only included DKA admissions from quarters 1 to 7, 3 to 9, and 10 to 15, respectively.

Glycated hemoglobin (HbA_{1c}) is an important biomarker that is the current gold standard for estimating average glycemic control over approximately the prior 90 days. Diagnostic and quarterly HbA_{1c} values were included as clinical features. Diagnostic HbA_{1c} was defined as the youth's first recorded $HbA1_c$ result, which in most cases reflected HbA_{1c} at the time of T1D diagnosis before the initiation of diabetes treatment. If HbA_{1c} was missing for a given quarter, the value was linearly interpolated between the closest actual observations before and after that quarter. Otherwise, the most recent HbA_{1c} from the prior 2 quarters was used. If no recent HbA_{1c} was present, we imputed missing HbA_{1c} values using the median HbA_{1c}. Youth were stratified by age at encounter before imputing missing values to account for age-specific HbA_{1c} variation. On average, approximately 60.69% (8357/13,770) of quarters had an available HbA_{1c} value, 6.81% (938/13,770) of HbA_{1c} values were imputed using linear interpolation, 10.16% (1399/13,770) were imputed using the last recorded value, and 22.34% (3076/13,770) were imputed using the population average by age.

To mitigate the possibility of overfitting (strong performance in the training data but poor performance in unseen data sets) and to improve the model training process, we limited the total number of clinical features in the trained model to the most common values observed across the population. Threshold numbers were chosen to determine how many CUI codes, laboratory results, vital signs, medications, patient-reported outcomes, patient-reported outcome surveys, and features derived from NLP of free-text clinical notes would be included in model development. All values were subsequently scaled to ensure that none of them would overpower the model. The LSTM model considered >500 features per observation period. A random forest model with the same input features and outcomes was trained in parallel to allow estimation of feature importance.

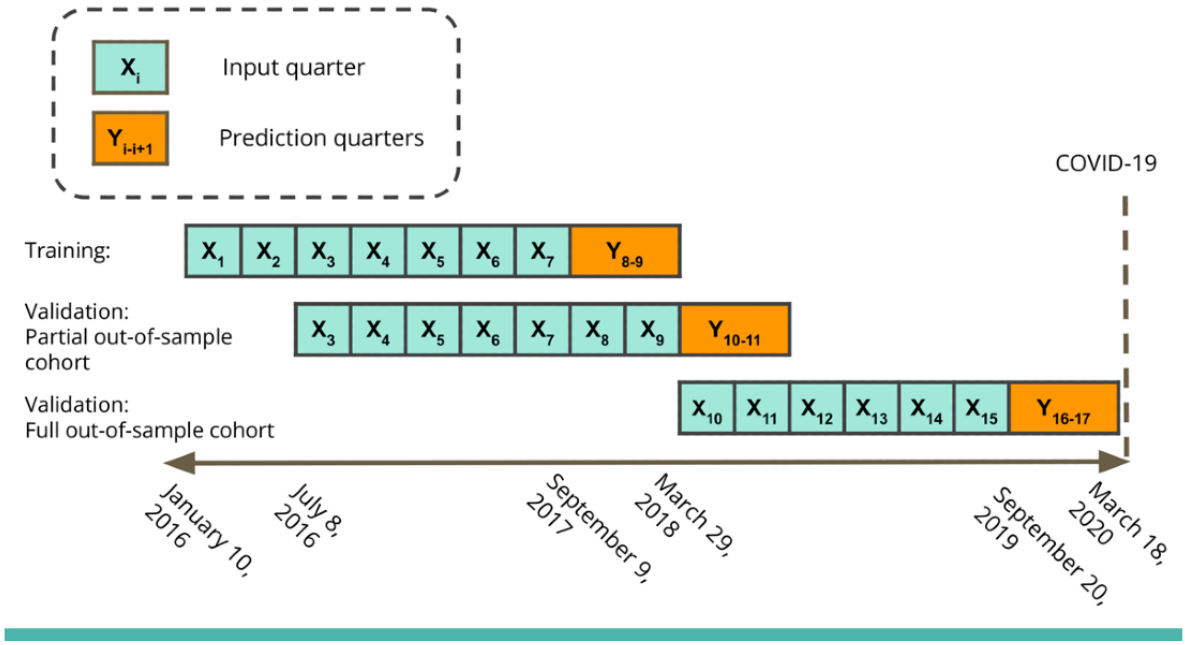
Outcome Definition

The LSTM model estimated the time to DKA-related hospitalization using the Weibull distribution, which is a continuous probability curve often used by engineers to analyze the time to failure for various machines and materials [15,16]. After determining the Weibull distribution for DKA-related hospitalization, we calculated the youth's cumulative daily probability of DKA-related hospitalization within 180 days as our final model output.

LSTM Model Development and Validation

Figure 1 illustrates the LSTM data structure. We created a training set using 7 consecutive 90-day periods of input data from quarters 1 to 7 (January 10, 2016, to September 30, 2017) for 1377 youths, and we predicted the risk of DKA-related hospitalization in the next 180 days (quarters 8 and 9). We first sought to evaluate whether an OOS-P cohort could be used to validate the model performance using input data from quarters 3 to 9 (July 8, 2016, to March 29, 2018) for 1505 youths. Our rationale for creating an OOS-P cohort was that this approach might be the ideal one for monitoring the model performance in an ongoing way during clinical implementation. Moreover, many clinics aiming to adopt this model may have limited data available for fine-tuning, validating, and monitoring the approach. The OOS-P cohort included the original training cohort (n=1377); an additional 72 new, model-naive youths who were randomly withheld from the training cohort (72/1377, 5.23% of the total); and 56 model-naive youths who entered the cohort as those with new T1D diagnoses during quarters 8 or 9. We used the OOS-P validation data set to assess risk in a new 180-day observation window: quarters 10 and 11 (March 3, 2018, to September 25, 2018).

Figure 1. Long short-term memory structure used to predict diabetic ketoacidosis–related hospitalization within the subsequent 180 days in youth with type 1 diabetes in the training, partial out-of-sample, and full out-of-sample validation cohorts.



We then performed a gold standard OOS-F validation of the model using data from quarters 10 to 15 (March 29, 2018, to September 20, 2019) for 354 new, model-naive individuals. The OOS-F cohort included 114 model-naive youths who were excluded from the training cohort, either because they were part of the planned, randomly selected 5.23% (72/1377) who were excluded or because they were not yet eligible for inclusion in model training because of the T1D diagnosis date occurring between quarters 1 and 7; an additional 240 youths entered the cohort (as those with new diagnoses or transfers of care) in quarters 10 to 15. We used the OOS-F validation data set to assess risk in quarters 16 to 17 (September 29, 2019, to March 18, 2020).

Statistical Analysis

Descriptive statistics were expressed as frequencies, percentages, medians, and IQRs. We created lists for the top 5.32% (80/1505) and 5.1% (18/354) of youth in each validation cohort with the highest cumulative probability of DKA-related hospitalization. As a result, list sizes of 80 and 18 were determined to be the most accurate approximations for the number of individuals who experienced DKA-related hospitalization within 180 days in the OOS-P and OOS-F validation cohorts, respectively. We compared youth within and outside the top 80 and top 18 for the OOS-P and OOS-F validation cohorts, respectively, using chi-square, Fisher exact, or 2-sample Wilcoxon rank-sum (Mann-Whitney) tests. To evaluate the proposed LSTM model's efficiency, we calculated precision (positive predictive value) and recall (sensitivity). We calculated precision as the proportion of members within a segment of the rank-ordered list (members 1 to 5, 1 to 10, etc) who experienced DKA-related hospitalization. We calculated recall by counting the number of youths in the rank-ordered list who actually experienced DKA-related hospitalization and then dividing by the list size (80 or 18, the number of admissions per 180-day period) for the OOS-P and the OOS-F validation cohorts, respectively. We produced the area under the receiver operating characteristic (AUROC) curve and the area under the precision-recall curve (AUPRC) to display the diagnostic performance of the machine learning model. All summary statistics and analyses were conducted using Stata/SE software (version 15.1; StataCorp LLC). The *P* values ≤.05 were considered statistically significant.

Ethics Approval

Clinical and model output data were coded and collected in an institutional review board–approved research data repository (IRB #11120355) that met the requirements for a waiver of written informed consent as outlined in US Department of Health and Human Services regulation 45 CFR 46.116.

Results

Overview

Table 1 shows the demographics and characteristics of the training, OOS-P validation, and OOS-F validation cohorts. For the OOS-P and OOS-F validation cohorts, the rate of DKA-related hospitalizations within the 180-day observation period was 5% (quarters 10 and 11) and 5% (quarters 16 and 17); the median age was 13.7 (IQR 11.3-15.8) years and 13.1 (IQR 10.7-15.5) years; 48.77% (734/1505) and 45.8% (162/354) were female, 80.26% (1208/1505) and 75.1% (266/354) were White; 50.56% (761/1505) and 50.3% (178/354) had private insurance; the median duration of T1D was 4.8 (IQR 2.5-7.9) years and 0.9 (IQR 0.6-1.6) years; 58.2% (876/1505) and 22.9% (79/344) were on an insulin pump; 29.1% (438/1505) and 40.9% (145/354) were documented as using a continuous glucose monitoring (CGM) device; median HbA_{1c} levels at enrollment were 8.6% (IQR 7.6%-9.8%) and 8.1% (IQR 6.9%-9.5%); and 14.15% (213/1505) and 12.7% (45/354) had a prior (after the T1D diagnosis) DKA-related hospitalization, respectively.

Table 1. Demographics and characteristics of the long short-term memory model.

	Training cohort (n=1377)	Partial out-of-sample validation cohort (n=1505)	Full out-of-sample validation cohort (n=354)	*P* value[a]
Sex (female), n (%)	670 (48.66)	734 (48.77)	162 (45.76)	.31
Age (years), median (IQR)	13.3 (10.9-15.4)	13.7 (11.3-15.8)	13.1 (10.7-15.5)	.009
Ethnicity , n (%)				.03
Non-Hispanic	1278 (92.81)	1399 (92.96)	317 (89.55)	
Hispanic	99 (7.19)	106 (7.04)	37 (10.45)	
Race, n (%)				.04
Asian	10 (0.73)	10 (0.66)	4 (1.13)	
Black or African American	120 (8.71)	132 (8.77)	28 (7.91)	
White	1104 (80.17)	1208 (80.27)	266 (75.14)	
Other race	15 (1.09)	16 (1.06)	5 (1.41)	
Unknown	128 (9.3)	139 (9.24)	51 (14.41)	
Insurance type, n (%)				.001
Public	676 (49.09)	742 (49.30)	169 (47.74)	
Private	699 (50.76)	761 (50.56)	178 (50.28)	
Self-pay	2 (0.15)	2 (0.13)	7 (1.98)	
Medical records				
Chronic conditions[b], n (%)	906 (65.8)	1010 (67.11)	167 (47.18)	<.001
Number of previous DKAs[c], n (%)				<.001
0	1212 (88.02)	1292 (85.85)	309 (87.29)	
1	61 (4.43)	82 (5.45)	36 (10.17)	
2	65 (4.72)	75 (4.98)	3 (0.85)	
≥3	39 (2.83)	56 (3.72)	6 (1.69)	
Youth without DKA in prior 365 days, n (%)	1268 (92.08)	1384 (91.96)	325 (91.81)	.93
DKA admission in subsequent 180 days, n (%)	68 (4.94)	80 (5.32)	18 (5.08)	.86
Last glycated hemoglobin (%) measured[d], median (IQR)	8.6 (7.6-9.7)	8.6 (7.6-9.8)	8.1 (6.9-9.5)	<.001
International Federation of Clinical Chemistry (mmol/mol)	70 (60-83)	70 (60-84)	65 (52-80)	
Days since last glycated hemoglobin measured[d], median (IQR)	54 (29.5-86)	58 (30-98)	63 (30-95)	.51
Age at T1D[e] diagnosis in years, median (IQR)	8.2 (5.4-10.8)	8.4 (5.6-11.0)	11.1 (9.0-13.9)	<.001
Duration of T1D in years, median (IQR)	4.6 (2.3-7.6)	4.8 (2.5-7.9)	0.9 (0.6-1.6)	<.001
Insulin delivery method[f], n (%)				<.001
MDI[g]	608 (44.25)	625 (41.56)	265 (77.03)	
Insulin pump	761 (55.39)	876 (58.24)	79 (22.97)	
No insulin	5 (0.36)	3 (0.2)	0 (0)	
Glucose monitoring method[h], n (%)				<.001
CGM[i]	350 (25.42)	438 (29.10)	145 (40.96)	
SMBG[j]	1027 (74.58)	1067 (70.9)	209 (59.04)	

[a]*P* values were generated via chi-square, Fisher exact, or 2-sample Wilcoxon rank-sum (Mann-Whitney) tests comparing partial and full out-of-sample validation cohorts.

[b]Chronic conditions were documented if any International Classification of Diseases codes were in the chronic condition indicator or warehouse, excluding diabetes.

[c]DKA: diabetic ketoacidosis.

[d]For the last glycated hemoglobin measurement and days since the last glycated hemoglobin measurement: training cohort, n=1336; partial out-of-sample validation cohort, n=1490; and full out-of-sample validation cohort, n=347.

[e]T1D: type 1 diabetes.

[f]For the insulin delivery method: training cohort, n=1374; partial out-of-sample validation cohort, n=1504; and full out-of-sample validation cohort, n=344.

[g]MDI: multiple daily injections.

[h]For continuous glucose monitoring method: training cohort, Dexcom (G4, G5 or G6): n=239 and Medtronic (Guardian): n=111; partial out-of-sample validation cohort, Dexcom (G4, G5 or G6): n=321 and Medtronic (Guardian): n=117; and full out-of-sample validation cohort, Dexcom (G4, G5 or G6): n=117, Medtronic (Guardian): n=13, and Freestyle Libre: n=15.

[i]CGM: continuous glucose monitoring.

[j]SMBG: self-monitoring of blood glucose.

Precision, Recall, and AUCs

To measure the performance of the LSTM model, we calculated precision and recall across various segments of the rank-ordered lists (Tables 2 and 3). As DKA-related hospitalization occurred in approximately 5.62% (98/1745) of youth in our study, we generated rank-ordered lists of the top 5.32% (80/1505) and 5.1% (18/354) of youth in the OOS-P (n=80) and OOS-F (n=18) validation cohorts, respectively, with the highest cumulative probability of DKA-related hospitalization. Those labeled with the highest probability of DKA-related hospitalization were assigned the highest ranks in each list. In the OOS-P validation cohort, for the list segment representing positions 1 to 10, precision was 100%, indicating that all 10 list members experienced DKA-related hospitalization. Recall for the same segment was 13% because the 10 members represented 10 (13%) of the 80 members of the total population who experienced DKA-related hospitalization in the subsequent 180 days. For list segments 1 to 25 and 1 to 80, precision was 56% and 33%, whereas recall was 18% and 33%, respectively. In the OOS-F validation cohort, for the list segment representing positions 1 to 5, precision was 80%, indicating that 4 of the 5 list members experienced DKA-related hospitalization. Recall for the same segment was 22% because the 4 members represented of the 18 members of the total population who experienced DKA-related hospitalization in the subsequent 180 days. For list positions 1 to 10 and 1 to 18, precision was 60% and 50%, whereas recall was 33% and 50%, respectively.

Next, we generated a receiver operating characteristic curve to examine the relationship between sensitivity and specificity at various cutoff values. Owing to data imbalance, we also generated a precision-recall curve to examine the relationship between the true positive rate (recall) and the positive predictive value (precision) at different probability thresholds. The model demonstrated an AUROC of 0.72 and 0.85 and an AUPRC of 0.29 and 0.42 for the OOS-P and OOS-F validation cohorts, respectively (Figure 2).

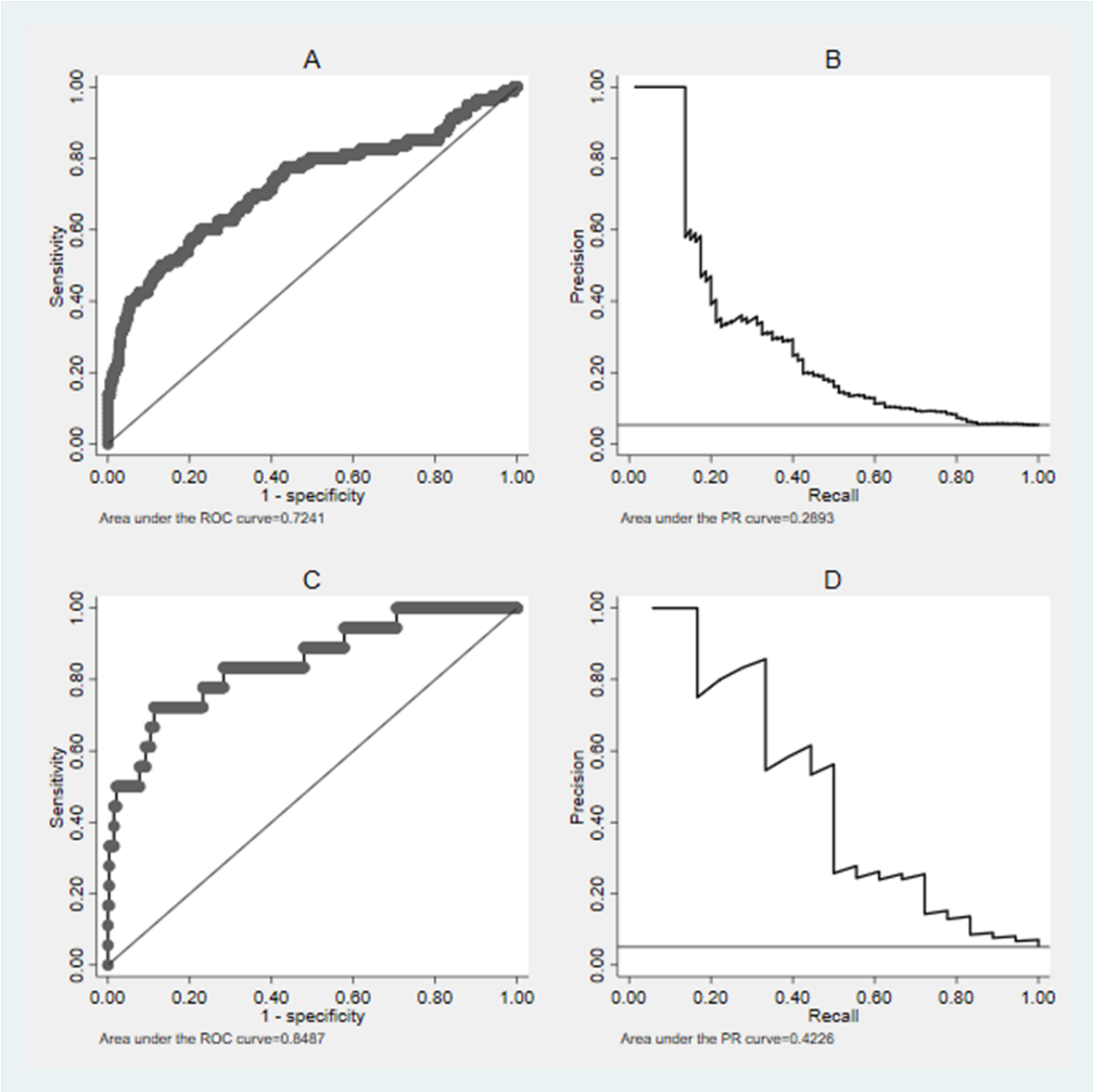
Table 2. Precision and recall according to diabetic ketoacidosis (DKA) admission frequency in the long short-term memory (LSTM) model for the partial out-of-sample validation cohort.

List size	Members with subsequent DKA within 180 days, n	Precision (actual members/list size), n (%)	Recall (actual members/80), n (%)
5	5	5 (100)	5 (6)
10	10	10 (100)	10 (13)
25	14	14 (56)	14 (18)
50	17	17 (34)	17 (21)
80	26	26 (33)	26 (33)

Table 3. Precision and recall according to diabetic ketoacidosis (DKA) admission frequency in the long short-term memory (LSTM) model for the full out-of-sample validation cohort.

List size	Members with subsequent DKA within 180 days, n	Precision (actual members/list size), n (%)	Recall (actual members/18), n (%)
5	4	4 (80)	4 (22)
10	6	6 (60)	6 (33)
18	9	9 (50)	9 (50)

Figure 2. Area under the receiver operating characteristic (AUROC) curve and area under the precision-recall (PR) curve for the prediction of diabetic ketoacidosis–related hospitalization within the subsequent 180 days in youth with type 1 diabetes. For the partial out-of-sample validation cohort: (A) area under the ROC curve=0.72 and (B) area under the PR curve=0.29. For the full out-of-sample validation cohort: (C) area under the ROC curve=0.85 and (D) area under the PR curve=0.42.



Next, we compared youth within the top 5% with youth outside the top 5% for the OOS-P (youth within the top 80 vs outside the top 80) and OOS-F (youth within the top 18 vs outside the top 18) validation cohorts (Table 4). For the OOS-P validation cohort, we observed significant differences in sex, age in years, race, insurance, proportion with other chronic conditions, proportion with any previous DKA episodes, proportion with no DKA episodes in the previous 365 days, last HbA_{1c}, duration of T1D in years, and proportion using an insulin pump or a CGM device between those in the top 5% and those not in the top 5% by risk of DKA-related hospitalization. We also observed a difference in the proportion of youth with DKA-related hospitalization in the subsequent 180 days. In the OOS-F validation cohort, we observed differences in sex, race, proportion with other chronic conditions, proportion with any previous DKAs, proportion with no DKA episodes in the previous 365 days, last HbA_{1c}, and proportion using a CGM device. We also observed differences in the proportion of youth with DKA-related hospitalization in the subsequent 180 days.

Table 4. Comparison of youth outside to within top 80 and top 18 ranks, respectively, for the partial and full out-of-sample validation cohorts.

	Partial out-of-sample validation cohort (n=1505)			Full out-of-sample validation cohort (n=354)		
	Outside top 80 (n=1425)	Top 80 (n=80)	*P* value[a]	Outside top 18 (n=336)	Top 18 (n=18)	*P* value[a]
Sex (female), n (%)	677 (47.51)	57 (71.25)	<.001	149 (44.35)	13 (72.22)	.03
Age (years), median (IQR)	13.6 (11.3-15.7)	15.3 (13.5-16.6)	<.001	12.9 (10.6-15.4)	14.4 (12.7-16.1)	.08
Ethnicity, n (%)			.65			.42
Non-Hispanic	1323 (92.84)	76 (95)		302 (89.88)	15 (83.33)	
Hispanic	102 (7.16)	4 (5)		34 (10.12)	3 (16.67)	
Race, n (%)			<.001			.03
Asian	10 (0.7)	0 (0)		4 (119)	0 (0)	
Black or African American	102 (7.16)	30 (37.5)		24 (7.14)	4 (22.22)	
White	1169 (82.04)	39 (48.75)		257 (76.49)	9 (50)	
Other race	16 (1.12)	0 (0)		4 (1.19)	1 (5.56)	
Unknown	128 (8.98)	11 (13.75)		47 (13.99)	4 (22.22)	
Insurance type, n (%)			<.001			.09
Public	672 (47.16)	70 (87.5)		157 (46.73)	12 (66.67)	
Private	751 (52.7)	10 (12.5)		173 (51.49)	5 (27.78)	
Self-pay	2 (0.14)	0 (0)		6 (1.79)	1 (5.56)	
Medical records						
Chronic conditions[b], n (%)	938 (65.82)	72 (90)	<.001	151 (44.94)	16 (88.89)	<.001
Number of previous DKAs[c], n (%)			<.001			<.001
0	1281 (89.89)	11 (13.75)		301 (89.58)	8 (44.44)	
1	69 (4.84)	13 (16.25)		32 (9.52)	4 (22.22)	
2	53 (3.72)	22 (27.50)		1 (0.3)	2 (11.11)	
≥3	22 (1.54)	34 (42.5)		2 (0.6)	4 (22.22)	
Youth without DKA in prior 365 days, n (%)	1361 (95.51)	23 (28.75)	<.001	317 (94.35)	8 (44.44)	<.001
DKA admission in subsequent 180 days, n (%)	54 (3.79)	26 (32.5)	<.001	9 (2.68)	9 (50)	<.001
Last glycated hemoglobin (%) measured[d], median (IQR)	8.5 (7.5-9.6)	11.5 (10.8-13)	<.001	8.0 (6.9-9.4)	10.6 (8.8-11.9)	<.001
International Federation of Clinical Chemistry (mmol/mol)	69 (58-81)	102 (95-119)		64 (52-79)	92 (73-107)	
Days since last glycated hemoglobin measured[d], median (IQR)	59 (30-98)	51.5 (28.5-101)	.42	64 (30-95)	31 (23-81)	.12
Age at T1D[e] diagnosis in years, median (IQR)	8.3 (5.6-10.9)	9.4 (6.5-11.7)	.07	11.1 (9.0-13.8)	12.5 (9.6-14.3)	.33
Duration of T1D in years, median (IQR)	4.8 (2.3-7.9)	5.2 (3.7-7.4)	.04	0.9 (0.6-1.5)	1.2 (0.4-2.5)	.79
Insulin delivery method[f], n (%)			.02			.13
MDI[g]	580 (40.73)	45 (56.25)		250 (76.22)	15 (93.75)	
Insulin pump	841 (59.06)	35 (43.75)		78 (23.78)	1 (6.25)	
No insulin	3 (0.21)	0 (0)		0 (0)	0 (0)	
Glucose monitoring method[h], n (%)			<.001			.05
CGM[i]	433 (30.39)	5 (6.25)		142 (42.26)	3 (16.67)	
SMBG[j]	992 (69.61)	75 (93.75)		194 (57.74)	15 (83.33)	

[a]*P* values were generated using chi-square, Fisher exact, or 2-sample Wilcoxon rank-sum (Mann-Whitney) tests comparing outside top 80 and top 80 groups for the partial out-of-sample validation cohort and outside top 18 and top 18 groups for the full out-of-sample validation cohort.

[b]Chronic conditions were documented if any International Classification of Diseases codes were in the chronic condition indicator or warehouse, excluding diabetes.

[c]DKA: diabetic ketoacidosis.

[d]For the last glycated hemoglobin measured and days since the last glycated hemoglobin measurement: partial out-of-sample validation cohort (outside top-80), n=1410 and full out-of-sample cohort (outside top-18), n=329.

[e]T1D: type 1 diabetes.

[f]For insulin delivery method: partial out-of-sample validation cohort (outside top 80), n=1424; full out-of-sample validation cohort (outside top 18), n=328; and full out-of-sample validation cohort (top 18), n=16.

[g]MDI: multiple daily injections.

[h]For continuous glucose monitoring method: partial out-of-sample validation cohort (outside top 80), Dexcom (G4, G5 or G6): n=317 and Medtronic (Guardian): n=116; partial out-of-sample validation cohort (top 80), Dexcom (G4, G5 or G6): n=4 and Medtronic (Guardian): n=1; full out-of-sample validation cohort (outside top 18), Dexcom (G4, G5 or G6): n=116, Medtronic (Guardian): n=13, and Freestyle Libre: n=13; and full out-of-sample validation cohort (top 18), Dexcom (G4, G5 or G6): n=1, Medtronic (Guardian): n=0, and Freestyle Libre: n=2.

[i]CGM: continuous glucose monitoring.

[j]SMBG: self-monitoring of blood glucose.

Feature Weights

To determine the features that most impacted the predictions, we applied a random forest model using the same input features that were used in the LSTM model. The 10 top-weighted features were diagnostic HbA_{1c}, HbA_{1c} in the past year, HbA_{1c} from the last 90 days, age at prediction, heart rate, number of previous DKA admissions, days since DKA, BMI, Immunoglobulin A test in the past year, and median household income (additional data are provided in Multimedia Appendix 1).

Discussion

Principal Findings

We developed and examined the initial validity of a deep learning model to predict hospitalization for DKA within 180 days among youth with previously diagnosed T1D. We examined model performance using lists containing the rank-ordered top 5% of youth with the highest probability of hospitalization (selected to match the 180-day incidence of DKA among established patients aged 8 to 18 years in the clinic). AUPRC showed a steep drop in precision to achieve recall measures of approximately >10% and >33% in the OOS-P and OOS-F validation cohorts, respectively. Precision increased progressively as the threshold for inclusion rose on the rank-ordered list (including all 80, vs the top 25, vs the top 10 youth for the OOS-P cohort), suggesting the model's ability to produce variably risk-enriched cohorts of individuals who might be considered eligible for more intensive intervention. Compared with the incidence of DKA-related hospitalization in this study of 0.05, the AUPRC values of 0.29 and 0.42 in the OOS-P and OOS-F validation cohorts, respectively, are significantly larger. Receiver operating characteristic curves for the OOS-P and OOS-F validation cohorts demonstrated that the model had a 72% and 85% probability, respectively, of identifying youth with T1D who will experience DKA-related hospitalization within 180 days.

Prior multinational and single-center studies have shown that multiple demographic and clinical care factors are associated with increased risk of hospitalization for DKA in United States–and European-based populations: hospital admissions for DKA in the prior 12 months, nonprivate insurance, elevated HbA_{1c}, racial and ethnic minority individuals, lower household income, mental health comorbidities, female sex, missed endocrine appointments, higher insulin doses, and insulin delivery by injection [17-21]. In a multinational registry of approximately 50,000 children, Maahs et al [22] identified female sex, ethnic minority groups, and individuals with HbA_{1c} ≥7.5% (≥58 mmol/mol) as having an increased risk of experiencing DKA. Their aim was to identify the factors associated with DKA and not to implement a model that clinically predicts future DKA admissions. They used a limited number of discrete variables available in the EHR and cross-sectional data, which did not consider changes in predictors or the recurrence of discrete events over time. In addition, most of the factors were not modifiable. Notably, our comprehensive prediction model uses a greater variety of data that are widely recorded in EHRs and identifies a considerable number of at-risk youth who did not experience DKA-related hospitalization in the previous 12 months. The rate of DKA in this cohort (5%) is consistent with the annual rates (1% to 15% per established patient per year) reported in prior studies [19,23,24]. Prior work suggests that 20% of annual admissions for DKA involve readmissions of the same individual within 1 year [25]. Youth in the top 5% of the rank-ordered lists for both validation cohorts consisted of more female individuals, were older, were more often racial and ethnic minority individuals, and more frequently experienced other chronic conditions. They also had a higher prevalence of previous DKA admissions, a higher prevalence of DKA admission in the subsequent 180 days, elevated HbA_{1c}, and a lower proportion of CGM use compared with youth outside the top 5%. Compared with the OOS-P validation cohort, fewer youth in the OOS-F cohort were on insulin pumps. This is likely related to the shorter duration of T1D in the OOS-F cohort versus the training and OOS-P cohorts.

Few studies have sought to develop and validate risk prediction models for DKA that could be deployed in clinical care. One study developed a multivariable prediction model using generalized estimating equations to predict DKA events within the next 12 months among youth with T1D. In that study, hospital admission in the prior year, HbA_{1c}, nonprivate

insurance, female sex, and racial and ethnic minority individuals predicted DKA admissions, whereas age, duration of diabetes, and number of office visits in the prior year did not. The AUROC curve for that model was 0.735 to 0.746, compared with 0.72 to 0.85 for the model used in this study. The prior model resulted in a 5-fold risk-enriched population, which is comparable with our model's overall performance in the 5.62% (98/1745) of individuals with the highest risk probabilities. In contrast, the approach used in this study allows significantly greater risk enrichment (16 to 20 fold) if one focuses on patients with higher ranks on the rank-ordered list by probability of admission [26]. An independent study of youth reported on the development of a risk index that achieved an AUROC curve of 0.709. However, the generation of that index required the use of a 20- to 30-minute psychosocial screening tool, which could be a significant barrier to clinical adoption [27]. Another study reported the performance of different machine learning approaches in predicting DKA among adults with T1D using EHR data and a small set of hand-selected features [28]. This nested case-cohort study leveraged the Optum database of EHR records, which consisted of 3400 potential DKA cases and 11,780 control cases. The authors found that different machine learning techniques demonstrated similar performance and identified overlapping but different top 10 predictors. As their purpose was to identify factors associated with hospital admission for DKA, they did not report a prespecified observation window for predicting the outcome. This omission may make the models, as reported, challenging to translate into practice by clinicians who want to forecast the probability of hospital admission for DKA within defined periods.

This study differs substantially from prior studies in its focus on predicting DKA events within 180 days in a pediatric population; in its model development approach, which combined discrete data elements with features derived from NLP of free-text clinical documents; in the diversity and scale of data features used to create the model; and in the use of LSTM, which retains a memory of more distal historical events when weighting features. The approach used in this study is also novel because it introduces the use of a simple-to-interpret list that is rank ordered by the probability of hospital admission, allowing clinicians to choose the number of top-ranked patients they will select for intervention based on capacity. The threshold rank that clinicians use to select individuals for intervention is directly tied to the level of risk enrichment (eg, 5.5 to 20 fold) they will achieve in the target cohort, which makes it easier to determine the number needed to treat to have a chance of preventing 1 hospitalization for DKA. For example, using the OOS-P findings, targeting youths 1 to 10 on the rank-ordered list would require treating only 1 youth to potentially prevent DKA-related hospitalization. In contrast, one would have to treat 3 youths from individuals comprising the top 5% of risk (ranks 1 to 80 in the OOS-P cohort) to have a chance of preventing DKA-related hospitalization in at least 1 youth. How clinicians use the rank-ordered list can thus impact the cost-effectiveness of any chosen interventional strategy.

These results are clinically meaningful because they offer a practical approach for continuous DKA risk stratification in youth within a T1D clinical population. Creating rank-ordered lists of youth based on the probability of admission is clinically intuitive and adaptable to clinical workflows that involve care navigation (enrolling youth in specific care pathways based on risk or established eligibility criteria). Even clinics with limited resources can benefit from this approach by a priori defining the number of youths per 6-month period for which they have the capacity to intervene. Longitudinal DKA risk scores based on the probability of hospital admission can be tracked as a process metric to drive resource allocation and quality improvement projects. When health systems apply deep learning, best practices should be followed to protect data to uphold privacy, design transparent and interpretable models, and prevent bias or discrimination among groups. Health care providers and developers need to collaborate, be critical, and be discretionary regarding the application of artificial intelligence (AI) in scenarios where human health and well-being are impacted; they should not simply defer to AI outputs [29]. For example, predictive models generated via deep learning may include multiple variables, such as race and ethnicity and socioeconomic status, as input features that are used to improve model prediction. Predicted probabilities and model performance should be examined across segments of the population by age, sex, race and ethnicity, insurance type, or socioeconomic status to uncover potential health inequities or model bias. The identification of inequities or model bias in specific groups can drive quality improvement projects to rectify them.

Currently, clinicians have limited knowledge about how to prevent hospitalization for DKA. Harris et al [30] developed and evaluated the Novel Interventions for Children's Healthcare program as an approach to preventing hospital admissions in youth with chronic diseases. Although the start-up cost to health systems or payers can be a barrier to adoption, this remains a promising approach [30-33]. Others have reported case studies on the successful use of remote patient monitoring in preventing DKA among adults with T1D [34]. One study demonstrated that quality improvement methods, with the implementation of longitudinal multiple care delivery interventions, can reduce the rate of DKA admissions in a clinical population of youth with T1D [9].

Limitations and Strengths

This study must be considered in the context of its notable limitations and strengths. One limitation of this study is that the data and source population were derived from a regional clinic network located in the Midwestern United States; therefore, the findings may not be generalizable outside of this network's catchment area. Future research should replicate this strategy in other geographic areas and health systems, including those using alternate EHR systems. Diabetes self-management device data were not included in this study; future studies should evaluate the inclusion of this information on model performance. Hundreds of variables were considered, which could lead to overfitting. Although we addressed this by performing an out-of-sample validation on model-naive individuals, future research should still examine this model's performance in new institutional data sets. Another limitation lies in the use of either the most recent value carried forward or the population average as a means of interpolating missing data. Future studies should consider other methods to address missingness. Finally, we did

not seek to develop an explainable model, which may limit clinicians' trust. The use of more explainable AI models has been proposed to improve the trust of clinicians and other stakeholders [35]. These models may help clinicians identify characteristics that are heavily weighted in the prediction. For instance, it would be useful to determine whether CGM use contributes to the assignment of lower risk by the prediction model. Other researchers have experimented with various methods (the Shapley additive explanations algorithm) to achieve explainable LSTM models [36]. A future goal is to further validate feature sets that are heavily weighted in the prediction. These features could represent valuable targets for intervention.

The strengths of this study include the novel application of advanced machine learning to predict pediatric health outcomes and the quantity and variety of data evaluated compared with previous studies. Although clinical researchers have minimally used recurrent neural networks and LSTMs with medical data, opportunities exist to examine and highlight this approach for forecasting outcomes. For example, using a Weibull loss function could theoretically allow for the prediction of the probability of admission along with the time until likely admission [15,16]; this could enable the development and dissemination of just-in-time interventions to prevent DKA. Our simple imputation approach for handling missing data is another strength, enabling the model to predict the risk for youth with fewer measurements owing to reduced access to care. Risk indices that do not use imputation to address missing data among repeated measures may exclude susceptible youth who demonstrate reduced access to care. Another strength is the ability of advanced machine learning models such as LSTMs to process robust and diverse data sets with large numbers of variables per participant, even when some data are missing or inaccurate [13]. We also included features derived from NLP of free-text clinical documents, allowing a largely untapped source of clinical data from the EHR to be considered during predictive model development. Future studies should examine the relative importance of NLP- and non–NLP-derived features. Finally, we validated the predictive model using a model-naive out-of-sample cohort.

Conclusions

Clinicians can leverage advanced machine learning to identify and rank individuals at the highest risk of experiencing DKA. We found that an LSTM model identified individuals at the highest risk of experiencing DKA-related hospitalization with reasonable precision. We proposed that clinics may apply the model used in this study to generate monthly rank-ordered lists by the probability of DKA-related hospitalization to identify at-risk individuals for targeted intervention. Clinics can determine the number of patients per month or quarter who can receive an intervention based on the available resources. This will enable future research that designs and tests novel interventions to prevent DKA-related hospitalization in those at risk. Future studies should refine and evaluate the performance of this LSTM model using data over a more extended period and in multiple clinics to ensure validation in racially, geographically, and socioeconomically diverse cohorts receiving care across different health systems.

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Authors' Contributions

MAC, DDW, DF, LD, CM, and LS participated in the concept and design, analysis, and interpretation of data and drafting or revising the manuscript and approved the version being submitted. SM, SRP, BL, EMT, CAV, MSB, RM, CS, and ML participated in data interpretation and manuscript revision and approved the version being submitted.

Conflicts of Interest

MAC is a consultant for Glooko, Inc and receives research support from Dexcom and Abbott Diabetes Care. ML has received research grants from Eli Lilly and Novo Nordisk and has been a consultant or has received honoraria from Astra Zeneca, Boehringer Ingelheim, Eli Lilly, and Novo Nordisk. LD, CM, and LS are employees of Cyft, Inc. All other authors are responsible for the reported research and stated that they have no affiliation, financial agreement, or involvement with any company or other organization with a financial interest in the subject matter of the submitted manuscript.

Multimedia Appendix 1
The top 25 non–natural language processing weighted features, listed in order of descending feature importance, identified via the parallel random forest exercise.
[PDF File (Adobe PDF File), 49 KB - diabetes_v8i1e47592_app1.pdf]

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Abbreviations

AI: artificial intelligence
AUPRC: area under the precision-recall curve
AUROC: area under the receiver operating characteristic
CGM: continuous glucose monitoring
CUI: Concept Unique Identifier
DKA: diabetic ketoacidosis
EHR: electronic health record
HbA1c: glycated hemoglobin
LSTM: long short-term memory
NLP: natural language processing
OOS-F: full out-of-sample
OOS-P: partial out-of-sample
T1D: type 1 diabetes

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