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Original Paper

Feasibility and Impact of Remote Glucose Monitoring Among Patients With Newly Diagnosed Type 1 Diabetes: Single-Center Pilot Study

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Abstract

Background: Caregivers of children with newly diagnosed type 1 diabetes (T1D) maintain close contact with providers for several weeks to facilitate rapid adjustments in insulin dosing regimens. Traditionally, patient glucose values are relayed by telephone for provider feedback, but digital health technology can now enable the remote sharing of glucose data via mobile apps.

Objective: The aim of this study was to test the feasibility of remote glucose monitoring in a population of children and adolescents with newly diagnosed T1D and to explore whether remote monitoring alters habits for self-review of glucose data or perceived ease of provider contact in this population as compared to a nonrandomized control group.

Methods: Data were collected from families who chose to participate in remote monitoring (intervention group) as well as from patients receiving usual care (control group). The intervention group received Bluetooth-capable glucose meters and Apple iPod Touch devices. Patient-generated glucose data were passively relayed from the meter to the iPod Touch and then to both the electronic health record (EHR) and a third-party diabetes data platform, Tidepool. The principal investigator reviewed glucose data daily in the EHR and Tidepool and contacted the participants as needed for insulin dose adjustments during the time between hospital discharge and first clinic appointment. Families in the control group received usual care, which involved keeping written records of glucose values and contacting the diabetes team daily by telephone to relay data and receive treatment recommendations. A total of 40 families (20 for the intervention group and 20 for the control group) participated in the study. All families were surveyed at 1 month and 6 months regarding self-review of glucose data and ease of contacting the diabetes team.

Results: Patient-generated glucose data were remotely accessible for 100% of the participants via Tidepool and for 85% via the EHR. Survey data indicated that families in the intervention group were more likely than those in the control group to review their glucose data using mobile health apps after 1 month (P<.001), but by 6 months, this difference had disappeared. Perceived ease of contacting the clinical team for assistance was lower for the intervention group after 6 months (when receiving usual care) in comparison to during the intervention period (P=.48) and compared with a control group who did not have exposure to remote monitoring (P=.03).

Conclusions: Remote glucose monitoring is feasible among pediatric patients with newly diagnosed T1D and may be associated with the earlier adoption of mobile health apps for self-management. The use of broadscale remote monitoring for T1D in the future will depend on improved access to Bluetooth-enabled mobile devices for all patients, improved interoperability of mobile health apps to enable data transfer on Android as well as Apple devices, and new provider workflows to handle large-scale panel management based on patient-generated health data.

Trial Registration: ClinicalTrials.gov NCT04106440; https://clinicaltrials.gov/ct2/show/NCT04106440

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KEYWORDS

remote monitoring; type 1 diabetes; pediatrics; diabetes; T1D; patient-generated data; mobile health; application

Introduction

The management of type 1 diabetes (T1D) is labor-intensive and data-driven for both patients and providers. The advent of continuous glucose monitoring (CGM) devices and insulin pumps has dramatically increased the volume of patient-generated health data (PGHD) available for T1D management [1,2], and mobile health apps have begun to make these data accessible remotely. However, advanced therapeutic technologies such as pumps and CGM are less frequently utilized by racial or ethnic minority patients and those from low-income households [3], and they are often not available directly after diagnosis due to payor restrictions. In addition, data from most insulin pumps can only be shared remotely using broadband internet, making this type of remote monitoring less feasible for individuals from racial or ethnic minorities or low-income households, who are more likely to depend on cellular devices for internet access [4]. Remote access to intermittent self-monitoring of blood glucose (SMBG) data has also become possible in the last five years via Bluetooth-enabled glucose meters, over a dozen of which are now commercially available [5]. SMBG meters remain the standard of care for T1D [6] and are provided to patients at the time of diagnosis; therefore, the remote monitoring of SMBG data via a mobile device has the potential to be broadly applicable within the T1D patient population.

The period directly after diagnosis of T1D involves frequent (often daily or biweekly) interaction between patients and providers to review glucose trends and adjust insulin doses to account for the effects of partial remission (“honeymoon phase”) and changes in diet and activity. These interactions have traditionally taken place via telephone but are well suited to remote monitoring. This pilot study evaluated the feasibility of remote glucose monitoring among pediatric patients with newly diagnosed T1D by using mobile devices and digital health apps to relay intermittent patient-generated glucose values into both the electronic health record (EHR) and a secure, third-party platform designed for diabetes data management [7]. This study also explored whether the use of remote monitoring in this patient group may alter habits for self-review of glucose data and the perceived ease of contacting providers for help during 6 months after diagnosis, as compared to a control group receiving usual care.

Methods

Setting

This study took place at the University of California, Davis (UCD) medical center in Sacramento, California. At our medical center, children with newly diagnosed T1D are typically hospitalized for 2-3 days for initiation of insulin therapy and to receive caregiver education about home T1D management. After hospital discharge, patients are scheduled for an appointment in the pediatric diabetes clinic approximately 2-6 weeks later, depending on availability. During the time between hospital discharge and first clinic appointment, caregivers are instructed to record patients’ glucose measurements on a daily basis and contact the clinic team or on-call pediatric endocrinologist by telephone to relay these glucose values and discuss any needed dose changes.

Recruitment

In this nonrandomized study, the recruitment of participants for the intervention and control groups took place separately. The participants for the intervention group were recruited during their initial hospitalizations at the time of T1D diagnosis. Inclusion criteria for children in the intervention group were (1) aged 1-17 years, (2) newly diagnosed with T1D during current hospitalization, (3) daily access to the internet via Wi-Fi, and (4) planning to receive care from the UCD pediatric diabetes clinic for the next 6 months. The participants for the control group were recruited during their first visits to the UCD pediatric diabetes clinic. Inclusion criteria for children in the control group were (1) aged 1-17 years, (2) newly diagnosed with T1D 2-6 weeks earlier, (3) not already enrolled in the intervention arm of the study, and (4) planning to receive care from the UCD pediatric diabetes clinic for the next 6 months. The control participants included children who were diagnosed with T1D during the 6 weeks prior to study initiation, families whom the research team was unable to approach for the intervention arm at the time of diagnosis (due to limited staff availability), and 3 families who had declined the intervention due to a preference to receive usual care. The only exclusion criterion for participants in either group was if a primary caregiver did not speak English, due to concern that the mobile health apps did not offer non-English versions and could therefore introduce a communication barrier as compared to usual care. Twenty participants were recruited to each study arm.

The recruitment for this study took place between October 2019 and October 2020. All aspects of the study were reviewed and approved by the UCD Institutional Review Board and were conducted in accordance with COVID-19–related policies enacted by the UCD Office of Research. The study was also registered on ClinicalTrials.gov (NCT04106440).

Intervention

The families in the intervention group were given a Bluetooth-capable glucose meter (OneTouch Verio Flex) and Apple iPod Touch device and instructed on their use prior to hospital discharge. Mobile health apps (OneTouch Reveal, Apple Health, Tidepool, and Epic MyChart) were installed on each iPod to facilitate the relay of patient-generated glucose data to provider-accessible platforms. As depicted in Figure 1, glucose data were transmitted via Bluetooth from the meter to the mobile device’s OneTouch Reveal app, then via Apple Health to Tidepool and Epic MyChart apps on the same device. When the device connected to Wi-Fi, these apps transmitted

data to the cloud, making them viewable by the providers in Epic (via a flowsheet within the patient's chart) and Tidepool (via the patient profile, which was linked to the clinic's account). Research staff assisted the study participants in establishing user profiles within these apps and enabling data sharing between them.

Figure 1. Relay of glucose data via mobile health apps.

After hospital discharge, the principal investigator reviewed glucose data for children in the intervention group daily in both Tidepool (a secure web-based platform for diabetes data management) [8] and Epic (the EHR used at UCD) and called their caregivers to discuss any needed changes in insulin dosing. This continued until each child's first visit at the pediatric diabetes clinic. Children in the control group received usual care between hospitalization and first clinic visit, as described above under "Setting."

Data Collection

At the time of enrollment, demographic data, including age, sex, race, ethnicity, and insurance type, were abstracted from the EHR for each participant in order to characterize the study population. In addition, clinical data were abstracted from the EHR for all participants 6 months after diagnosis—including their most recent hemoglobin A_{1c} values, and whether they were using CGM and insulin pump technology for diabetes management—in order to identify any significant clinical differences between the study groups. At 1 month and 6 months after diagnosis, a brief survey of multiple choice questions was administered to the participants' caregivers. This survey asked about typical frequency and modality for the self-review of glucose data and about the perceived ease of contacting the clinical diabetes team for help between clinic visits. For control participants who were enrolled >1 month after diagnosis, the 1-month survey was administered at the time of enrollment.

Analysis

Demographic and clinical characteristics of the intervention and control groups were compared using the Fisher exact test for categorical variables and the Student *t* test for the means of continuous variables. The feasibility of remote glucose monitoring was assessed by the proportions of intervention participants for whom patient-generated glucose data were successfully relayed into (1) Tidepool and (2) the EHR for the duration of the intervention period. The differences in survey responses for the study groups at 1 month and 6 months were evaluated using the Fisher exact test.

Results

Study Population

The demographic characteristics of children in the control and intervention groups were similar at the time of enrollment except that the intervention group was significantly older, with a mean age of 11.3 years (SD 3.9) versus 8.4 years (SD 3.3) for the control group, *P*=.02 (Table 1).

The 2 groups were also similar in their clinical characteristics after 6 months, with no significant differences in glycemic control or in the use of CGM or insulin pumps (Table 2).

Table 1. Demographic characteristics of study participants at enrollment.

Characteristics	Values		
	Control (n=20)	Intervention (n=20)	*P* value[a]
Age (years), mean (SD)	8.4 (3.3)	11.3 (3.9)	.02
Race, n (%)			.31
White	14 (70)	12 (60)	
Non-White	4 (20)	2 (10)	
Unknown	2 (10)	6 (30)	
Hispanic ethnicity, n (%)	2 (10)	4 (20)	.66
Insurance, n (%)			.87
Public	10 (50)	9 (45)	
Private	9 (45)	10 (50)	
Self-pay	1 (5)	1 (5)	

[a]Calculated using the Fisher exact test or the Student *t* test.

Table 2. Clinical characteristics of study participants after 6 months.

Characteristics	Values		
	Control (n=20)	Intervention (n=20)	*P* value[a]
CGM[b] use, n (%)	19 (95)	17 (85)	.60
Insulin pump use, n (%)	8 (40)	4 (20)	.30
HbA_{1c}[c], mean (SD)	8.3 (1.1)	8.2 (1.3)	.77

[a]Calculated using the Fisher exact test or the Student *t* test, as appropriate.

[b]CGM: continuous glucose monitor.

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

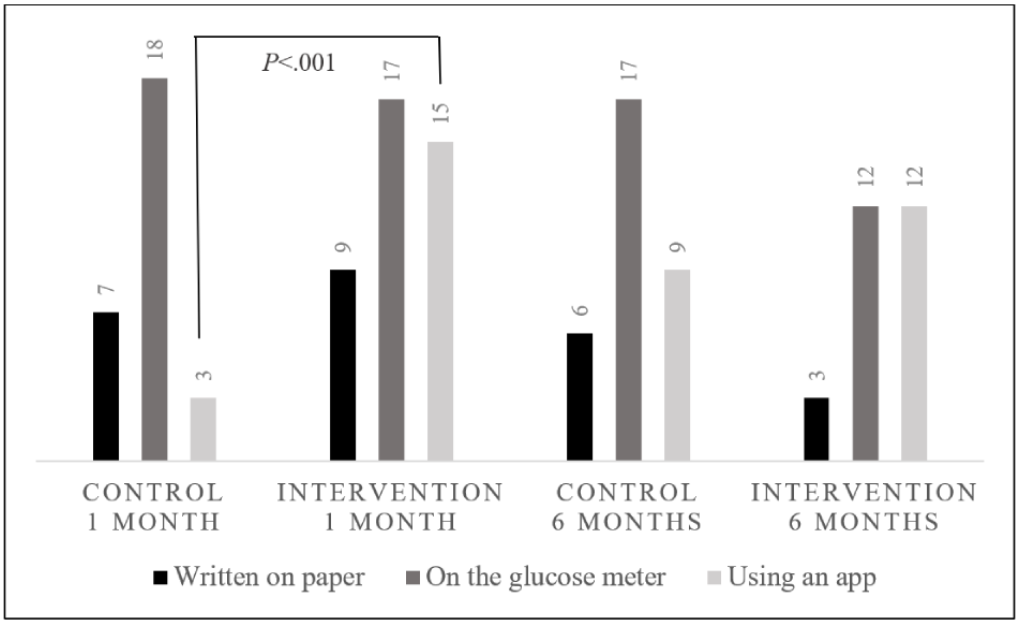
Feasibility of Remote Monitoring

Remote glucose monitoring was successfully established for 100% of the families in the intervention group via Tidepool and for 85% of the families via Epic. Difficulties establishing remote monitoring via Epic resulted from problems creating full access MyChart accounts for 3 of the participants due to medical-center–specific policies, rather than technical errors. The issues encountered for these 3 participants were later resolved at a system level, but not during the intervention period for this study.

Survey Findings

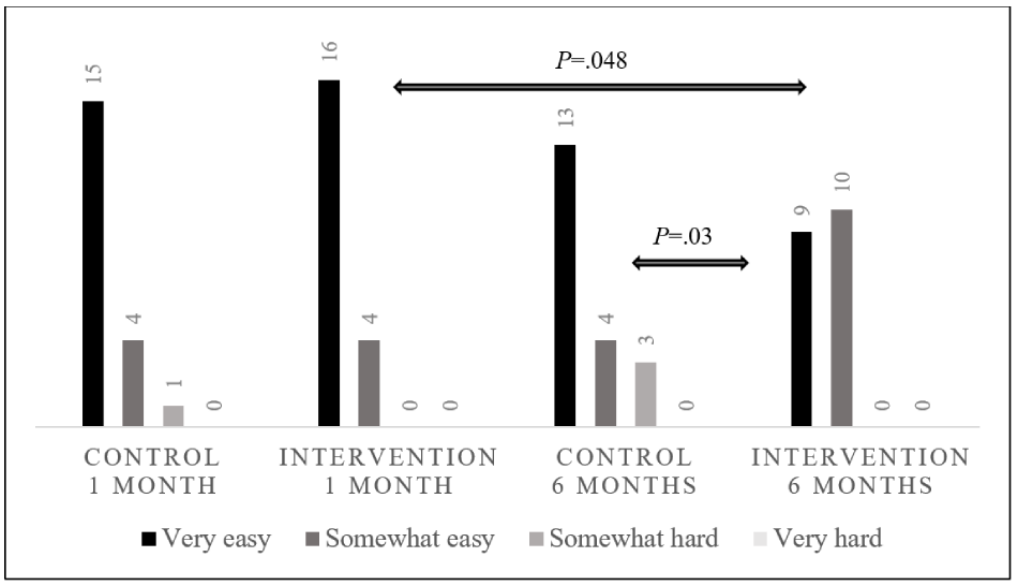
One-month surveys were completed for all participants, and 6-month surveys were completed for 39 of the 40 participants. At both 1 month and 6 months, all families in the intervention and control groups reported that they reviewed their glucose values at least daily. Their chosen method for reviewing these values differed significantly at 1 month but not at 6 months (Figure 2), with greater use of mobile apps in the intervention group as compared with the control group at 1 month after diagnosis. In Figure 2, survey responses to “How do you review your child’s glucose levels (select all that apply)?” were analyzed. The Fisher exact test was performed for each response, comparing control and intervention groups at each time interval, and comparing time intervals within each group.

Figure 2. Survey responses to "How do you review your child's glucose levels (select all that apply)?" All *P* values >.05, except as shown.



At 1 month after diagnosis, the majority of participants in both groups felt it was "very easy" to contact the clinical diabetes team for help between visits. By 6 months, this perceived ease of contact had decreased significantly for families in the intervention group in comparison with their own responses at 1 month (during the intervention period) and compared with the control group responses (Figure 3). In Figure 3, the survey responses to "How easy is it to discuss your child's glucose levels with his/her diabetes team between clinic visits (select one)?" were analyzed. The Fisher exact test was performed for the overall distribution of responses, comparing control and intervention groups at each time interval, and comparing time intervals within each group.

Figure 3. Survey responses to "How easy is it to discuss your child's glucose levels with his/her diabetes team between clinic visits (select one)?" All *P* values >.05, except as shown.



Discussion

Primary Findings

This pilot study demonstrates the feasibility of remote glucose monitoring among pediatric patients with newly diagnosed T1D using Bluetooth-capable glucose meters and Wi-Fi–enabled mobile devices. Remote glucose monitoring has been utilized previously for adults with type 2 diabetes [9,10], and for children with T1D utilizing insulin pumps [11] or CGM devices [12]. To our knowledge, this is the first published study to utilize remote glucose monitoring via finger-stick glucose meters among pediatric patients with newly diagnosed T1D.

Our survey results suggest that the use of remote monitoring accelerated patients' and caregivers' adoption of mobile health apps for the self-review of glucose data during the first month after diagnosis. The use of remote monitoring did not appear to alter the frequency of glucose self-review during the first 6 months after diagnosis, because all control and intervention

families reported daily review of glucose data during this time; however, it is possible that differences might emerge with a longer duration of follow-up. Interestingly, ease of glucose review and insulin dosage adjustment via remote monitoring was such that after the completion of the intervention period, routine methods for contacting the diabetes care team were perceived as less easy by the intervention group, as demonstrated on their 6-month surveys.

In addition to these reported findings, remote glucose monitoring was also noted to improve the efficiency of provider workflows in several ways during the study. Easy access to remotely shared glucose data reduced the amount of time spent verbally recounting glucose values by telephone with families, enabling a greater amount of time to be spent on the discussion of glucose trends and diabetes management behaviors. In addition, the ability to review glucose data for all participants prior to contacting them improved provider efficiency by facilitating focus on those children most in need of insulin dose adjustments. Finally, the wide-scale adoption of video and telephone care necessitated by the COVID-19 pandemic—which began midway through this study—further highlighted the utility of remote monitoring from a provider standpoint by facilitating easy access to patient-generated data during telehealth appointments.

It is important to note that CGM technology is increasingly utilized in pediatric T1D and can be successfully initiated within several weeks of diagnosis [13]. However, we sought to provide remote monitoring starting at the time of hospital discharge (2-3 days after diagnosis) and continuing for 2-6 weeks afterward, during which time payors and suppliers have typically not yet authorized or provided CGM devices. We therefore evaluated the feasibility of remote monitoring of intermittent finger-stick glucose measurements. Because finger-stick glucose meters are universally available at the time of diagnosis, this study's results have broad applicability for patients with newly diagnosed T1D. In addition, the outcomes we evaluated in terms of patient experience are likely generalizable to patients utilizing CGM devices, because they center on the patient's interactions with mobile device apps and clinical providers rather than with the glucose monitoring device itself.

Limitations

This study was designed as a pilot and feasibility study, and as such, it was limited in its size and scope. Because the assignment to the intervention was not randomized, the participants were able to self-select into intervention and control groups to a certain extent. Although the intervention participants were not required to own a mobile device or have knowledge to set up the necessary apps and data relays (since these were provided by research staff), children and families choosing to participate in the intervention may have had higher comfort using mobile devices and apps. The higher mean age of the participants in the intervention group may reflect this difference, as adolescent patients tend to have higher digital literacy than younger children. This type of self-selection reflects the realities of clinical practice, and this study therefore retains high validity in demonstrating the feasibility of remote glucose monitoring among willing participants. However, our results should not be generalized to infer what the experience of remote monitoring would be among all children with newly diagnosed T1D. In addition, the processes and outcomes for relaying glucose data into the EHR in this study may not be generalizable to practices utilizing non-Epic EHR systems, which may import and display glucose data differently. Furthermore, although our study population was diverse socioeconomically (50% publicly insured), 65% of the participants were of White racial backgrounds and 100% were English speaking, which limits the generalizability of our findings for minority demographic groups. Finally, it is important to note that this study's survey questions were not specifically validated for use in this population and clinical context, and the survey findings should therefore be interpreted primarily as hypothesis-generating, to be used in developing future research studies.

Future Directions

The purpose of any pilot study is to explore whether the intervention may be of benefit if applied on a larger scale. In the case of our remote monitoring intervention, translation from research into standard practice is feasible, but requires that several challenges be addressed.

On the patient side, Bluetooth-capable glucose meters are fortunately now approved by most if not all payors, and most brands have developed corresponding mobile apps that can collect glucose data and relay it to the cloud as well as to other compatible programs on a mobile device. However, the patient must have a personal mobile device with Bluetooth and internet capability, which can download and run multiple digital health apps simultaneously. Although it is preferable that this device remain with the patient the majority of the time (which can be problematic, particularly for school-aged children who may not have their own mobile phones), glucose data can be synced from the meter to the mobile device at a later time with full data retention. This is an advantage over some continuous glucose monitors that can only store up to 3 hours of data for later transmission to a mobile device. The data relay into the EHR in this study required the use of Apple Health and therefore could only be performed using an Apple device. As other health data apps such as Google Fit are expanding their compatibility, it is possible that this limitation will soon disappear. Battery life for the Bluetooth-capable meters and data use for the mobile devices proved to be an issue for some study participants, so in practice, patients would need to be warned about possible additional expenses for battery replacement and internet or cellular data transmission.

For providers, the primary challenge to broadening the use of this intervention is the need for new workflows and an expanded workforce. In most pediatric diabetes centers, the review of patient-generated glucose data is a reactive process for providers, performed in response to patient-initiated contact. The efficient use of remote monitoring could transform this to a provider-initiated process whereby data are reviewed on a regular basis and outreach to patients occurs based on predetermined criteria. Our study's intervention did not significantly increase the provider workload for newly diagnosed patients (a cohort with whom frequent contact is routine); however, the expansion of remote monitoring to established patients with T1D would increase provider burden substantially

by broadening the target population and by augmenting the frequency of contact with these patients. This type of expansion would necessitate a larger clinical workforce and the development of patient care algorithms which could be enacted primarily by nonphysician care team members. In addition, supplementary time and personnel would be needed to provide technical assistance and technology-related patient education—roles that were filled by research staff in this study—to assist with initiating remote glucose monitoring in clinical practice.

In addition to identifying specific patient and provider challenges to implementing remote glucose monitoring, this study generated several positive findings that deserve mentioning in the context of future directions. First, this study provided a proof-of-concept for importing glucose data directly into the EHR, but also demonstrated that the data relay was simpler to establish, and the visualization of data was superior via a diabetes-specific data platform (Tidepool), compared with the EHR. Therefore, although EHR integration of patient-generated data is an important goal for clinicians and health systems, future remote monitoring initiatives for diabetes will likely be most successful if they utilize the data visualization capabilities of existing third-party diabetes management tools and integrate these platforms with the EHR using single sign-on functionality. Second, our research team observed improved clinician efficiency using remote monitoring versus usual care. This observation should be explored quantitatively in future trials, comparing overall provider time alongside patient-centered outcomes to better understand the total benefits of remote monitoring protocols. Third, our study's intervention had positive effects on the use of mobile diabetes apps and communication with diabetes providers after 1 month, but it is unclear if these benefits were due to the remote monitoring of diabetes data, the supply of mobile devices and orientation to diabetes apps, or the daily provider-initiated contact to families. Future, larger trials of remote monitoring would benefit from enrolling multiple intervention arms in order to separate the effects of these factors.

Conclusions

This pilot study demonstrates the feasibility of remote glucose monitoring among pediatric patients with newly diagnosed T1D using Bluetooth-capable glucose meters and internet-connected mobile devices. The future application of remote monitoring to broader T1D populations hinges on the ability to establish passive, continuous data sharing via a broad array of mobile devices and glucose meters, and the development of provider algorithms for managing T1D populations on a continuous basis.

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Conflicts of Interest

None declared.

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Abbreviations

CGM: continuous glucose monitoring
EHR: electronic health record
PGHD: patient-generated health data
SMBG: self-monitoring of blood glucose
T1D: type 1 diabetes
UCD: University of California, Davis

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Original Paper

An Innovative, Paradigm-Shifting Lifestyle Intervention to Reduce Glucose Excursions With the Use of Continuous Glucose Monitoring to Educate, Motivate, and Activate Adults With Newly Diagnosed Type 2 Diabetes: Pilot Feasibility Study

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Abstract

Background: Type 2 diabetes (T2D) is a growing epidemic in the United States, and metabolic control has not been improved over the last 10 years. Glycemic excursion minimization (GEM) is an alternative lifestyle treatment option focused on reducing postnutrient glucose excursions rather than reducing weight. GEM has been proven to be superior to routine care when delivered face to face, and equivalent or superior to conventional weight loss therapy, but it has not been evaluated among patients newly diagnosed with T2D or in a self-administered format.

Objective: This pilot study evaluated the feasibility of a self-administered version of GEM, augmented with continuous glucose monitoring (CGM), to improve metabolic control (hemoglobin A_{1c} [HbA_{1c}]) while diminishing or delaying the need for diabetes medications in adults recently diagnosed with T2D. These primary objectives were hypothesized to be achieved by reducing carbohydrate intake and increasing physical activity to diminish CGM glucose excursions, leading to the secondary benefits of an increase in diabetes empowerment and reduced diabetes distress, depressive symptoms, and BMI.

Methods: GEM was self-administered by 17 adults recently diagnosed with T2D (mean age 52 years, SD 11.6 years; mean T2D duration 3.9 months, SD 2.5 months; mean HbA_{1c} levels 8.0%, SD 1.6%; 40% female; 33.3% non-White), with the aid of a 4-chapter pocket guide and diary, automated motivational text messaging, and feedback from an activity monitor, along with CGM and supplies for the 6-week intervention and the 3-month follow-up. Treatment was initiated with one telephone call reviewing the use of the technology and 3 days later with a second call reviewing the use of the GEM pocket guide and intervention.

Results: At 3-month follow-up, 67% of the participants' diabetes was in remission (HbA_{1c} levels <6.5%), and only one participant started taking diabetes medication. Participants demonstrated a significant reduction in HbA_{1c} levels (–1.8%; P<.001). Participants also experienced significant reductions in high-glycemic-load carbohydrates routinely consumed, CGM readings that were >140 mg/dL, diabetes distress, depressive symptoms, and BMI. Participants felt that use of the CGM was the most significant single element of the intervention.

Conclusions: GEM augmented with CGM feedback may be an effective initial intervention for adults newly diagnosed with T2D. A self-administered version of GEM may provide primary care physicians and patients with a new tool to help people

recently diagnosed with T2D achieve remission independent of medication and without weight loss as the primary focus. Future research is needed with a larger and more diverse sample.

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KEYWORDS

type 2 diabetes; continuous glucose monitoring; glycemic excursion minimization; initial treatment; diabetes distress; diabetes; monitoring; treatment; distress; pilot study; lifestyle; intervention; motivation.

Introduction

Type 2 diabetes (T2D) is an epidemic in the United States, with 1.5 million new cases diagnosed annually, 34 million patients currently with the condition, and costing the US economy US $327 billion annually [1]. While the American Diabetes Association recommends weight loss of at least 7% and at least 150 minutes per week of moderate to vigorous physical activity to help manage T2D [2], up to 15% of these patients do not need to lose weight [3], while others are either unwilling or unable to lose weight and to maintain weight loss [4]. Further, glycemic control has not improved over the past decade [5-7]. International and national guidelines recommend diabetes self-management education and support (DSMES) for people with T2D around the time of diagnosis, but DSMES at the time of diagnosis is severely underutilized (only 6.8% of privately insured individuals and 5% of Medicare individuals receive DSMES within the first 12 months of being diagnosed with T2D) [8]. We developed an alternative lifestyle treatment option, glycemic excursion minimization (GEM), focusing on reducing postnutrient blood glucose (BG) excursions that contribute to both hemoglobin A_{1c} (HbA_{1c}) [9] and to cardiovascular disease [10,11]. Although not classified as DSMES, GEM presents an additional method that may empower people with diabetes to better understand the impact of food and exercise on their blood glucose levels. GEM has been administered as a face-to-face intervention to adults diagnosed with T2D within the past 10 years and was superior to routine care [12,13] and equivalent or superior to conventional weight loss therapy in regard to reduction of HbA_{1c} levels, cardiovascular risk, and improvement in psychological function and BMI [14,15]. However, GEM has never been evaluated among patients newly diagnosed with T2D, in a self-administered format, outside of the University of Virginia, with automated daily text prompts. Such an intervention might not only improve metabolic control but also reduce the reliance on diabetes medications.

Given accessibility issues owing to the pandemic, we investigated the efficacy of a remote GEM delivery program. Given that earlier intervention of T2D has greater long-term benefits [16] and may provide access to more motivated persons [17], we focused on newly diagnosed patients. Given that GEM has only been evaluated at the University of Virginia, we delivered GEM at diverse medical settings (external validity). Given that daily text messages have been demonstrated to improve engagement by adults with T2D [18], we employed text messaging for the first time. The primary hypotheses tested were that GEM combined with feedback from continuous glucose monitors (CGMs) and activity monitors, with automated text messages could improve metabolic control with reduced reliance on diabetes medication, while producing the secondary benefits of improved psychological function and reduced BMI.

Methods

Ethics Approval

This study was performed in accordance with the principles of the Declaration of Helsinki. Ethical approval for this study was obtained from the University of Virginia Institutional Review Board for Health Sciences Research (protocol HSR200250).

Recruitment

To maximize external validity, one-third of the participants were recruited from each of three diverse centers: University of Virginia (n=5), University of Colorado (n=6), and West Virginia University (n=6). Inclusion criteria were as follows: age of 35-85 years, HbA_{1c} levels of 6.5%-11.5%, diagnosed with T2D within the past 12 months, not taking diabetes medication, no medical condition or medication that precludes reducing carbohydrates or walking 120 steps per minute for 10 minutes (eg, prednisone, severe neuropathy, cardiovascular disease, chronic obstructive pulmonary disease or emphysema, osteoarthritis, stroke, severe gastroparesis, ulcers, or food allergies), and ablilty to read English. Our age criteria aimed to select individuals most likely to be in control of their daily routine, HbA_{1c} criteria aimed to ensure the diagnoses of T2D but to avoid individuals whose condition was so progressive that immediate medication management was indicated, the no diabetes medication criterion was essential to test the hypothesis that GEM would prevent or diminish the need for diabetes medication, and the remaining criteria aimed to ensure the feasibility of engaging in the comprehensive GEM lifestyle.

Procedure

After signing a University of Virginia IRB-approved consent, each participant's primary care physician or clinician was contacted to affirm that the participant met eligibility criteria and to provide written approval for participation. Next, participants were sent a weblink to complete a series of questionnaires (Baseline: routine consumption of high and low glycemic load foods [19]; psychological questionnaires to assess diabetes empowerment [20], diabetes distress (emotional and regimen) [21], and depressive symptoms [22]; and diabetes knowledge as it relates to GEM principles [23].

After completing questionnaires, participants were mailed a CGM reader and 4.5 months of sensor supplies, (FreeStyle Libre 2 CGM system), a Fitbit Charge 3 activity monitor, and the GEM pocket guide (hard copy). This was followed by a telephone call introducing them to the CGM and activity monitor technology, inserting the CGM sensor, registering and activating

the technology, and selecting seven personalized text messages, for example, “Food choices are life choices, Exercise is my friend,” which would be delivered at a time and frequency selected by the participant, to encourage GEM engagement [18]. Three days later, they received the second and final call to review the GEM pocket guide to initiate treatment.

GEM is neither a behavior modification nor a prescription program. Rather, GEM is an empowerment program [24,25] that provides information that a patient can choose to employ, to identify food and activity choices that either exacerbate or diminish postnutrient glucose excursions (represented by the area under the curve in Figure 1). The GEM pocket guide is a 4.25×5.50-inch booklet with four units. In unit 1, with CGM feedback, participants spend 5 days learning which of their routine food and physical activity choices have major and minor impacts on their glucose excursions. In unit 2 participants spend 14 days focusing on reducing, substituting, replacing, or eliminating high impact carbohydrates to diminish glucose excursions; for example, replacing breakfast oatmeal with unsweetened Greek yogurt and fresh fruit or substituting cauliflower rice for white rice. In unit 3, participants spend 14 days learning how to hasten recovery of glucose excursions by changing the type, intensity, duration, and timing of routine physical activity, such as walking the dog after supper instead of sitting in front of the television or computer. In unit 4, participants learn to continue experimenting with new nutrients and activities, sustain support of significant others, and prevent, anticipate, and recover from relapses resulting from fatigue, life stress, or change in routine. GEM was executed in the context of self-monitoring with diary entries, personal feedback from the CGM and the activity monitor, and automated daily motivational text messages. Following unit 1, there were 5 diary pages, and following units 2-4, there were 14 days of diaries where participants recorded their food and activity choices and how these impacted their glucose excursions.

Figure 1. Continuous glucose monitoring data from one participant at the beginning and end of glycemic excursion minimization: change in the area under the receiver operating characteristic curve 27,600 to 8475 and change in hemoglobin A_{1c} levels 8.8% to 5.7%.

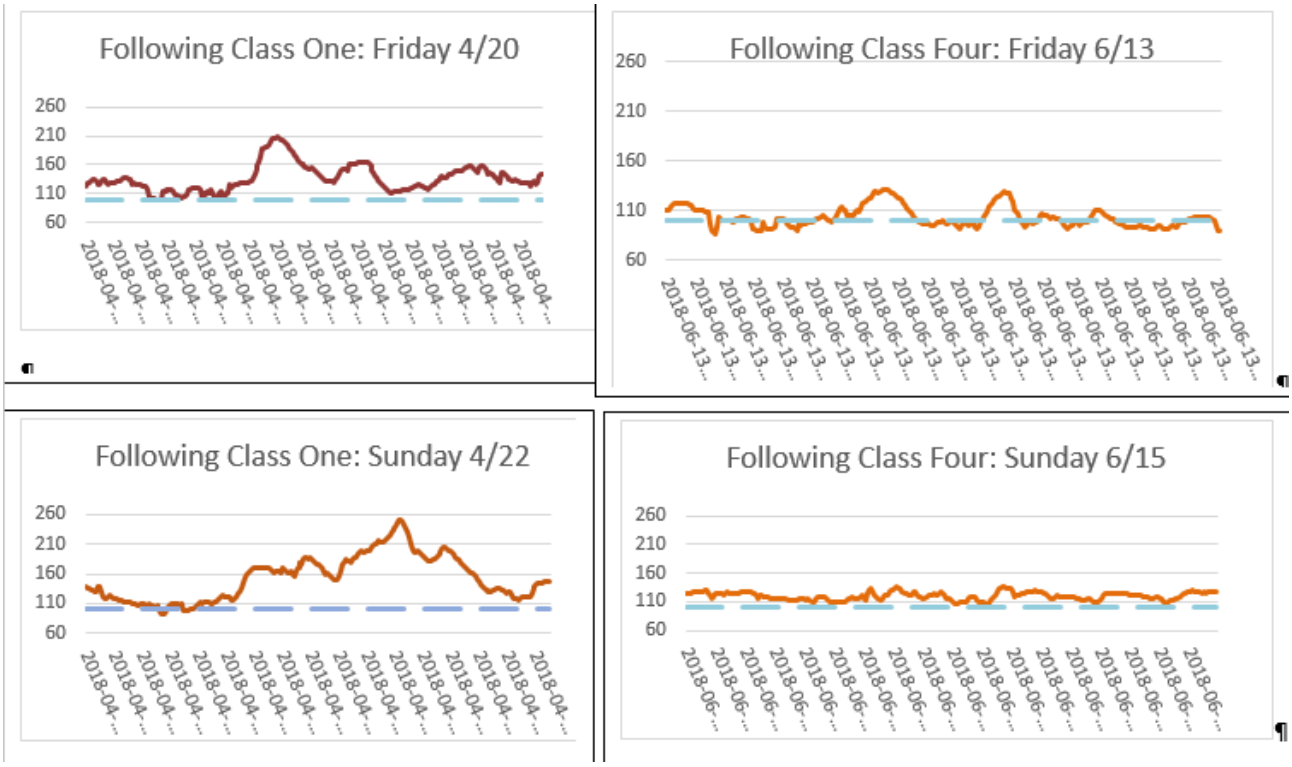
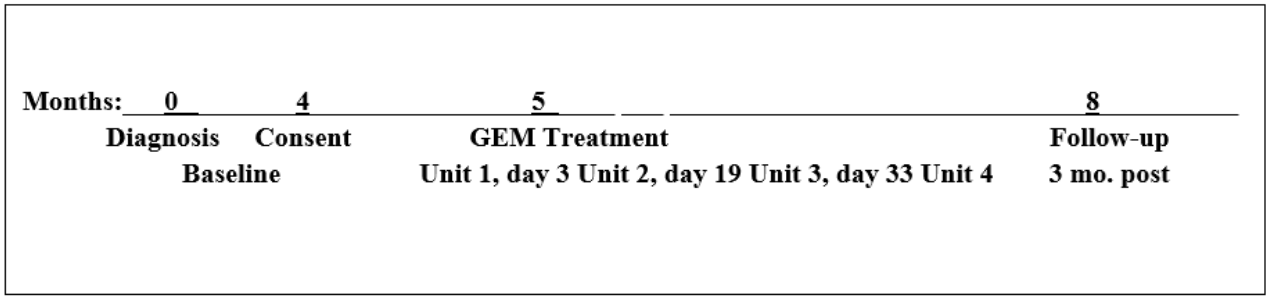


Figure 1 displays 2 days of pre- and post-CGM data for 1 participant, illustrating how GEM reduces glucose excursions.

After this 6-week GEM program, for the next 3 months, participants continued exploring the principles of GEM with the assistance of their CGM and Fitbit feedback. A 3-month posttreatment assessment involved downloading their CGM data, and repeating the web-based questionnaires. Following completion of these questionnaires, participants rated how “helpful” different elements of the program were on a Likert scale (0=not helpful at all, 1=slightly helpful, 2=somewhat helpful, 3=very helpful, and 4=extremely helpful).

Investigators then extracted participants’ diagnostic and post-GEM HbA_{1c} levels, BMI, and prescribed diabetes medications from their medical records (Figure 2).

Figure 2. Timeline from diagnoses through follow-up assessment. GEM: glycemic excursion minimization.



Statistical Analysis

SPSS (version 27, IBM Corp) was used to perform 2-tailed paired *t* tests to test for differences in means between GEM participants' diagnostic (baseline, preintervention) and 3-month postintervention data among the following outcome variables: HbA_{1c} levels, metformin dose, number of CGM readings that were >140 mg/dL, CGM glucose variability expressed as SD values [26,27], BMI, and weight. Pre- and postintervention mean scores were also compared for the following questionnaires or scales: high-carbohydrate food intake, low-carbohydrate food intake, diabetes knowledge, diabetes empowerment, diabetes distress (emotional subscale), diabetes distress (regimen subscale), and depressive symptoms. The Benjamini-Hochberg procedure [28] was used to control for multiple comparisons, correcting for all *P* values in Table 1. Exploratory Pearson correlations were performed between HbA_{1c} levels and both baseline and postintervention variables. There were no missing data, and none of the data sets violated the assumptions of a normal distribution.

Results

Participants' mean age at diagnosis was 52 (SD 11.6) years, the mean time between diagnosis and consent was 3.9 (SD 2.5) months, the mean duration of diabetes at postintervention assessment was 8.5 (SD 3.3) months, 40% of participants were female, and 33.3% of participants were non-White. Table 1 provides more detailed baseline data. There was 1 adverse event (contact dermatitis from CGM sensor adhesive) and 2 dropouts (owing to oral surgery and family crisis).

Table 1 illustrates that at 3 months follow-up, GEM led to a significant reduction in HbA_{1c} levels ($P<.001$), with 66.7% of participants qualifying as having their diabetes in remission (HbA_{1c} level <6.5%) [29]. Further, 80% of the participants were classified as Responders (decrease in HbA_{1c} levels of at least 0.5%), with a mean pre-post change in HbA_{1c} levels of –2.3% (SD 1.3%).

Table 1. Variables, pretreatment, and 3 months post–glycemic excursion minimization intervention.

Variable	Pretreatment	3 months post–glycemic excursion minimization	*P* value	Baseline correlation with change in hemoglobin A_{1c} levels	Change in correlation with change in hemoglobin A_{1c} levels
Primary outcome variables, mean (SD)					
Hemoglobin A_{1c} levels (%)	8.0 (1.6)	6.2 (1.1)	<.001[a]	–0.755[b]	
Metformin (mg/day)	0 (0)	133 (516)	.33		–0.219
Mechanism variables					
Continuous glucose monitoring data, unblinded weeks 1 and 18, mean (SD)					
Percentage of time when continuous glucose monitoring values were >140 mg/dL	23.9 (28.9)	14.5 (22)	.03	–0.012	–0.086
Glucose variability	22.4 (10.1)	20.2 (8.3)	.08	0.132	–0.208
High-carbohydrate foods	39.6 (21.9)	10.3 (6.8)	<.001[a]	–0.243	0.238
Low-carbohydrate foods	50.2 (20.8)	48.6 (20.0)	.69	–0.413	0.635[c]
Secondary benefits, mean (SD)					
Diabetes knowledge	15.5 (3.0)	15.9 (3.0)	.53	0.061	0.555[c]
Diabetes empowerment	31.0 (5.9)	34.6 (3.8)	.06	–0.253	0.251
Diabetes distress, emotional	2.2 (0.8)	1.8 (1.0)	.10	–0.580[c]	0.015
Diabetes distress, regimen	2.8 (1.4)	1.8 (0.9)	.03	0.363	–0.052
Depressive symptoms	6.1 (4.5)	2.3 (3.9)	.001[a]	0.400	0.132
BMI	36.5 (8.1)	34.4 (8.2)	.002[a]	0.013	0.333

[a]Significant with the Benjamini-Hochberg procedure.

[b]Correlation with $P<.01$.

[c]Correlation with $P<.05$.

Three months post GEM, participants presented reduced CGM readings >140 mg/dL ($P=.03$) and consumed high-carbohydrate foods routinely ($P<.001$). Secondary benefits included reduction of depressive symptoms ($P=.001$) and BMI ($P=.002$).

Table 1 additionally presents correlations of baseline variables with post-GEM reduction in HbA_{1c} levels. Change in HbA_{1c} levels was negatively correlated with baseline HbA_{1c} levels ($r=–0.755$) and emotional diabetes distress ($r=–0.580$). The last column in Table 1 shows how improvement in variables correlated with improvement in HbA_{1c} levels. Greater increase in diabetes knowledge ($r=0.555$) and greater increase in routine intake of low glycemic foods ($r=0.635$) were associated with greater improvement in HbA_{1c} levels.

Reduction in HbA_{1c} levels was only associated with higher baseline HbA_{1c} levels ($r=–0.755$) and emotional diabetes distress ($r=–0.580$). Greater reduction in HbA_{1c} levels was associated with greater pre-post reduction in low-glycemic-load carbohydrate ingestion ($r=0.635$) and improved diabetes knowledge ($r=0.555$).

Posttreatment mean ratings (0-4) for how helpful each of the different elements were: Libre 2 CGM=3.9, Fitbit=3.4, GEM Pocket Guide=2.9, diaries=2.6, GEM Supplement=2.5, and text messages=2.4.

Discussion

Principal Findings

Our primary hypotheses were confirmed. Mean HbA_{1c} levels were reduced by 1.8% among all participants, with 67% being classified as having diabetes remission and 80% being classified as responders with a mean HbA_{1c} level reduction of –2.3% among responders. This was achieved with only one participant needing to start taking medication. This participant's HbA_{1c} level decreased 3.6%, from 12.7% to 9.1%, which was a clinically important improvement that subsequently required the additional introduction of metformin.

Regarding secondary hypotheses, there was a posttreatment decrease in diabetes distress, depression symptoms, and BMI, and a trend toward increased diabetes empowerment.

The strengths of this study are that it was a multicenter, brief, self-administered intervention, which recruited a diverse sample by diverse investigators. The mean change in HbA_{1c} levels of –1.8% by these GEM participants incorporating CGM compares favorably to the –1.0% change in HbA_{1c} levels by a similar group in a randomized controlled trial delivered in a face-to-face format with adults having T2D for an average of 5.3 years of taking diabetes medication [12].

Limitations

Limitations of our study include a small sample size, no control group, and a limited follow-up duration. Additionally, pre-post change in physical activity, a presumed primary mechanism of GEM, was not monitored in this study. Despite these limitations and multiple positive findings, this is still a pilot study in need of replication with a larger and more diverse sample, which could tease out whether CGM alone would lead to such benefits.

Comparison With Prior Work

This compares favorably to a mean reduction in HbA_{1c} levels of 1.5% and no psychological benefits with maximum dosage of metformin [30].

Despite being a self-directed program, these results were better than any of our previous efforts [12,15]. This could have resulted from our subject sample consisting of recently diagnosed adults who had not yet begun diabetes medication. This speculation is supported by the UK Prospective Diabetes Study [31], which initiated treatment for newly diagnosed T2D with 3 months of "dietary counseling" alone, with no medication, which led to a reduction in HbA_{1c} levels by ~1%. It could also be because of all participants in this study wanting this intervention—no random assignment. However, it may also be due to the multidimensional nature of the intervention: feedback from CGM and activity monitors, a structured and brief pocket guide and diary, and daily text messages, all of which were considered helpful by participants. It could have been that a reduction in HbA_{1c} levels was highly associated with baseline HbA_{1c} levels, since those with a higher HbA_{1c} level had the possibility of lowering it further, or that greater diabetes distress was associated with greater reduction, as this could reflect greater motivation. Likewise, the greater knowledge acquired about the impact of diet and activity on diabetes, and the greater reduction in routine carbohydrate ingestion were associated with more reduction in HbA_{1c} levels, as these were the hypothesized mechanisms. Reduction in BMI was a secondary benefit and was not correlated with improvement in HbA_{1c} levels.

Conclusions

GEM augmented with CGM feedback may be an effective initial intervention for adults newly diagnosed with T2D. A self-administered version of GEM may provide primary care physicians and their patients with a new tool to help people recently diagnosed with T2D to achieve remission independent of medication and without weight loss as the primary focus. Future research is needed with a larger and more diverse sample.

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Conflicts of Interest

The funding sources were not involved in the design or conduct of the study, or in the preparation of this manuscript. TKO has served on a physician advisory board for Cecilia Health and Dexcom.

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Abbreviations

BG: blood glucose
CGM: continuous glucose monitoring
DSMES: diabetes self-management education and support
GEM: glycemic excursion minimization
HbA_{1c}: hemoglobin A_{1c}
T2D: type 2 diabetes

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Original Paper

Continuous Glucose Monitoring Data Sharing in Older Adults With Type 1 Diabetes: Pilot Intervention Study

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Abstract

Background: Family members or friends (care partners [CPs]) of older adults with type 1 diabetes (T1DM) regularly become part of the diabetes care team, but they often lack knowledge about how to become involved to prevent hypo- and hyperglycemia. Continuous glucose monitoring (CGM) allows a person with diabetes to see their glucose levels continuously and to receive predictive alerts. A smartphone data-sharing app called the Follow app allows the person with diabetes to share continuous glucose numbers with others and to receive predictive alerts of impending hypo- and hyperglycemia. However, there are barriers to sharing this continuous glucose level data with CPs.

Objective: This study aimed to address the barriers to sharing CGM data. Our objective was to examine the feasibility of using CGM with the Follow app and a data-sharing intervention called SHARE *plus* in older adults with T1DM and their CPs. SHARE *plus* includes dyadic communication strategies, problem-solving strategies, and action planning to facilitate CGM data sharing.

Methods: Older adults with T1DM (n=20) and their CPs (n=20) received the SHARE *plus* intervention at baseline. People with diabetes wore the CGM for 12 weeks while sharing their glucose data using the Follow app with CPs. Feasibility data were analyzed using descriptive statistics.

Results: The SHARE *plus* intervention was feasible and was associated with high self-reported satisfaction for people with diabetes and their CPs as well as high adherence to CGM (mean 96%, SD 6.8%). Broad improvements were shown in the diabetes-related quality of life through the use of CGM in people with diabetes and their CPs. Although the majority of people with diabetes (11/20, 55%) were willing to share hyperglycemia data, several chose not to. The majority of people with diabetes (14/20, 70%) were willing to talk about glucose numbers with a CP.

Conclusions: Older adults with T1DM and their CPs identified having someone else aware of glucose levels and working together with a partner on diabetes self-management as positive aspects of the use of the SHARE *plus* intervention. Clinicians can use these results to provide data sharing coaching in older adults and their CPs.

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KEYWORDS

older adults; type 1 diabetes; caregiver; CGM; data sharing; mobile phone

Introduction

An estimated 1.59 million individuals have type 1 diabetes (T1DM) in the United States [1], with a growing number of adults living into late adulthood, as life expectancy has increased by 15 years in the past 70 years [2]. Severe hypoglycemia occurs most frequently in adults >50 years old with T1DM and results in seizure or loss of consciousness [3]. The risk for severe hypoglycemia is markedly increased in older adults because of reduced awareness of hypoglycemic warning symptoms, reduced hormonal counter-regulatory response, and changes in dexterity, visual acuity, fine motor skills, cognitive function, depression, and anxiety that may prevent affected individuals from taking corrective actions [4]. These age-related changes result in increased complications related to hypo- and hyperglycemia, including myocardial infarction, cerebrovascular accidents, dementia, dementia-related falls, fractures, and sudden death [4,5]. Moreover, hyperglycemia increases the risk of dehydration, electrolyte imbalances, urinary incontinence, dizziness, and falls [6]. Family members and friends of older adults with T1DM regularly become part of the diabetes care team. However, these care partners (CPs) often lack knowledge about when or how to become more involved to prevent hypo- and hyperglycemia.

Since Medicare began covering continuous glucose monitoring (CGM), access to CGM has increased among older adults with T1DM and it has shown some efficacy at reducing risk of hypo- and hyperglycemia in these individuals. The Diamond and WISDM (Wireless Intervention for Seniors with Diabetes Mellitus) trials [7,8] demonstrated that CGM in older adults improves time in range (70-180 mg/dL), reduces glucose variability, hypoglycemia, and improves hemoglobin A_{1c} in comparison to blood glucose monitoring. Although time in range improved significantly in both trials at 6 months, time in range only increased by 93-100 minutes per day in the majority of CGM users. Mixed results were seen for participant satisfaction and diabetes-related quality of life (DQOL) across the 2 trials. Though this evidence supports the use of CGM in older adults, limited research is focused on using CGM with CPs and how it may affect a person with diabetes.

Several CGM systems have apps that allow a CP to see CGM glucose levels continuously and receive alerts and a hypoglycemia alarm. Dexcom has a mobile app called Follow that allows CPs to access glucose data for people with diabetes [9]. Although no studies have assessed the experience of using CGM with the Follow app in older adults and their CPs, data suggest that adults and their CPs may benefit from assistance in knowing how to be involved for optimal diabetes management [10,11]. However, there are barriers to using Follow, such as the need for knowledge on smartphone technology, difficulties setting up the sharing features [10], and challenges in communication between people with diabetes and CPs that reflect difference in expectations with regard to CP involvement [10]. People with diabetes and their CPs indicate that expectations of CP involvement in diabetes management frequently differ between them. People with diabetes often regard diabetes as “their own illness,” whereas their spouses view the condition as “shared” [12,13]. However, when people with diabetes and their spouses both appraise T1DM as shared, collaboration and support are more frequent [10,13]. Specifically, there is increased self-care and self-efficacy in people with diabetes because of increased perceptions of emotional support and decreased critical communication from the CP [10,14]. Notably, older adults are more likely to appraise diabetes as shared [11].

Our prior research with adults and CGM reveals several barriers to the use of Follow among adults, namely the need for knowledge on smartphone technology, difficulties setting up the sharing features, and challenges in dyadic communication that reflect people with diabetes and partners’ different expectations regarding family involvement [10]. SHARE *plus* addresses these barriers by providing instruction to use the technology, training in dyadic communication and problem solving, and a data-sharing action plan developed with people with diabetes and their CPs. However, there is a lack of effective interventions to support people with diabetes and their families in adopting and successfully using CGM with the Follow app.

To address the current gaps in CGM data sharing among older adults with T1DM, this study examined the feasibility of a CGM with a Follow app intervention, SHARE *plus*, among people with diabetes and their CPs.

Methods

Study Design

A 1-group experimental design was chosen to determine if there was interest and adherence to the intervention and to identify the components of the intervention that need refinement. This study was approved by the University of Utah Institutional Review Board (00114642). Participants signed an institutional review board informed consent.

Participants were recruited from an academic endocrinology clinic and an internal medicine/diabetologist office in Utah and included people with diabetes and their CPs (spouse, adult child, friend; henceforth called dyads when both are referenced). People with diabetes were included if they were ≥60 years, were diagnosed as having T1DM, had normal or mild cognitive impairment (MCI; Montreal Cognitive Assessment [MoCA] score 18-26) [15], were unfamiliar with using personal CGM with a Follow app, had hemoglobin A_{1c} values of 6%-12% within the last 6 months, were able to read and write English, had a CP willing to participate, and owned a smartphone compatible with the Dexcom G6 data sharing system. People with diabetes with or without an insulin pump were included. People with diabetes were excluded if they had the following: an estimated life expectancy of less than 1 year; unstable recent cardiovascular disease, significant malignancy, or other conditions resulting in physical decline; a history of visual impairment that would hinder their ability to perform all study procedures safely; or a history of psychiatric, psychological, or psychosocial issues that could limit adherence to required study tasks. CPs were included if they were identified by the person with diabetes, willing to participate in the CGM education sessions and CGM, ≥18 years of age, and owned a smartphone compatible with the Dexcom G6 CGM data sharing system. CP

exclusion criteria included no self-report of cognitive impairment or dementia or other medical conditions that the investigator determined would make it inappropriate or unsafe to fulfill a CP's role.

From the pool of potential participants (N=123), 20 (16.2%) people with diabetes and their CPs (20, 16.2%) met the recruitment criteria. The remaining participants did not meet the recruitment criteria for the following reasons: could not be reached by phone or letter (65/123, 52.8%), had no time or interest in research (16/123, 13%), had no CP (6/123, 4.8%), had an incompatible phone (7/123, 5.7%), had cancer (2/123, 1.6%), had Parkinson disease (1/123, 0.8%), had moderate or severe dementia (3/123, 2.4%), and exhibited delusional behavior (2/123, 1.6%).

Procedures

Following a screening visit and participant enrollment, data were collected at baseline and at 3 months. After baseline data were collected, people with diabetes and CPs received basic CGM training using technical manuals and components of a Dexcom G6 training video that was adapted for use in older adults with CPs by a trained research assistant. At that same visit, people with diabetes and their CPs received the SHARE *plus* intervention. People with diabetes were asked to wear the CGM with the Follow app for 3 months and share CGM data using the intervention strategies. They continued to follow up with their health care provider to manage any changes in their treatment plan. Final study data were collected at a 3-month follow-up visit, followed by a one-on-one interview with the person with diabetes and the CP. All visits were conducted in the home of the person with diabetes to minimize difficulty associated with navigating a large academic health science center.

Intervention

Dyads participated in an interactive CGM with data sharing intervention (Textbox 1). The intervention included the following behavioral components: communication strategies, problem-solving strategies, and action planning. SHARE *plus* included evidence-based strategies such as motivational interviewing, problem solving, self-efficacy enhancement, and action planning [16-18].

Textbox 1. Components of the data sharing intervention SHARE plus.

1. Communication strategies

- Communication strategies around using real-time continuous glucose monitoring with the Follow app. People with diabetes were asked about their willingness to talk about glucose numbers (hypo- and hyperglycemia). The objective of this discussion was to determine what glucose information the person with diabetes was comfortable sharing.

2. Problem-solving strategies

- Barriers to sharing glucose levels were identified and discussed (eg, glucose levels are private, people with diabetes do not want to be judged).
- Problem-solving around expectations and length of waiting time before the care partner should contact the person with diabetes for a concerning glucose level and the preferred mode that the care partner uses to contact the person with diabetes (eg, phone call, SMS text messaging, email) were identified. Dyads engaged in a discussion and problem solving around alarms for the Follow app on the person with diabetes and care partner's smartphone to determine an agreeable strategy. The objective of this step was to guide the dyad on how to manage real-time continuous glucose monitoring expectations and how to incorporate SHARE into their lives.
- People with diabetes identified how they wanted the care partner involved (when and how to respond, troubleshooting). Care partners were asked how they feel about this type of communication and if it is acceptable. The objective of this discussion was to explore supportive and unsupportive conversation strategies between dyads.

3. Action plan

- Communication plan in writing that includes how to give feedback, length of waiting time, communication mode.
- Set alarms with people with diabetes and care partners (each can have different alarms).
- Written responsibility and frequency of monitoring glucose levels for people with diabetes and care partners.
- Actions to take for severe low blood sugar, chest pain and symptoms of heart attack or stroke, etc.

Measures

Quantitative Feasibility Measures

The following data were examined: retention, reasons for study discontinuation, feasibility (appointment attendance, length of all sessions, number of unscheduled appointments for extra assistance, number of telephone calls for the person with diabetes or CP support), and implementation (percentage of protocol completion, barriers).

Clinical and Person With Diabetes-Reported Outcomes

Demographics and cognitive status (MoCA) [15] were assessed at baseline. Adherence data were obtained via Dexcom Clarity, a secure online program that captured the amount of wear time from the CGM data of the person with diabetes [19]. Glucose data were obtained via Dexcom Clarity [19]. Data included percentage of time in range (70-180 mg/dL), hypoglycemic range (<60 mg/dL), hyperglycemic range (>250 mg/dL), and glycemic variability coefficient value.

DQOL using CGM was measured at 12 weeks using a 15-item instrument with 3 subscales: perceived control (α=.88),

hypoglycemia safety (α=.84), and interpersonal support (α=.75) [20]. Individuals were asked to indicate how each item has changed since they started using CGM with the Follow app. Responses were rated on a 5-point scale (scores 1 to 5), with higher scores indicating improvement [20].

Qualitative Satisfaction Data

Dyads were asked 4 questions on what they liked and did not like about sharing CGM data with their CP, what recommendations they have for others who share CGM data, and what recommendations they have for intervention improvements.

Analytic Plan

Data were analyzed using descriptive statistics with means and SDs for continuous variables (summary scores) and frequency counts and percentages for categorical data. A content analysis was conducted on the open-ended satisfaction questions. The satisfaction responses were read word for word and then coded. Next, the coded data were categorized and summarized.

Results

Feasibility, Demographics, and Clinical Characteristics

People with diabetes (n=20) had a mean age of 70 (SD 5) years and diabetes duration of 31 (SD 18.30) years, and the majority were married (13/20, 65%), White individuals (18/20, 90%), and male (11/20, 55%). The majority wore an insulin pump (11/20, 55%) and had previously used CGM but were naïve to using the Follow app (11/20, 55%), while 9/20 (45%) had never used CGM. There were 8/20 (40%) participants that required extra assistance or support with initial CGM use; 4 (50%) of these participants were naïve to wearing CGM and 4 (50%) had previous experience with CGM. The people with diabetes had a variety of comorbid conditions (Table 1). CPs (n=20) had a mean age of 57 (SD 17) years, and the majority were White individuals (19/20, 95%) and female (13/20, 65%). The retention rate was 95% over 3 months. One participant discontinued the study—a person with diabetes who reported that the alarms were disruptive, loud, and too frequent (alarm settings chosen by the participant were 90 mg/dL lows and 180 mg/dL highs) and that sensor adhesion was poor (did not use the waterproof film offered). This participant also had a MoCA score of 24, which was consistent with MCI.

Table 1. Demographics for people with diabetes and their care partners.

Demographics	RT-CGM[a] user (n=20)	CP[b] (n=20)
Age (years)		
Mean (SD)	70.45 (4.90)	56.6 (16.75)
Median (IQR)	69 (66-73.8)	62.5 (41.5-69.8)
Gender, n (%)		
Male	11 (55)	7 (35)
Female	9 (45)	13 (65)
Ethnicity, n (%)		
Hispanic or Latino	2 (10)	1 (5)
Not Hispanic or Latino	18 (90)	19 (95)
Race, n (%)		
White	17 (85)	19 (95)
African American	0 (0)	0 (0)
Native American/Alaskan/Pacific Native	2 (10)	0 (0)
Other	1 (5)	1 (5)
Marital status, n (%)		
Single	2 (10)	5 (25)
Married	13 (65)	13 (65)
Divorced	5 (25)	2 (10)
Highest education, n (%)		
High school or less	1 (5)	2 (10)
Technical/associate/some college	6 (30)	7 (35)
Bachelor’s degree	6 (30)	7 (35)
Master’s degree	4 (20)	3 (15)
Doctoral degree	3 (15)	1 (5)
Employment status, n (%)		
Full-time	6 (30)	9 (45)
Part-time	2 (10)	3 (15)
Retired	11 (55)	6 (30)
Unemployed	0 (0)	2 (10)
With a disability	1 (5)	0 (0)
Household income, n (%)		
$34,999 or less	3 (15)	4 (20)
$35,000 to $49,999	2 (10)	3 (15)
$50,000 to $99,999	5 (25)	10 (50)
$100,000 to $149,999	6 (30)	3 (15)
Declined to state income	4 (20)	0 (0)
Diabetes duration, mean (SD)	30.9 (18.27)	
Comorbid conditions, n (%)		
Hypothyroidism	10 (50)	N/A[c]
Hypertension	7 (35)	N/A
Dyslipidemia	5 (25)	N/A

Demographics	RT-CGM[a] user (n=20)	CP[b] (n=20)
Gastrointestinal disease	5 (25)	N/A
Retinopathy	4 (20)	N/A
Neuropathy	4 (20)	N/A
Depression	4 (20)	N/A
Stroke	3 (15)	N/A
Myocardial infarction	2 (10)	N/A
Nephropathy	2 (10)	N/A

[a]RT-CGM: real-time continuous glucose monitoring.

[b]CP: care partner.

[c]N/A: not applicable.

The MoCA screening test showed that 45% (9/20) of people with diabetes had a MoCA score <26 (range 20-29), indicating MCI. Those with MCI had a mean age of 71.4 (SD 6) years and median diabetes duration of 30 (IQR 7-45) years, and the majority were White individuals (8/9, 89%) and male (6/9, 67%). Those without MCI had a mean age of 69.6 (SD 4) and median diabetes duration of 30 (IQR 20-45) years, and the majority were White individuals (9/11, 81%) and female (6/11, 56%). The majority of people with diabetes without MCI wore an insulin pump (8/11, 73%), had previously used CGM but were naïve to using the Follow app (8/11, 73%), and had Medicare insurance coverage (8/11, 73%). There were no differences in CGM glycemic data or the results of the satisfaction survey between those who completed the assessment and had a MoCA score in the MCI range and those who did not have a score in this range.

Feasibility Results

The initial SHARE *plus* appointment averaged approximately 1 hour (19 appointments; mean time 67.65 minutes, SD 29.12 minutes). Unscheduled appointments for extra assistance were for the following: sensor failure (6/20, 30%), transmitter failure (1/20, 5%), and connectivity issue that was solved by disconnecting and waiting for 30 seconds (1/20, 5%). Sensor and transmitter difficulties were attributed to storage at a high temperature. All participants received 100% of the intervention. People with diabetes wore CGM for the majority of the 12-week study (mean adherence 96%, SD 6.8%).

All participants were willing to share their hypoglycemia data, but only 55% (11/20) were willing to share their hyperglycemia data (Table 2). The interventionist was trained to give participants a choice about sharing their hyperglycemia data. The primary reasons cited for declining to set alarms for hyperglycemia were “do not care about hyperglycemia because the person with diabetes can handle that on their own without problems” and “already understand highs and do not need help with this.” There were no reported complications from this decision to use the Follow app for hypoglycemia only. The majority of dyads set the Follow app alarms higher than the alarms for people with diabetes.

Table 2. SHARE plus intervention data.

SHARE intervention components	Responses, n (%)
Agreement to share hypoglycemia data (yes)	20 (100)
Agreement to share hyperglycemia data	
Yes	11 (55)
Maybe	1 (0.5)
Agreement by people with diabetes to share hyperglycemia data by age (years)	
65-69	4 (20)
70-74	4 (20)
75-79	2 (10)
80-84	2 (10)
People with diabetes willing to talk about glucose numbers with a CP[a]	14 (70)
Helpful comments to support a person with diabetes	
"Are you okay"	11 (55)
"Your sugar is low, what do you need"	4 (20)
"What can I do to help"	2 (10)
"Your blood sugar is low, you need to eat"	3 (15)
Alarms on the Follow app	
Same alarms for CPs and people with diabetes	6 (30)
Higher alarms for CPs	5 (25)
CP turns alarms off for highs	9 (45)
Waiting time to contact the person with diabetes about low alarm (min)	
0 (immediately)	6 (30)
5	8 (40)
10	2 (10)
15	2 (10)
20	1 (0.5)
Contact mode	
Phone call	12 (60)
SMS text messaging	6 (30)
Phone call and SMS text messaging	2 (10)
No data	1 (0.5)
Action to take if no reply to low alarm	
Call friend/family	10 (50)
Come to the home of the person with diabetes	6 (30)
Call emergency medical services	4 (20)

[a]CP: care partner.

Clinical and Participant Reported Outcomes

People with diabetes spent the majority (median 62%) of their time in range (70-180 mg/dL) and had minimal time spent in the hypoglycemic range (median <1%). The SHARE *plus* intervention was not targeted at improving glucose levels, and there were no observed trends in the CGM data showing significant differences between baseline and 12 weeks. Hemoglobin A_{1c} data were not obtained because of limited funding, but the glucose management indicator obtained from CGM data was hemoglobin A_{1c} of 8.3%.

At the end of the third month, DQOL using CGM was measured. Broad improvement was noted for the perceived control domain (77% people with diabetes, 75% CP), hypoglycemia safety

(74% people with diabetes, 63% CP), and interpersonal support (63% people with diabetes, 63% CP).

Qualitative Feasibility Measures

People with diabetes and their CPs reported high satisfaction with SHARE *plus*, with more likes than dislikes reported (Table 3-5).

Table 3. Satisfaction survey responses for people with diabetes.

Question and theme for people with diabetes	Value, n (%)
Likes about RT-CGM[a] data sharing	
Having someone else aware of glucose levels	8 (40)
Having a partner work together	4 (20)
Receiving help from care partner	4 (20)
Partner can notice challenges	2 (10)
Dislikes about RT-CGM data sharing	
Nothing	10 (50)
Partner nagging or overreacting	3 (15)
Recommendations for other people like you for RT-CGM with data sharing	
Highly recommend	11 (55)
Take time to understand diabetes	1 (5)
Recommended intervention improvements	
Nothing	9 (45)
More education	4 (20)

[a]RT-CGM: real-time continuous glucose monitoring.

Table 4. Satisfaction survey responses for care partners.

Question and theme for care partner	Value, n (%)
Likes about RT-CGM[a] data sharing	
Constantly being able to see the glucose numbers	13 (65)
Peace of mind knowing partner is alright	7 (35)
Work as a team	3 (15)
Dislikes about RT-CGM data sharing	
Nothing	12 (60)
Not always accurate	2 (10)
Scared with seeing lows	2 (10)
Recommendations for other people like you for RT-CGM with data sharing	
Highly recommend	10 (50)
Important to have a good relationship	3 (15)
Have good communication established	2 (10)
Recommended intervention improvements	
Nothing	13 (65)
More education	6 (30)

[a]RT-CGM: real-time continuous glucose monitoring.

Table 5. Exemplar satisfaction quotes from people with diabetes and their care partners.

Question	Exemplar quotes from people with diabetes	Exemplar quotes from care partners
Likes about RT-CGM[a] data sharing	• "That if I am having a low blood sugar someone else is aware and can help if I need it" • "Made us both aware of my situation and allowed us to work together on my progress and challenges" • "He saved me by calling when I had a very low blood sugar" • "She sees how challenging it is to maintain good control"	• "I liked being able to have instant access to her numbers" • "It was comforting to know where his blood sugars were" • "It is very helpful and allows us all as a family to suggest treatment decisions"
Dislikes about RT CGM data sharing	• "I usually knew what was going on, was a little irritating to have him remind me" • "They over-reacted"	• "Some inconsistencies between [meter] and CGM and variable times losing contact with sensor data" • "I got scared a few times when he had lows and maybe I worried about him more than when I didn't know"
Recommendations for other people like you for RT-CGM with data sharing	• "I felt freedom and constant knowledge of glucose. Do it! Do it! Freedom" • "Be patient and just know that your partner is looking out for you" • "Diabetes is a roller coaster experience, it will take time to learn how to deal with it!"	• "Highly recommend the CGM and shared data, has helped the family dynamics (i.e., reducing anxiety and constant stress of asking ___ to check his blood sugars" • "My husband is exceptional with no temper. It might be hard for some people if they didn't have the right kind of relationship" • "As long as there is already good communication and the [person with diabetes] is willing to take responsibility rather than making you their 'blood sugar police,' I think it can be great"
Recommended intervention improvements	• "I need to know more about adjusting alarm sounds for highs" • "A bit more training on the computer program that stores the results?" • "The clarity apps are helpful, and produce a big picture of the complications of the disease, but they do not help much when I want to know how many units of insulin I need to drop or increase the reading by 'x' units"	• "Follow up every week" • "….Talk about the [CGM] data over time" • "Remember older people might forget certain things over time like" calibrating" CGM with [meter] blood glucose readings" • "Could have used additional written instructions on how to install a new transmitter to the phone"

[a]RT-CGM: real-time continuous glucose monitoring.

The majority of people with diabetes liked the CP support they received from data sharing. However, 3/20 (15%) individuals reported that CPs nagged or overreacted. The CPs liked the ability to see the data, which gave them peace of mind. A total of 2/20 (10%) CPs reported concerns about CGM accuracy. With regard to education, 4/20 (20%) people with diabetes and 6/20 (30%) CPs wanted more education. The majority of dyads recommended CGM with data sharing, and a few CPs cited the importance of having a good relationship and good communication skills.

There were 9/20 (45%) people with diabetes who were new to using CGM. Of these 9, 5 (56%) requested more education on insulin adjustments, changing sensors and alarms, and tracking events and alarms. Of the 11/20 (55%) people with diabetes who had previously worn the CGM device, only 3 (27%) requested more education on using Dexcom Clarity and adjusting alarm sounds for high glucose readings.

Of the 20 dyads, 18 (90%) were cohabiting. Of the remaining 2/20 (10%) CPs, 1 was a son and the other was a friend. The friend CP only had positive feedback on the satisfaction survey, but the son CP did not like "getting alarms at all hours" and wanted more education on how to "review past data and be able to do comparisons to see if things are getting worse or better."

Our key recommendations based on these feasibility data are in Textbox 2. These recommendations include increasing the acceptability around data sharing and hyperglycemia data sharing, decreasing nagging and overreaching behaviors, increasing diabetes education, and implementing strategies to monitor SHARE *plus* behaviors in real time.

Textbox 2. Key recommendations.

1. Overarching recommendations

- Increase acceptability of data sharing
- Increase willingness to share hyperglycemia and hypoglycemia data
- Improve communication to decrease nagging and overreaching
- Increase dyad diabetes education around diabetes self-management using CGM with Follow
- Monitor SHARE plus behaviors in real time

2. Specific strategies

- Coach dyads on the concept of sharing diabetes vs viewing diabetes as only the person with diabetes
- Intensify the case for using the Follow app for hyperglycemia (teamwork, support, working together)
- Provide 3-4 diabetes education sessions to address intensified problem-solving and communication strategies and dyadic self-management—management of hyper- and hypoglycemia
- Measure SHARE plus agreement changes and how conflicts were addressed over time using ecologic momentary assessment methods

Discussion

The SHARE *plus* intervention comprised communication strategies, problem solving, and an action plan and was feasible and associated with high satisfaction among dyads. Our results show broad improvements in DQOL across dyads in the following domains: perceived control of diabetes, hypoglycemia safety, and interpersonal support. Although the majority of people with diabetes were willing to share hyperglycemia data and discuss glucose levels with their CPs, some chose not to. Lastly, people with diabetes identified having someone else aware of glucose levels and working together with a partner on diabetes self-management as positive aspects of using CGM with SHARE *plus*.

Similar to our study, both the WISDM and Diamond trials showed an average wear time of 6 days a week or greater during the study period [7,8]. While several people with diabetes chose not to share their hyperglycemia data or discuss their glucose numbers with their CPs at baseline, the SHARE *plus* intervention in its present form provided little discussion around these topics. These agreements may have changed over time and were not measured in this study.

Several key recommendations for future studies include intensifying the case for hyperglycemia data sharing (teamwork, support, working together). Additional recommendations include more diabetes education sessions that include communication and problem-solving strategies, glucose management, and the use of CGM software to track glucose trends. In another study, our team found that spouses understand how to assist with some diabetes-related recommendations, such as supporting hypoglycemia [11]. However, they may not understand how to manage microadjustments around glucose levels, which older adults with diabetes may need assistance with as they age [11]. However, some people with diabetes may never want to involve their CPs in diabetes management. Further studies are needed to examine changes in the attitudes of people with diabetes with intensification of SHARE *plus* combined with diabetes education. Additionally, further research is needed to track the number of diabetes management interventions (changes in diet and insulin dosing) resulting from use of the Follow app and whether there is a difference in the behavioral and glucose outcomes between those who agree to engage more with their CPs and those who do not. Ecological momentary assessment allows researchers to track behavior in real time and may be a method to capture many SHARE *plus*–related behaviors, including conflicts and how sharing agreements change over time [21].

There are benefits and disadvantages of CP involvement in CGM data sharing. The positive aspects of CGM data sharing identified by people with diabetes included having someone else aware of glucose levels, working together with a partner on diabetes self-management, and receiving help from a partner. This type of collaboration likely occurs as the person with diabetes and their partners see T1DM as shared [13]. Further research is needed to assess if people with diabetes and their CPs appraise T1DM as shared in the context of SHARE *plus*; this is associated with better self-care and self-efficacy in people with diabetes because of increased perceptions of greater emotional support and decreased critical communication from CPs [14].

CPs often walk the line between trying to be supportive and being overbearing [11]. Very few individuals in our study reported “nagging” or “overreacting” to data sharing. It is unclear if our study’s reported benefits are related to CGM alone or the SHARE *plus* intervention. However, dyads receiving SHARE *plus* rated their interpersonal support much higher (63%) than those in a CGM study without data sharing (37%) [22]. Yet, this higher rating of interpersonal support in our study may be attributed to differences between older adults in our study and middle-aged individuals in the comparison study [22]. A fully powered randomized controlled trial is needed to demonstrate the effects of the SHARE *plus* intervention versus CGM alone and the difference in interpersonal support.

SHARE *plus* is promising as it addresses gaps related to CGM data sharing in older adults. However, our results indicate that further strategies are needed to improve SHARE *plus*. Future iterations of SHARE *plus* should include diabetes education specific to glucose management and the use of Dexcom Clarity

for glucose pattern management. Additional communication strategies are also needed to reduce the nagging and overreacting associated with data sharing that people with diabetes reported. Lastly, it is unknown how frequently CPs viewed the Follow app. It is possible that the frequency of viewing the app may be related to a person with diabetes' experience of more or less critical behaviors. Future studies are needed to elucidate this possible relationship. Opportunities exist for clinicians working with CGM to encourage conversations with CPs that are positive, helpful, and acceptable to people with diabetes.

This study is not without limitations. This study intended to examine the feasibility and therefore was not powered to detect significant changes across variables, and findings should be interpreted cautiously. A total of 16 people with diabetes declined to participate in this study because of lack of time or disinterest in research. This may be attributed to a disinterest in using CGM or involving CPs in diabetes management. However, there has been growing interest in CGM since CGM was covered by Medicare in 2017. Further exploration of people with diabetes' disinterest in participating in a dyadic study is needed. This study lacked racial and ethnic diversity. Moreover, participants were highly educated. However, this feasibility study's initial results suggest the need for a larger study with a more diverse sample and an assessment of technology literacy. Willingness of a person with diabetes to share hyperglycemia data or discuss glucose data was only assessed at baseline. This initial reaction may have changed either positively or negatively over time. Future studies should evaluate this willingness over time.

The results are promising in that they show that older adults with T1DM are open to sharing their glucose data with CPs and that CPs report benefits with assistance in communication and problem-solving strategies as to how to collaborate most effectively with people with diabetes. The benefits of such an intervention may become more important as older adults age and experience complications from lifelong diabetes, especially cognitive challenges that make self-management more challenging. The potential benefits of SHARE *plus* are consistent with those of dyadic approaches to chronic illness management that may enhance not only self-care but the quality of life for both people with diabetes and their CPs.

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Conflicts of Interest

MLL has received funding from Abbott for an investigator-initiated grant. There are no other potential conflicts of interest relevant to this article.

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Abbreviations

CGM: continuous glucose monitoring
CP: care partner
DQOL: diabetes-related quality of life
MCI: mild cognitive impairment
MoCA: Montreal Cognitive Assessment
T1DM: type 1 diabetes
WISDM: Wireless Intervention for Seniors with Diabetes Mellitus

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Original Paper

Barriers and Drivers Regarding the Use of Mobile Health Apps Among Patients With Type 2 Diabetes Mellitus in the Netherlands: Explanatory Sequential Design Study

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Abstract

Background: Self-monitoring of blood glucose levels, food intake, and physical activity supports self-management of patients with type 2 diabetes mellitus (T2DM). There has been an increase in the development and availability of mobile health apps for T2DM.

Objective: The aim of this study is to explore the actual use of mobile health apps for diabetes among patients with T2DM and the main barriers and drivers among app users and nonusers.

Methods: An explanatory sequential design was applied, starting with a web-based questionnaire followed by semistructured in-depth interviews. Data were collected between July and December 2020. Questionnaire data from 103 respondents were analyzed using IBM SPSS Statistics (version 25.0). Descriptive statistics were performed for the actual use of apps and items of the Unified Theory of Acceptance and Use of Technology (UTAUT). The 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). Differences between users and nonusers were analyzed using chi-square tests for individual items. Independent 2-tailed *t* tests were performed to test for differences in mean scores per the UTAUT construct. In total, 16 respondents participated in the interviews (10 users and 6 nonusers of apps for T2DM). We performed content analysis using a deductive approach on all transcripts, guided by the UTAUT.

Results: Regarding actual use, 55.3% (57/103) were nonusers and 44.7% (46/103) were users of apps for T2DM. The main driver for the use of apps was the belief that using apps for managing diabetes would result in better personal health and well-being. The time and energy required to keep track of the data and understand the app were mentioned as barriers. Mean scores were significantly higher among users compared with nonusers of apps for T2DM for the constructs performance expectancy (4.06, SD 0.64 vs 3.29, SD 0.89; $P<.001$), effort expectancy (4.04, SD 0.62 vs 3.50, SD 0.82; $P<.001$), social influence (3.59, SD 0.55 vs 3.29, SD 0.54; $P=.007$), and facilitating conditions (4.22, SD 0.48 vs 3.65, SD 0.70; $P<.001$). On the basis of 16 in-depth interviews, it was recognized that health care professionals play an important role in supporting patients with T2DM in using apps. However, respondents noticed that their health care professionals were often not supportive of the use of apps for managing diabetes, did not show interest, or did not talk about apps. Reimbursement by insurance companies was mentioned as a missing facilitator.

Conclusions: Empowering health care professionals' engagement is of utmost importance in supporting patients with T2DM in the use of apps. Insurance companies can play a role in facilitating the use of diabetes apps by ensuring reimbursement.

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KEYWORDS

type 2 diabetes; self-management; mobile health, mobile apps; prevention; mixed methods research; acceptance; mobile phone

Introduction

Background

Type 2 diabetes mellitus (T2DM) is a serious public health concern globally. The prevalence of T2DM is increasing at a rapid pace in developed regions, such as Western Europe including the Netherlands, and causes a substantial economic burden [1-3]. Various lifestyle factors are important for the development of T2DM [4,5]. To manage diabetes sufficiently, adherence to regular physical activity and a healthy diet are important. Several studies have reported the positive effects of lifestyle interventions, including regular physical activity and healthy food intake, on the stabilization of blood glucose levels and health status of patients with T2DM [5-10].

Mobile Health Apps

T2DM requires self-management and support. Self-monitoring of blood glucose levels, food intake, and physical activity can support the self-management of patients with T2DM. In recent years, there has been an increase in the development and availability of technologies for diabetes self-monitoring, especially mobile health apps [11], for example, an app to integrate and keep track of blood glucose levels in combination with data regarding physical activity and food intake. These apps have considerable potential to support diabetes self-management and have a positive effect on a person's lifestyle [12-14]. However, studies have shown that the uptake of apps for managing diabetes is rather low [15-18]. Insight is needed into how apps can be integrated into diabetes self-management care [19]. Research regarding the acceptance of apps for managing diabetes among patients is important for their successful implementation. Several quantitative and qualitative studies have been performed to gain further insight into the acceptance of apps for managing diabetes among patients with diabetes [20-24]. Zhang et al [22] investigated predictors of the intention to use apps for managing diabetes using a web-based questionnaire. They found that performance expectancy (ie, perceived usefulness) and social influence were the most important determinants of the intention to use apps for managing diabetes. Torbjørnsen et al [23] conducted interviews to obtain an in-depth understanding of users' acceptance of a mobile app for diabetes. They found that users' acceptance of mobile apps for diabetes self-management differed. Regular use of an app could be useful (supportive and educational) but could also become a burden, requiring too much time and not contributing enough to the effort needed to change lifestyles. Furthermore, Torbjørnsen et al [23] concluded that both practical (ie, usability and utility) and social aspects (ie, attitude and shared understanding) are important for the acceptability of mobile apps for diabetes. Jeffrey et al [24] conducted semistructured phone interviews among patients with T2DM and found that a lack of knowledge and awareness of apps as health care tools was one of the barriers.

Unified Theory of Acceptance and Use of Technology

The unique aspect of this study is the use of an explanatory sequential design (mixed methods) among both users and nonusers. To explore the actual use of apps for T2DM and gain greater insight into the main barriers and drivers, a web-based questionnaire using the Unified Theory of Acceptance and Use of Technology (UTAUT) was deployed along with in-depth interviews. The UTAUT is a unified model that was developed by Venkatesh et al [25] and is commonly used globally in studies regarding health technology acceptance. The UTAUT is based on the Social Cognitive Theory with a combination of 8 prominent information technology acceptance research models (Theory of Reasoned Action, Theory of Planned Behavior, Technology Acceptance Model, Motivation Model, a model combining the Technology Acceptance Model and the Theory of Planned Behavior, Model of Personal Computer Use, Diffusion of Innovation theory, and Social Cognitive Theory). Validation by Venkatesh et al [25] showed that the UTAUT accounts for 70% of the variance in behavioral intention to use and about 50% in actual use. On the basis of the results of this study, recommendations are described for future research and the integration of apps with diabetes self-management care.

Aim

The aim of this study is to investigate the actual use and the barriers and drivers among users and nonusers of mobile health apps for T2DM. The use of a mixed methods approach is different compared with most previous studies using the UTAUT and investigating the use of eHealth among patients with diabetes. Most studies have applied quantitative research methods, and some have conducted interviews. The addition of in-depth interviews based on the quantitative findings is therefore different from previous studies and could show more explicitly where patients with T2DM need support and how the barriers and drivers influence their use of apps to self-manage diabetes. Furthermore, the focus on patients with T2DM is rather novel, as is the inclusion of nonusers of apps. These nonusers were included to understand their view toward apps, and the hypothesis of this study is that some of them are not unwilling to use apps but rather are unaware of the availability.

Methods

Research Design

An explanatory sequential design [26], using a mixed methods approach, was applied to assess the actual use, barriers, and drivers among users and nonusers of apps for T2DM. This study started with the collection and analysis of a web-based questionnaire using Qualtrics software (Qualtrics International Inc). The web-based questionnaire was designed and reported based on the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) [27]. The web-based questionnaire was pretested for usability and technical functionality before fielding. The qualitative data were used to design the interview

guide (Multimedia Appendix 1) so that it follows from the quantitative phase and provides the opportunity to obtain in-depth information. The following in-depth semistructured phone interviews lasted between 25 and 50 minutes, audiotapes were made, and field notes were taken. Ethical approval was obtained from the University of Twente Ethical Committee (reference number 201213). Participants were informed about the purpose of the study and length and time of the questionnaire and which data were stored and where before the start of the web-based questionnaire. They provided web-based consent and were informed about their right to withdraw at any time. Data were anonymized, confidentiality was maintained, and the data will be retained for 10 years.

Recruitment Strategy and Sample Size

The study population included patients with T2DM aged ≥16 years spread across the Netherlands. Recruitment for the web-based questionnaire was performed using convenience sampling by publishing the link on web-based platforms for patients with T2DM, in the newsletter of the Dutch Diabetes Association, and social media. A total of 183 respondents completed the questionnaire. In total, 80 respondents did not complete the questionnaire sufficiently (missing data on actual use or barriers and drivers) and were excluded. Questionnaire data were analyzed from 103 respondents. At the end of the questionnaire, participants were asked to leave their phone number if they were willing to participate in a follow-up phone interview. A total of 16 respondents participated in the phone interviews; 10 were users and 6 were nonusers of apps to manage T2DM. Data were collected between July and December 2020.

Measures

Actual Use

In the web-based questionnaire, 1 item was included to measure the actual use of apps for T2DM, namely, “Do you use apps for T2DM specifically (for example health-apps to get insight into your blood glucose levels or a digital coach for support in daily life with diabetes)?”

Barriers and Drivers

The well-established UTAUT has been demonstrated to be a reliable theoretical framework for studying barriers and drivers for users’ acceptance of information technology [25,28]. The UTAUT has been used in many studies globally [29]. The UTAUT includes 4 key constructs (ie, performance expectancy, effort expectancy, social influence, and facilitating conditions). Focusing on diabetes apps, performance expectancy is the level to which an individual believes that an app will help them gain health performance, whereas effort expectancy is the level of ease associated with the use of an app. Social influence is the degree to which an individual finds it important that others believe they should use the app, whereas facilitating conditions are the measure of infrastructural support available for app use [25]. The questionnaire used in this study was drawn based on the classification of the Flemish UTAUT questionnaire [30,31]. The scales consisted of the 4 key constructs: (1) performance expectancy (4 items), (2) effort expectancy (3 items), (3) social influence (4 items), and (4) facilitating conditions (3 items). Furthermore, the constructs anxiety (2 items), trust in data security (2 items), and knowledge (2 items) were added [30]. For each item, respondents answered on a 5-point Likert scale ranging from strongly disagree to strongly agree. The interview guide (Multimedia Appendix 1) was based on the findings of the quantitative data collected.

Data Analysis

The questionnaire data were analyzed using IBM SPSS Statistics (version 25.0). Descriptive statistics were performed for the actual use of apps among patients with T2DM and the individual items of the UTAUT. Differences between users and nonusers were tested using chi-square tests for the individual items. Independent 2-tailed *t* tests were performed to test for differences in mean scores per UTAUT construct. Therefore, 3 items were reverse-coded: *Using apps would cost me a lot of time and energy (effort expectancy)*, *Other people would think bad of me if I used apps (social influence)*, and *When I think about using apps, I fear that confidential information could end up in the wrong hands (trust in data security)*. To analyze the qualitative data, interviews were transcribed verbatim. Content analysis with a deductive approach was performed on all transcripts guided by the UTAUT [32]. The UTAUT was used in this analysis to align the integration of quantitative and qualitative data. Data management was performed using the NVivo (version 11) software package. During the organizing phase of the analysis, a matrix was developed comprising the components of performed expectancy, effort expectancy, social influence, facilitating conditions, anxiety, and trust in data security and knowledge. Categories were created within each component of the analysis matrix (Multimedia Appendix 2).

Validity

Credibility was established using several procedures [33]. Method triangulation was performed using multiple data collection methods, namely questionnaires and individual interviews with audio recording. Researcher triangulation was achieved by 3 researchers (MB, CMvL, and TJJO) who performed the interviews and read and compared the findings. Peer debriefing took place during weekly meetings with the project team, where scientific and organizational aspects were discussed. When data collection was complete, a member check was performed by sharing an infographic with the respondents. A thick description was developed for transferability [33], which included the sampling method, recruitment, data collection, questionnaire and interviewing method, and analysis process.

Results

Participants

Of the respondents who completed the questionnaire, 55.3% (57/103) were men and 41.7% (43/103) were women (Table 1). The mean age was 69 years (SD 10.8; range 27-90 years). Most respondents (97/103, 94.2%) were of Dutch origin, and 28.2% (29/103) had a lower education, 17.5% (18/103) had an intermediate education, and 50.5% (52/103) had a higher education. Most respondents (84/103, 81.6%) had been diagnosed with T2DM ≥10 years ago. Demographic characteristics of the respondents from the interviews (n=16)

were comparable with the demographic characteristics of the overall respondents from the questionnaire (N=103; Table 1).

Table 1. Demographic characteristics of respondents.

Characteristics	Questionnaire (N=103), n (%)	Interviews (n=16), n (%)
Gender		
Male	57 (55.3)	10 (62.5)
Female	43 (41.7)	6 (37.5)
Unknown	3 (2.9)	0 (0)
Age (years)		
<30	1 (1)	0 (0)
30-49	5 (4.9)	2 (12.5)
50-69	42 (40.8)	7 (43.8)
≥70	51 (49.5)	7 (43.8)
Unknown	4 (3.9)	0 (0)
Ethnicity		
Dutch	97 (94.2)	16 (100)
Non-Dutch	3 (2.9)	0 (0)
Unknown	3 (2.9)	0 (0)
Educational level[a]		
Low	29 (28.2)	5 (31.3)
Intermediate	18 (17.5)	2 (12.5)
High	52 (50.5)	9 (56.3)
Unknown	4 (3.9)	0 (0)
Marital status		
Single	20 (19.4)	5 (31.3)
Married or cohabiting	77 (74.8)	10 (62.5)
Other	3 (2.9)	1 (6.3)
Unknown	3 (2.9)	0 (0)
Disease duration (years)		
<1	3 (2.9)	0 (0)
1-3	2 (1.9)	0 (0)
4-6	2 (1.9)	0 (0)
7-9	9 (8.7)	3 (18.8)
≥10	84 (81.6)	13 (81.3)
Unknown	3 (2.9)	0 (0)

[a]Lower education (ie, primary education, lower general or lower vocational education, or less), intermediate (ie, secondary general or vocational education), and higher education (ie, higher professional education or university).

Actual Use

On the basis of the questionnaire, 55.3% (57/103) were nonusers and 44.7% (46/103) were users of apps for managing T2DM. Of the 46 respondents who reported using apps for T2DM, 35 (78%) had used them for ≥12 months.

Barriers and Drivers

Performance Expectancy

Most of the app users, that is, 74% (34/46) to 85% (39/46), expected benefits for personal health and well-being because of the use of apps for managing T2DM (Multimedia Appendix 3). In total, 85% (39/46) of users believed that apps would help them deal with their health problems and 78% (36/46) believed that apps would help them reduce their health problems. A participant stated, by using an app to assist with diabetes care,

"I hoped that the app would help me achieve better blood sugar levels, because it has the ability to measure more often and react immediately when necessary." Among nonusers, there were more doubts whether using apps would result in improving personal well-being or reducing health problems, that is, 46% (26/57) believed that using apps would improve their personal well-being or would help them deal with their health problems. However, in the interviews, nonusers also believed that an app that shows or registers blood glucose levels would be beneficial. Most nonusers saw benefits in the use of apps for an active and healthy lifestyle: "It should give me a reminder that I have to go out and move a little."

Effort Expectancy

Regarding the expected ease of app use, most (42/46, 91%) users (strongly) agreed that the use of apps would be an easy task, and half of the nonusers (30/57, 53%) thought that apps would be clear and easily comprehensible to them (Multimedia Appendix 3). Time and energy were the main topics in the in-depth interviews. It would cost time to keep track of the data, but it would also cost time and energy to understand the app: "A more user-friendly app would be desirable." Owing to the complexity of some apps, "many are not interested and I do not want to spend so much energy learning how to use it." This was agreed upon by one of the users, but he also stated that "initially it took more effort to measure and register all food, after that it became easy to keep track of my food intake." Furthermore, all participants agreed that app use should be a joint task involving their health care professional. Although the use of apps may seem time- or energy-consuming, most users experienced less effort in real life to manage their diabetes sufficiently: "Based on the blood sugar level, my weight, and carbohydrate intake, the app communicates how much insulin I need."

Social Influence

Regarding the influence of the social environment, a minority of respondents thought that their general practitioner would recommend the use of apps, that is, 37% (17/46) of users and 19% (11/57) of nonusers (Multimedia Appendix 3). Findings from the in-depth interviews showed that respondents wanted to use apps and acquire data together with their health care professional. They agreed that, "as a layman I can see if my blood sugar level is too high, but my knowledgeable physician has to take over at that point." However, most respondents said that health care professionals were not supportive and they did not talk about apps or acquired data or that respondents did not ask them about apps. Some respondents acknowledged that health care professionals could not know all apps: "I understand that it is impossible to give advice about these apps, they do not know all apps on the market, which is best for me and how all apps function." In addition to health care professionals, family and friends are also important. In all interviews, the respondents talked about support from family and friends. On the one hand, regarding self-managing their diabetes sufficiently and, on the other hand, about the use of apps: "My grandchildren love the funny little man in the app, because if my glucose is too high, he says 'fie, fie, fie' or if it is too low, he says 'eat, eat, eat'." Whereas health care professionals and family and friends are very important to all respondents, regular contact with other diabetics is seen as not so important in daily life. However, there was 1 respondent who started using a diabetes app owing to a recommendation by another member of the diabetes association.

Facilitating Conditions

Most respondents (98/103, 95.1%) had a computer or smartphone with internet access and could use apps (Multimedia Appendix 3). Among the nonusers, almost half of the respondents (26/57, 46%) were convinced that they possessed the knowledge to use apps, and 37% (21/57) had someone available to support them in case of problems. The interviews showed that patients expect health care professionals to facilitate their use of apps. Although almost all respondents had a computer or smartphone and none had experienced failure in using technology, another missing facilitator was financing or reimbursement by insurance companies: "People with Type 2 Diabetes do not get reimbursement for all these apps, now I have to pay for it myself and that is of course too much."

Anxiety

In total, 82 (79.6%) of the 103 respondents were not afraid of making irrevocable mistakes when using the internet or apps (Multimedia Appendix 3). In addition, most users (37/46, 80%) and nonusers (36/57, 63%) strongly disagreed with the statement that "the internet feels like something threatening." However, interviews indicated that some of the nonusers were afraid of the speed of innovations coming into the market. There was a wide range of responses regarding how the respondents reacted to using apps. Some respondents were anxious about touching the wrong key in an app, whereas others did not mind if something went wrong. Other respondents thought it was logical, and mistakes were impossible: "The app does not bite, if I do something wrong what can happen?" Furthermore, they felt threatened by considering the influence of the app on their life: "I do not want my life to be run by an app."

Trust in Data Security

Most users (35/46, 76%) and nonusers (37/57, 65%) trust that the information they provide when using apps is handled with strictest confidence (Multimedia Appendix 3). However, 19% (11/57) of nonusers feared that confidential information could end up in the wrong hands. Similar findings were found in the in-depth interviews. All respondents handed over the data acquired while using an app to their health care professional. All respondents who used apps to keep track of their diabetes and made graphs of their blood glucose levels shared this during their regular appointments: "That is super, because she can immediately see a visualization of my values and understand that I sometimes like to eat a bar of chocolate and how my body reacts." However, there were health care professionals who were not interested in the data. Most respondents were not concerned with privacy issues, but one nonuser distrusted all apps, because "there are too many privacy risks in using smartphones, and too much pressure from software companies."

Knowledge

Approximately three-quarters of the users (34/46, 74%) and 42% (24/57) of the nonusers knew what to expect from apps (Multimedia Appendix 3). Although the interviews showed that

none of the nonusers knew any useful apps to support the management of T2DM, most respondents were open to trying apps to support them in daily life, "I am willing to try new innovations, that much I know!" In addition, not all have the knowledge needed or interest in using apps: "It is too difficult for me to learn more about these new technologies, I do not know how to use them, and it costs me a lot of effort to try to understand them."

Differences in Perceptions Between Users and Nonusers

Table 2 shows the differences in mean scores between users and nonusers of apps for T2DM per the UTAUT construct. Mean scores were significantly higher among users of apps for managing T2DM for the constructs performance expectancy, effort expectancy, facilitating conditions, and knowledge compared with nonusers (P<.001). In addition, users scored significantly higher regarding social influence (P=.007) compared with nonusers, whereas mean scores regarding anxiety were significantly lower among users compared with nonusers (P=.003). Finally, the mean scores for trust in data security were significantly higher among users compared with nonusers (P=.02).

Table 2. Differences between users and nonusers of apps for type 2 diabetes mellitus per the Unified Theory of Acceptance and Use of Technology construct.

Construct	Nonusers (n=57), mean (SD)	Users (n=46), mean (SD)	Values	
			t test (*df*)	*P* value
Performance expectancy	3.29 (0.89)	4.06 (0.64)	5.15 (101)	<.001
Effort expectancy	3.50 (0.82)	4.04 (0.62)	3.71 (101)	<.001
Social influence	3.29 (0.54)	3.59 (0.55)	2.77 (101)	.007
Facilitating conditions	3.65 (0.70)	4.22 (0.48)	4.94 (101)	<.001
Anxiety	2.11 (0.86)	1.65 (0.71)	−2.93 (101)	.003
Trust in data security	3.48 (0.75)	3.85 (0.74)	2.48 (101)	.02
Knowledge	3.28 (0.97)	4.11 (0.74)	4.91 (101)	<.001

Discussion

Summary of Findings

The aim of this study was to investigate the actual use and the barriers and drivers among users and nonusers of mobile health apps for T2DM. This study showed that the main drivers were the belief that using apps for managing diabetes will result in better personal health and well-being and that, by sharing their data with health care professionals, users will receive improved support. The barriers included time and energy to keep track of data and understand the app, lack of support by health care professionals, and no financial support or reimbursement by insurance companies. Nonusers had more doubts regarding the improved support provided by apps and showed more anxiety and distrust toward the use of apps. However, most nonusers were willing to try apps to help manage their diabetes.

Reflection With the Literature

Performance Expectancy

This study showed that performance expectancy (ie, the belief that using apps for managing diabetes will help to deal with health problems and improve personal well-being) was one of the main drivers for the use of apps for managing diabetes. Performance expectancy, next to social influence, was also found in other studies as one of the drivers for the intention to use apps for managing diabetes [22-24]. In line with the interviews, Torbjørnsen et al [23] described that routine use of apps for managing diabetes could provide a meaningful overview of blood glucose levels, diet, and activity and provide fresh insight into self-management. In a study by Jeffrey et al [24], most of the participants concluded that app use improved their diabetes management. Additional measurements help patients with T2DM gain insight into their disease and allow them to react immediately when necessary.

Effort Expectancy

In line with previous studies regarding effort expectancy (ie, the level of ease associated with the use of apps for managing diabetes), respondents stated that it takes time to keep track of data and understand an app. Regular measurements of parameters such as physical activity and food intake, in addition to blood glucose levels, are time-consuming in a busy everyday life and can be stressful [23]. Hence, the use of apps for managing diabetes has an impact on the daily life of patients with T2DM. If the impact is noticed by users and positively changes behavior, persistence in use will increase [21]. However, the use of these apps should be easy [20,21], and automation is desirable to reduce the time required to perform tasks [21]. Both Scheibe et al [20] and the nonusers in our study did not expect any benefit from apps and expected the effort required to be so high that it would not be worth starting to use apps.

Social Influence

Social influence is an important factor that contributes to the intention to use apps [34]. On the one hand, patients stated that health care professionals are an important source of support when it comes to using apps and want to share their app use and data [21,35,36]. Stühmann et al [35] conducted a cross-sectional survey in Germany and found that participants who obtained health advice from a physician were more likely to use health apps compared with those who received no advice

on any health behavior. On the other hand, patients are dissatisfied with the supervision or involvement of their professional in the use of apps for diabetes self-care. In our study, respondents noticed that their health care professionals were often not supportive of the use of apps for managing diabetes, did not show interest, or did not talk about apps or acquired data. A lack of knowledge about apps may be the main barrier for health care professionals. Hence, transfer of knowledge (ie, information and education) regarding apps for managing diabetes should not only focus on patients with T2DM but also focus on health care professionals. They can intervene as social agents to explain the use, usefulness, and benefits of apps [37]. Research has shown that support from health care professionals empowers patients to use apps and improves diabetes self-management [36]. Therefore, apps can have a positive effect on the relationship between health care professionals and patients [38]. However, a higher workload for health care professionals could also negatively affect the relationship [36]. Furthermore, information about the use and experience of apps for managing diabetes of peers with T2DM can be a motivator in the acceptance of app use. In this study, regular contact with other patients with T2DM seemed of little importance, but patients with T2DM could be motivated by peers and learn from others' experiences regarding app use.

Facilitating Conditions

Regarding facilitating conditions, both our study and previous studies have shown that nonusers have limited knowledge about what to expect from apps, where to find them, or how to use them [24]. Using apps for managing diabetes requires not only knowledge but also digital competences of end users in order to become familiar with the use of apps and to integrate them into daily life. The need for competence and digital literacy has been acknowledged in many other studies [20,21,24,39,40]. Thorsen et al [40] concluded that the implementation of health technology among patients with T2DM should be based on a comprehensive consideration of readiness for health technology. Reimbursement by insurance companies was mentioned as a missing facilitator, as often the financial resources are lacking among patients with T2DM in the Netherlands. Insurance companies can play a role in facilitating the use of apps for managing diabetes, for example, by assuring reimbursement despite the availability of financial resources. Besides reimbursement, incentives are a common mechanism applied in mobile health apps for managing diabetes for engaging, empowering, and retaining patients [41]. Finally, trust in data security is a major issue, especially among nonusers. They expected more privacy risks and had a higher anxiety level when considering app use. Similar to the findings of Cimperman et al [37], focus should be placed on portraying the apps as secure and easy to use. This could be a key factor in the acceptance of all patients with T2DM. The limitation of problems with connectivity [24] was not a barrier experienced by respondents in our study.

Strengths and Limitations

One strength of this study is the triangulation method of applying an explanatory sequential design. Hence, rich data were collected, which provided in-depth insight into the actual use of mobile health apps among patients with T2DM and the main barriers and drivers for use. Second, the well-established UTAUT model was used as the base for the questionnaire [25]. The interviews provided in-depth insight and a more explicit description of each UTAUT item. Finally, the study was performed, and data were analyzed by 3 researchers, which contributed to researcher triangulation. There were some limitations to this study. A possible bias considers digital literacy and respondents' interest in technology. Most respondents were of Dutch origin and had a higher educational level. Barriers to and motivators for the use of mobile health apps for managing diabetes may differ among specific subgroups (ie, people of non-Dutch ethnicity or people with a lower level of education). Approximately half of the respondents were app users for T2DM, which is a rather high percentage compared with other studies [15-18]. It might be the case that most respondents who filled out the questionnaire had a personal interest in this topic. Furthermore, the response and completion rates (103/180, 57.2%) of respondents who completed the web-based questionnaire were relatively small.

Recommendations

The literature, as well as this study, has shown that apps may increase diabetes self-management. It is important to integrate apps for managing diabetes into the daily practice of diabetes self-management care, with health care professionals playing an important role. On the basis of the findings of this study, we recommend that health care professionals get more involved and acquire relevant knowledge about mobile health apps specifically for patients with diabetes. The technology involved assists patients with T2DM to self-manage diabetes and assists professionals in supporting clients in their self-management. Currently, multiple apps are available for the management of diabetes. Therefore, it is difficult to know which apps would be most beneficial to whom and why. A study to investigate patient experiences among specific subgroups (ie, people of non-Dutch ethnicity or people with a lower level of education) in the use of different apps for managing diabetes is the next step for research. In addition, training patients with T2DM and professionals regarding the availability and use of apps is recommended. Important topics for such training include digital knowledge and competencies, learning about apps, how to track data, and how to read and use the collected data. The implementation of apps for managing diabetes in daily practice is complex. This study provides recommendations that focus on the main drivers and barriers. However, other factors (such as the type of organization, availability, and type of patients) also play a role in the implementation process.

Conclusions

One of the main drivers for use was the belief that using apps for managing diabetes would result in better personal health and well-being. The time and energy required to keep track of the data and understand the app were mentioned as barriers. Patients with T2DM stated that health care professionals' engagement is of the utmost importance in supporting them in app use. In addition, patients stated that insurance companies can play a role in facilitating the use of diabetes apps, for example, by assuring reimbursement. Further research should

focus on the evaluation of patients' experiences with different apps for managing diabetes, how to integrate apps into diabetes self-management care, and investigating barriers and motivators in the use of mobile health apps for the management of diabetes among specific subgroups (ie, people of non-Dutch ethnicity or people with a lower level of education).

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Authors' Contributions

All authors contributed to the design and preparation of the study. MB, CMvL, and TJJO conducted the interviews, read, 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 data collection, a member check was performed by sharing an infographic with the respondents. All authors contributed to writing the paper and have approved the latest version of the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide (English translation of Dutch original).
[DOCX File , 14 KB - diabetes_v7i1e31451_app1.docx]

Multimedia Appendix 2
Coding matrix.
[PNG File , 58 KB - diabetes_v7i1e31451_app2.png]

Multimedia Appendix 3
Quantitative results per the Unified Theory of Acceptance and Use of Technology item.
[DOCX File , 21 KB - diabetes_v7i1e31451_app3.docx]

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Abbreviations

T2DM: type 2 diabetes mellitus
UTAUT: Unified Theory of Acceptance and Use of Technology

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Review

Integrating Multiple Inputs Into an Artificial Pancreas System: Narrative Literature Review

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Abstract

Background: Type 1 diabetes (T1D) is a chronic autoimmune disease in which a deficiency in insulin production impairs the glucose homeostasis of the body. Continuous subcutaneous infusion of insulin is a commonly used treatment method. Artificial pancreas systems (APS) use continuous glucose level monitoring and continuous subcutaneous infusion of insulin in a closed-loop mode incorporating a controller (or control algorithm). However, the operation of APS is challenging because of complexities arising during meals, exercise, stress, sleep, illnesses, glucose sensing and insulin action delays, and the cognitive burden. To overcome these challenges, options to augment APS through integration of additional inputs, creating multi-input APS (MAPS), are being investigated.

Objective: The aim of this survey is to identify and analyze input data, control architectures, and validation methods of MAPS to better understand the complexities and current state of such systems. This is expected to be valuable in developing improved systems to enhance the quality of life of people with T1D.

Methods: A literature survey was conducted using the Scopus, PubMed, and IEEE Xplore databases for the period January 1, 2005, to February 10, 2020. On the basis of the search criteria, 1092 articles were initially shortlisted, of which 11 (1.01%) were selected for an in-depth narrative analysis. In addition, 6 clinical studies associated with the selected studies were also analyzed.

Results: Signals such as heart rate, accelerometer readings, energy expenditure, and galvanic skin response captured by wearable devices were the most frequently used additional inputs. The use of invasive (blood or other body fluid analytes) inputs such as lactate and adrenaline were also simulated. These inputs were incorporated to switch the mode of the controller through activity detection, directly incorporated for decision-making and for the development of intermediate modules for the controller. The validation of the MAPS was carried out through the use of simulators based on different physiological models and clinical trials.

Conclusions: The integration of additional physiological signals with continuous glucose level monitoring has the potential to optimize glucose control in people with T1D through addressing the identified limitations of APS. Most of the identified additional inputs are related to wearable devices. The rapid growth in wearable technologies can be seen as a key motivator regarding MAPS.

However, it is important to further evaluate the practical complexities and psychosocial aspects associated with such systems in real life.

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KEYWORDS

diabetes mellitus, type 1; pancreas, artificial; algorithms; multivariate analysis; insulin infusion systems; control systems

Introduction

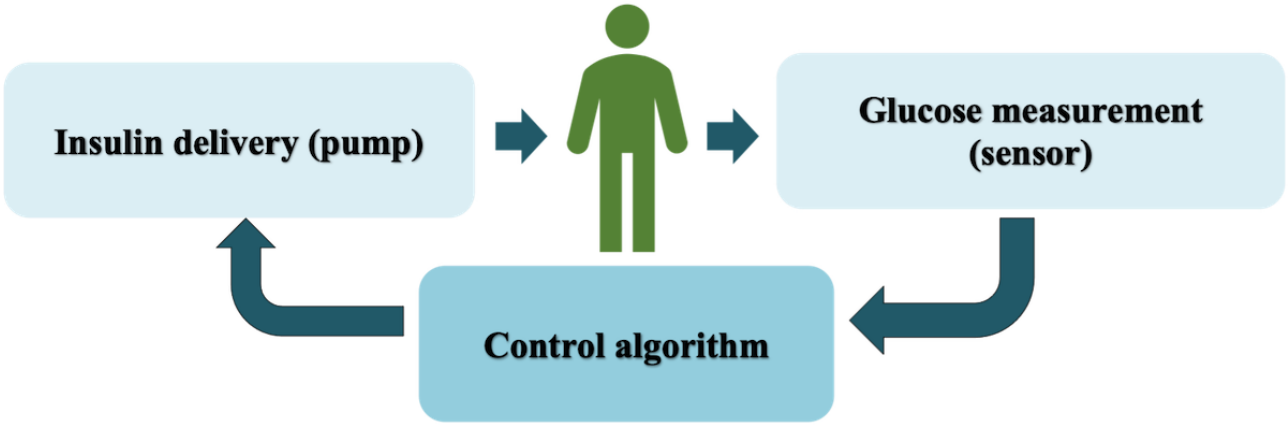
Background

In health, pancreatic islet β-cells respond to metabolic and neurohormonal signals to secrete insulin into the portal vein at finely controlled variable rates to ensure that blood glucose level and overall metabolic homeostasis are maintained. Diabetes is a metabolic disease characterized by elevated blood glucose concentrations as a consequence of an absolute deficiency of insulin secretion or inadequate insulin secretion to compensate for ineffective insulin action. Type 1 diabetes (T1D) is caused by the autoimmune destruction of the islet β-cells and results in absolute insulin deficiency [1]. An inability to match insulin delivery with an individual's changing insulin requirements results in either hypoglycemia (low blood glucose level) or hyperglycemia (high blood glucose level). Hypoglycemia, if severe, may result in loss of consciousness, seizures, or even death. Long-term exposure to hyperglycemia results in complications such as blindness, limb amputations, and cardiovascular disease. Maintaining blood glucose levels in a healthy range is essential for the avoidance of severe short- and long-term complications of diabetes [1].

The discovery and use of exogenous insulin administration since 1921 as a therapeutic agent has been life saving for people living with T1D. More recently, pancreas and islet cell transplants have also provided a solution for T1D, although organ donation shortage, the risks of surgery, and the need for immunosuppression are limiting factors [2]. As a result, there is a continued reliance on the subcutaneous administration of exogenous insulin to treat this condition. There have been continuous advancements in insulin preparations [3], insulin delivery [4], and blood glucose level monitoring [5]. Until recent years, best practice treatment of T1D, as was established in the Diabetes Control and Complications Trial [6], involved frequent self-monitoring of blood glucose level through using finger pricks to access capillary blood and multiple daily injections of short- and long-acting insulins. Information from the self-monitoring of blood glucose level as well as the carbohydrate content of meals and planned exercise informed the titration of insulin doses. The advent of rapid-acting insulin analogs, continuous glucose monitoring (CGM), continuous subcutaneous infusion of insulin (CSII), shortcomings in manual insulin-dose determination, and the significant psychological burden [7] have motivated the development of the artificial pancreas (AP; or AP systems [APS]) [8].

Although the concept of the AP has been around for >40 years, with the Biostator [9] identified as the first closed-loop glucose controlling system or AP [10], it is only in the last few years that the use of the AP has become a clinical reality. The first Food and Drug Administration (FDA)–approved commercial AP was released in 2016 in the United States, with a second system more recently approved [11,12]. The basic components of the APS are a sensor measuring subcutaneous interstitial fluid glucose on a near-continuous basis, a pump infusing rapid-acting insulin into the subcutaneous tissue, and a control algorithm (also known as the controller) that uses glucose measurements as the main input to calculate and operate the required rate of insulin infusion as the output (Figure 1). Proportional integral derivative control, model predictive control (MPC), fuzzy logic [13-15], adaptive control [16,17], and reinforcement learning [18] have been used in the recent past for controller development. The FDA has categorized the AP as a class III medical device, which is considered high risk. Hence, an investigation device exemption is required before conducting a clinical trial [19]. This requires initial testing of the proof of concept through animal trials, which is a time-consuming and costly exercise. A critical step toward AP advancement was the development of physiological models and simulators, which enabled the tuning and testing of different control algorithms in silico before conducting clinical studies, ensuring safety. The minimal model of glucose kinetics [20], the Sorenson model [21], the Hovorka model [22], the UVA/PADOVA simulator [23], the mGIPsim simulator [24], and the in silico patient population by Resalat et al [25] are some of the widely used models. The UVA/PADOVA simulator is currently the only FDA-approved simulator.

Figure 1. The basic system architecture of the artificial pancreas.



The major challenges with respect to the APS control algorithms relate to (1) delays in the onset and offset of insulin action because of delays of its absorption from subcutaneous depots (from CSII delivery) into the blood and (2) a time lag between glucose levels measured in subcutaneous interstitial fluid and blood glucose levels measured by currently available CGM devices. These limitations of APS imposed by the pharmacokinetics of subcutaneously delivered insulin and measured glucose levels are most evident in situations in which blood glucose levels and insulin requirements change rapidly and unexpectedly. These include meals, exercise, stressful events, and in response to acute illnesses. The current APS are hybrid closed-loop systems that require user input regarding meals and exercise; hence, similar to previous treatment methods, there remains a cognitive burden, affecting the quality of life of people with T1D [26]. Despite these limitations, systematic reviews and meta-analyses have verified that APS have shown better performance than conventional pump therapy [27]. However, there is still significant room for improvement.

Approaches used for improving APS functionality include advances in CGM accuracy and reliability; the development of faster-acting insulin analogs; and dual hormone infusion systems [28] in which glucagon, which can prevent hypoglycemia, as well as insulin can be delivered independently through the use of a controller. Complications of T1D can be related to meals, exercise, stress, and illness, all of which may affect glucose homeostasis. Current systems are unable to recognize these events and rely almost entirely upon inputs based on glucose level measurements and a record of the amount of insulin delivered. Inputs in addition to glucose level measurements may overcome some of the limitations of the current-generation APS. There has been recent focus on integrating additional external inputs captured from wearable devices and invasive sensors as part of experimental multi-input APS (MAPS). The addition of various signal inputs (eg, lactate and heart rate [HR]) is expected to provide more information and support the automatic identification of activities such as meals, exercise, sleep, stress, and other biological variations that affect the glucose profile [29]. The early detection of these activities would also help to counter limitations arising from CGM sensor delays [30]. This is also expected to reduce cognitive burden through lessening user interaction, leading to a better quality of life [31]. The rapid development of wearable sensor technologies can be identified as a strong motivator with respect to MAPS; however, it is important to analyze the potential improvement and additional device burden arising through the use of these systems.

Objectives

The main objective of this survey is to identify and review the MAPS that have been proposed to date in terms of used inputs, control architectures, and validation methods. To develop better systems, it is critical to understand the current state of MAPS and identify associated complexities. We aim to achieve this through conducting an in-depth analysis of previous related studies. The current pace of APS development has been slow, prompting movements such as #WeAreNotWaiting by people with T1D, which focuses on do-it-yourself APS [32]. This synthesis may accelerate work on developing improved MAPS. This survey identified a variety of additional signals that have been integrated into experimental APS. Most of the reviewed publications focused upon noninvasive inputs from wearable devices. These additional input signals have been integrated into different architectures to augment the controllers, in particular (1) for activity detection and switching of controller modes, (2) as direct inputs to the controller for decision-making, and (3) for the development of intermediate modules of the controller (eg, hypoglycemia prediction or meal detection). A variety of physiological models, simulation environments, and clinical studies have been used for validation of the results. A detailed analysis is presented in later sections.

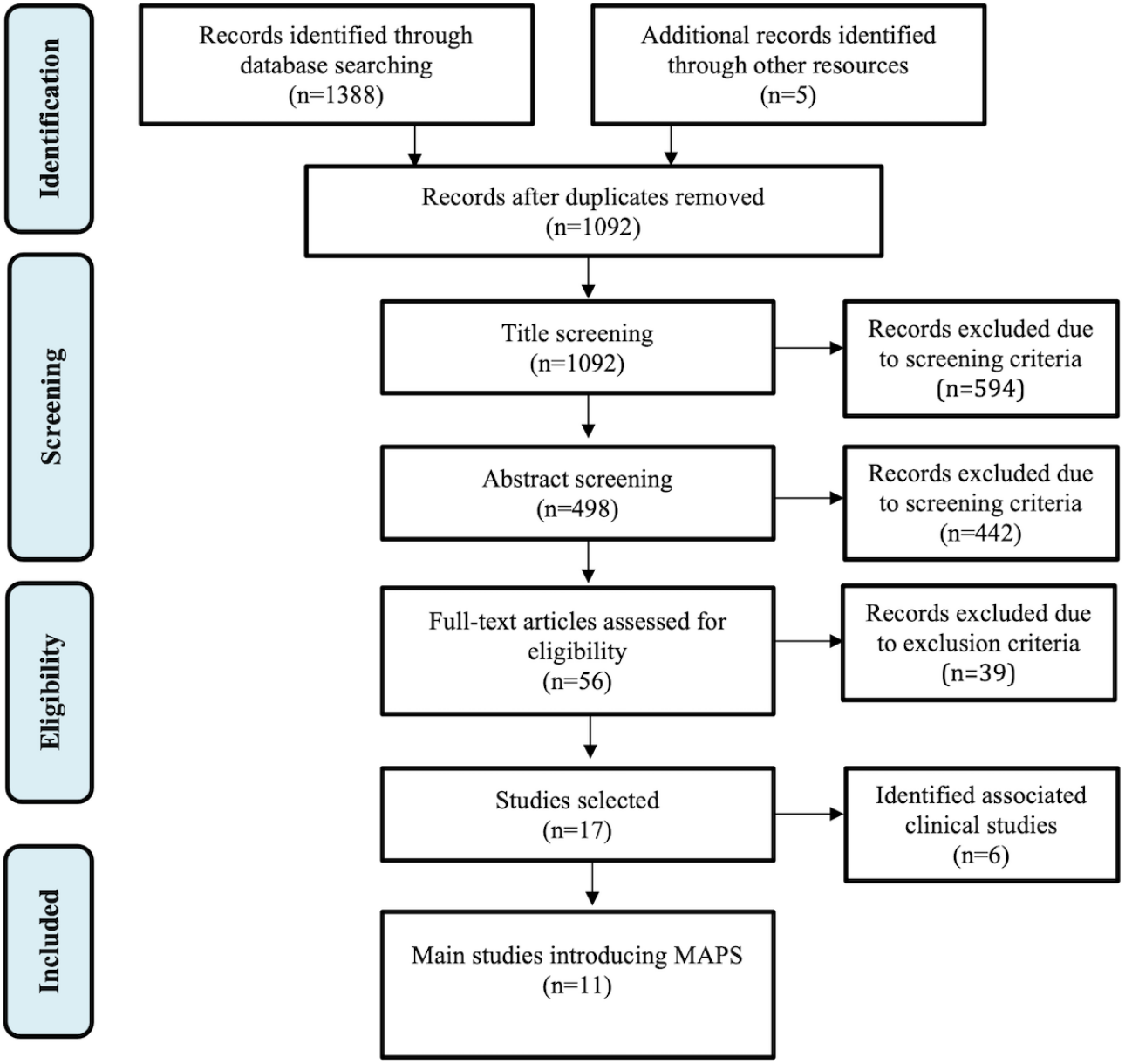
Methods

Overview

The survey was conducted by 3 independent reviewers (CH, ED, and HS) with research backgrounds in engineering, signal processing, machine learning, and health informatics, supported by a research librarian. The first reviewer conducted a systematic literature search and shortlisted studies through title and abstract screening. The second and third reviewers provided input to select the final studies for the survey and conducted the analysis. Throughout the reviewing process the researchers obtained valuable clinical expertise from 2 endocrinologists actively involved in T1D management and lived experience insights from young people with T1D within the Health Experience Team of the Our Health in Our Hands [33] strategic initiative of the Australian National University.

The literature survey was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) framework [34]. We searched Scopus and IEEE Xplore (to capture engineering studies on APS development, including multiple-input scenarios) and PubMed (to capture APS clinical studies conducted corresponding to the identified engineering approaches) databases between January 1, 2005, and February 10, 2020. The survey focused on analyzing and summarizing the different input sources, in addition to glucose level measurements, integrated into MAPS; control algorithms; architectures; and the validation methodologies used. The clinical transition of the identified studies was also considered to obtain a complete picture of the current state of progress of MAPS developments. The study selection process was carried out in 4 steps (Figure 2).

Figure 2. Study selection and identification flowchart. MAPS: multi-input artificial pancreas systems.



Identification Phase

A broad search query (Table 1) was developed to identify all papers related to control of the APS. The search query was not restricted further to ensure that all studies related to MAPS were captured. For the Scopus database, the search was restricted to articles and conference proceedings related to the subject areas of engineering, computer science, mathematics, decision sciences, and multidisciplinary specializations. The subject area restriction was not possible in PubMed; thus, the query was adjusted to exclude review articles and only include research related to humans. No additional filtering was carried out in the IEEE Xplore database because of it specific focus on computer science and electrical engineering. Additional records were identified through following the references in the selected studies (Multimedia Appendix 1).

Table 1. Search queries resulting in the identified studies (N=1388).

Database	Search strategy	Studies, n (%)
Scopus	(((*close** AND *loop*) AND (*diabet** OR *t1d*)) OR *artificial W/2pancreas*) AND (*control**); (filter: subject area and article type)	668 (48.12)
PubMed	(((*close** AND *loop*) AND (*diabet** OR *t1d*)) OR *artificial W/2pancreas*) AND (*control**) NOT (*review**); (filter: humans)	393 (28.31)
IEEE Xplore	(((*close** AND *loop*) AND (*diabet** OR *t1d*)) OR *artificial pancreas*) AND *control**	327 (23.56)

Screening Phase

Papers identified from the database search and other resources were first analyzed to remove duplicates. The titles and abstracts of the remaining papers were screened, where papers focusing on animal studies; CGM sensor development and errors analysis; insulin pumps; other aspects of the APS (eg, safety, user experience, and psychosocial aspects); physiological modeling; studies related to the chemical, biological, and medical aspects of APS design; studies focusing on developing submodules for the AP (eg, glucose-level estimation and meal detection); studies without additional input signals; and other irrelevant studies were excluded.

Eligibility Phase

The remaining full papers were analyzed and included in the study if the following selection criteria were met: (1) a control algorithm or architecture is present, (2) external additional inputs are used for the controller design (ie, in addition to CGM measurements, and the additional inputs are not control inputs, such as the coinfusion of glucagon), and (3) a validation is conducted in silico or in vivo (in humans). These criteria were formulated to encompass the 3 main verticals of the survey to understand and summarize the use of additional wearables in AP design, AP development technologies, and validation methodologies.

Inclusion Phase

Finally, the selected studies (N=17) were categorized into two groups: studies that introduce different unique MAPS (11/17, 65%) and their associated clinical studies (6/17, 35%). It is important to note that some of the studies in the first category also included clinical trial results (3/11, 27%). This separation was required to avoid the duplication of similar APS and ensure the overall analysis of the identified technical criteria of the unique MAPS studies. The main studies were analyzed based on the additional inputs used, APS controller design, and validation methodologies. The clinical studies were analyzed to discuss the feasibility of MAPS.

Quality Assessment

A quality assessment of the selected 17 studies were carried out using the Critical Appraisal Skills Programme Tool [35] (Multimedia Appendix 2 [36-52]). It is important to note that the main issues highlighted by the assessment were (1) difficulty in ascertaining the risk of bias in data collection or simulation data and (2) the failure of the study reports to provide sufficient information regarding ethical approvals.

Results

Results Overview

The analysis first identified the research groups working in the area of MAPS based on the selected studies and their clinical trials. Next, the shortlisted studies were evaluated based on the following main dimensions: (1) the types of additional signals used and their impact on glucose regulation, (2) the control algorithms and architectures, and (3) the validation methodologies.

Research Groups Focusing on MAPS

The Illinois Institute of Technology and Oregon Health & Science University were identified as the 2 main research groups developing MAPS, having produced 45% (5/11) of the main studies and 83% (5/6) of the associated clinical studies (Table 2). The diversity of researchers from different domains authoring the selected studies highlights the importance of multidisciplinary teams in APS development.

Table 2. Breakdown of main research groups focusing on developing multi-input artificial pancreas systems (N=17)[a].

Research group	Selected main studies (n=11), n (%)	Associated clinical studies (n=6), n (%)

• Illinois Institute of Technology, United States
  • Department of Chemical and Biological Engineering
  • Department of Biomedical Engineering
  • Department of Biobehavioral Health Science
  • Department of Pediatrics
  • Department of Electrical and Computer Engineering
• University of Illinois Chicago, United States
  • College of Nursing
• University of Chicago, United States
  • Biological Sciences Division
  • Department of Pediatrics and Medicine, Kovler Diabetes Center
• Michigan State University, United States
  • Sparrow Medical Group
	3 (27) [36-38]	3 (50) [39-41]

• Oregon Health & Science University, United States
  • Department of Biomedical Engineering
  • Department of Medicine
  • Division of Endocrinology, Harold Schnitzer Diabetes Health Center
• Oregon Clinical and Translational Research Institute Biostatistics & Design Program
  • Department of Medicine, Division of Health Promotion and Sports Medicine
	2 (18) [42,43]	2 (33) [44,45]

• Instituto Potosino de Investigación Científica y Tecnológica, Mexico
  • Division de Matematicas Alicadas
  • Biodinamica y Sistemas Alineales
	2 (18) [46,47]	—[b]

• National University of Sciences & Technology, Pakistan
  • Department of Electrical Engineering
• Northwestern Polytechnical University, China
  • School of Automation
• Center for Emerging Sciences Engineering and Technology, Pakistan
  • Department of Electronics Engineering
	2 (18) [48,49]	—

• Stanford University, United States
  • Division of Pediatric Endocrinology
• Rensselaer Polytechnic Institute, United States
  • Department of Chemical and Biological Engineering
	1 (9) [50]	—

• University of Virginia, Charlottesville, Virginia, United States
  • Center for Diabetes Technology, Division of Pediatric Endocrinology, Department of Pediatrics
  • Division of Endocrinology, Department of Medicine
• Virginia Commonwealth University
  • Division of Pediatric Endocrinology, Department of Pediatrics
	1 (9) [51]	1 (17) [52]

[a]The selected 11 studies and their corresponding 6 clinical trials are categorized according to their main institutions.

[b]No associated clinical studies identified through literature search.

Noninvasive Inputs

The types of additional inputs integrated or proposed to be integrated into APS that were identified can be categorized as (1) noninvasive inputs captured through wearable devices (most of them) and (2) invasive inputs of substances measured in body fluids. Most (9/11, 82%) of the selected studies focused on using noninvasive wearable input for MAPS development. Electrocardiogram (ECG), HR, accelerometers, skin resistance, energy expenditure (EE), and galvanic skin response (GSR) were identified as the noninvasive sensory inputs, and clinical studies were carried out for all these additional inputs, except for ECG for which simulations were conducted. However, it should be noted that wearable devices capable of capturing ECG measurements are currently available but might not have been available at the time the respective studies were carried out. Readers are directed to the study by Iqbal et al [53], which summarizes wearable devices in health care.

The additional inputs were introduced to the APS to address the previously explained limitations such as meals, exercise, stress detection, and illnesses and to counter the delays associated with glucose sensing and insulin action. It is important to analyze what additional signals have been used to counter these limitations and how they have been used in the APS design. A large portion of the studies (7/11, 64%) focused on exercise detection. They mainly used HR, accelerometer, and EE (also referred to as metabolic equivalent [MET]) for exercise detection.

Turksoy et al [36,37] and Hajizadeh et al [38] used the readily available EE data from wearables, whereas Jacobs et al [42] and Resalat et al [43] used a regression model introduced by Zakeri et al [54] to convert HR and accelerometer data to calculate MET. Stenerson et al [50] used HR and accelerometer data, and DeBoer et al [51] used HR data to identify exercise through predefined threshold values. It can be identified that exercise detection was the main focus of previous studies because of its practical importance.

Hypoglycemia prediction, using additional physiological signals, was the next popular approach to MAPS design. Predicting hypoglycemia in advance helps mitigate the glucose-sensing delays. Khan et al [48] and Qaisar et al [49] used HR, ECG (QT interval), and skin resistance for hypoglycemia detection. They identified the QT interval as the most prominent input and skin resistance as the least important input in hypoglycemia prediction. Turksoy et al [55] used EE and GSR to develop a module for hypoglycemia prediction. Stress detection was identified as another important aspect for MAPS design, where Turksoy et al [36,37] focused on using GSR signals. Patek [31], in his review, discusses a variety of other potential examples of how wearable sensory inputs can be used for MAPS design. They include the use of step counts, GPS, electroencephalography, chewing detection, finger and arm motion detection, and sleep detection data.

Managing meal effects is vital in APS development and at present it is challenging because of the heavy user burden, inaccuracies in carbohydrate counting, and forgetting to bolus. Turksoy et al [56,57] developed meal detection and carbohydrate estimation algorithms based on CGM measurements. However, in this survey, our focus was specifically on the use of MAPS design. Additional signals explored in the analyzed studies were not specifically used to improve glucose regulation related to meals.

Invasive Inputs

People with T1D who choose not to conduct multiple daily blood glucose level tests and use multiple daily injections are currently compelled to use minimally invasive CGM and CSII devices. This requires users to take necessary steps to regularly change the sensors [26,58-61]. Hence, an additional invasive sensor might be identified as practically burdensome. However, there exists the possibility of integrating additional sensors in currently used devices such as CGM and CSII to avoid additional user burden. Previous studies have identified relationships between invasive inputs and T1D (eg, ketone sensors to identify diabetic ketoacidosis [62]). Although rich relationships exist, progress is stunted because of the lack of sensors for carrying out continuous measurements. At present, real-time interstitial insulin sensors and ketone sensors are being developed [63].

Quiroz and Femat [46] and Quiroz et al [47] identified lactate and adrenaline as 2 important invasive inputs that were directly integrated as inputs in the controller. They are used in detecting exercise and hypoglycemia, respectively, which are important aspects in APS design to address the limitations identified previously. The studies described did not focus on clinical trials based on these additional invasive inputs, which again highlights the limited research conducted in the area because of the bottleneck in sensor development.

MAPS Architectures

The additional inputs identified in the previous section have been integrated into different architectures to augment the controllers (Table 3). They have been (1) used to switch controller modes through activity detection, (2) directly incorporated in the controller for decision-making, and (3) used for the development of intermediate modules for the controller (eg, hypoglycemia and meal detection).

Table 3. Summary of selected studies. Additional summarization is provided in Multimedia Appendix 3 [38,42,43,46-50].

Study	Additional inputs	Control algorithm	Architecture	Validation
Quiroz et al [46]	Lactate and adrenaline	H_∞ controller	Additional inputs directly integrated	MATLAB simulation
Quiroz et al [47]	Lactate and adrenaline	H_∞ controller	Additional inputs directly integrated	MATLAB simulation
Khan et al [48]	ECG[a], HR[b], and skin resistance	PID[c] controller	Fuzzy fusion controller to fuse the additional input to prompt glucagon infusion (dual hormone)	MATLAB simulation
Qaisar et al [49]	ECG, HR, and skin resistance	Neural network predictive controller	Fuzzy fusion controller to fuse the additional input to prompt glucagon infusion (dual hormone)	MATLAB simulation
Stenerson et al [50]	HR and accelerometer	PLGS[d] algorithm	Additional inputs used to switch between modes	Simulator (not specified)
DeBoer et al [51]	HR	Control to range	Additional inputs used to switch between modes (only basal rate is controlled)	Clinical study
Jacobs et al [42]	EE[e] (HR and accelerometer used to calculate)	FMPD[f] controller	Additional inputs used to switch the controller to a different mode (dual hormone)	Simulation; clinical study
Resalat et al [43]	MET[g] (HR and accelerometer)	Adaptive run-to-run MPC[h]	Inputs used to calculate MET, which is directly used by the controller for decision-making; meal data also provided to the controller	Simulation
Turksoy et al [36]	EE and GSR[i]	GPC[j]	Additional inputs integrated directly; ARMAX[k], recursive least squares, and constrained optimization used	Clinical study
Turksoy et al [37]	EE and GSR	GPC	Additional inputs integrated directly; time-varying forgetting factor for WRLS[l] algorithm and trajectory tracking	Clinical study
Hajizadeh et al [38]	EE (MET)	Adaptive MPC	Additional inputs integrated directly into the controller. Recursive subspace identification techniques, PIC[m], and meal estimates also used as inputs to the controller	Simulation

[a]ECG: electrocardiogram.

[b]HR: heart rate.

[c]PID: proportional integral derivative.

[d]PLGS: predictive low-glucose suspend.

[e]EE: energy expenditure.

[f]FMPD: fading memory proportional derivative.

[g]MET: metabolic equivalent.

[h]MPC: model predictive control.

[i]GSR: galvanic skin response.

[j]GPC: generalized predictive control.

[k]ARMAX: autoregressive moving average with external input.

[l]WRLS: weighted recursive least squares.

[m]PIC: plasma insulin concentration.

Stenerson et al [50], DeBoer et al [51], and Jacobs et al [42] focused on switching the mode of the controller based on detected activity. HR and accelerometer input were used in this approach, where the controller mode was changed through adjusting parameters and thresholds within the controller. Stenerson et al [50] suspended their predictive low-glucose suspend algorithm, and DeBoer et al [51] adjusted the hypoglycemia risk threshold in their control-to-range controller when exercise was detected. Jacobs et al [42] used a fading memory proportional derivative dual hormone controller that, upon the detection of exercise, carried out dosing of insulin and glucagon based on a set of static rules. This approach only focused on activity detection. However, the identified additional inputs may contain valuable information related to the glucose regulation process. Hence, studies have focused on direct integration of the additional inputs for decision-making.

Quiroz and Femat [46], Quiroz et al [47], Resalat et al [43], Turksoy et al [36,37], and Hajizadeh et al [38] focused on direct integration of additional inputs in the controller design. Quiroz and Femat [46] and Quiroz et al [47] directly integrated lactate and adrenaline input into their H_∞ control algorithm. Resalat et al [43] developed a run-to-run MPC that used continuous MET data for exercise detection. Turksoy et al [36] integrated EE and

GSR into a generalized predictive controller by developing time series models using autoregressive moving average with external input, recursive least squares, and constrained optimization techniques. They improved on their work by introducing a time-varying forgetting factor for the weighted recursive least squares algorithm and focusing on trajectory tracking [37]. Hajizadeh et al [38] used recursive subspace identification techniques to develop an adaptive MPC controller incorporating MET input. The continuously integrated inputs such as EE and GSR provided valuable and timely insights regarding the glucose regulatory process, which is valuable.

Designing submodules for the APS has also been widely explored, where the focus has been on using the input to enhance insulin and glucagon infusion and to design safety mechanisms for the APS. These submodules were mainly linked to identified limitations such as meal detection, activity detection, and hypoglycemia detection. Khan et al [48] and Qaisar et al [49] developed a hypoglycemia-detection module using HR, ECG (QT Interval), and skin resistance. In addition to the main controller focusing on insulin infusion, a fuzzy logic fusion controller was introduced to infuse glucagon based on the identified signals during a hypoglycemia event. Turksoy et al [41] performed a clinical trial where hypoglycemia early alarm [55], meal detection [56,64], hypoglycemia prediction, and carbohydrate recommendation [57] modules were integrated into the final APS design. Hajizadeh at al [38] focused on plasma insulin concentration estimation and meal effect estimation modules in their research. Resalat et al [43] proposed and evaluated an insulin sensitivity adaptation algorithm and an adaptive-learning postprandial hypoglycemia prevention algorithm. However, it is important to note that some of these submodules only used existing CGM measurements. Different safety modules have also been introduced, where Turksoy et al [36] and DeBoer et al [51] focused on hypoglycemia and hyperglycemia safety, respectively, through insulin-on-board estimates. The development of submodules enhances the interpretability of the APS operation, which is essential in safety-critical applications. Most of the studies have used submodules in their controllers, both with switching the controller mode through activity detection and when additional inputs are directly integrated. Hence, designing submodules using additional input targeting the identified limitations is beneficial in APS development.

Validation Methodologies

The designed APS have been validated through simulations and clinical studies (Tables 3 and 4). A variety of physiological models and tools have been used for simulations and different protocols used for clinical trials. The AP is classified as a high-risk medical device by the FDA, which requires proper simulation and testing before conducting clinical trials. However, it is important to note that an FDA-approved simulator is currently unavailable for testing MAPS. In all, 2 groups have focused on developing their own multiple-input simulators [24,25], which would be beneficial for the progress of MAPS development.

Table 4. Comparison of clinical trial results.

Author	Trial and controller setting	Results
Breton et al [52]	• 12 adults, randomized crossover trial, 24-hour closed-loop experiments each with exercise • Exercise detection using HR[a] • Meal bolus manually calculated	• Time in euglycemia[b] for AP[c] with HR and without HR overall 81% vs 75%, exercise 91% vs 85%, and overnight 89% vs 84% • Using HR resulted in fewer hypoglycemic events during exercise (0 vs 2)
DeBoer et al [51]	• 18 adolescents, randomized crossover trial, 24-hour closed-loop experiments each with exercise • Exercise detection using HR • Meal bolus manually calculated	• Time in euglycemia for AP with HR and without HR overall 77% vs 74%, exercise 96% vs 87%, and overnight 92% vs 84% • Small reduction in hypoglycemic events (0.39 HR-informed AP vs 0.50 without HR)
Jacobs et al [44]	• 21 adults, randomized crossover trial, 22-hour experiments each with exercise • Exercise-detection algorithm triggered manually	• Time in euglycemia with exercise detection 67%, without exercise detection 72%, and SAP[d] 68% • Time in hypoglycemia (<3.9 mmol/L) 0.3%, 3.1%, and 0.8%, respectively • Time in hyperglycemia (<10 mmol/L) 32%, 25%, and 31%, respectively
Castle et al [45]	• 20 adults, randomized crossover trial, 4-day experiments each with exercise • Exercise-detection algorithm triggered using wearable sensor in SH[e] and DH[f] controllers	• Time in euglycemia overall SH 74.3%, DH 72%, PLGS[g] 65.2%, and current care 63.1% • Time in hypoglycemia 2.8%, 1.3%, 2%, and 3.1%, respectively
Turksoy et al [36,39]	• 3 young adults, seven 32- or 60-hour closed-loop experiments with exercise • Additional signals integrated continuously	• Time in euglycemia 62% (overnight 75.3%, exercise 55%, and glycemic closed loop 56.1%)
Turksoy et al [37]	• 3 young adults, 70-hour closed-loop experiments with exercise • Additional signals integrated continuously	• Time in euglycemia 46.5%
Turksoy et al [40]	• 9 young adults, 2-day closed-loop experiments with exercise • Additional signals integrated continuously	• Time in euglycemia 58%
Turksoy et al [41]	• 10 young adults, eighteen 60-hour closed-loop experiments with exercise • Additional signals integrated continuously, with submodules	• Time in euglycemia 69.9% for exercise and recovery periods and 76.75% overall performance

[a]HR: heart rate.

[b]Euglycemia target range 70-180 mg/dL (Jacobs et al [44] report euglycemia as 3.9-10 mmol/L, range 70.2-180 mg/dL, whereas all other studies report results for the range 70-180 mg/dL).

[c]AP: artificial pancreas.

[d]SAP: sensor-augmented pump.

[e]SH: single hormone.

[f]DH: dual hormone.

[g]PLGS: predictive low-glucose suspend.

MATLAB was used in most of the studies to conduct simulations. Quiroz et al [46,47] simulated the use of invasive inputs based on the Sorenson model [21], the Bergman minimal model [65], the glucose–adrenaline relationship discussed in the study by Schultes et al [66], and the glucose–lactate relationship discussed in the study by Stuart et al [67]. Khan et al [48] and Qaisar et al [49] also used the Bergman minimal model, as well as simulated meals, ECG, and subcutaneous delays. Jacobs et al [42] used the Hovorka insulin pharmacodynamics model [68], the insulin pharmacokinetics model by Wilinska et al [69], the glucagon pharmacokinetics model by Lv et al [70], the glucagon pharmacodynamics model by Bakhtiani et al [71], and the exercise model by Hernandez-Ordonez et al [72] for their simulation. Resalat et al [43] and Hajizadeh et al [38] conducted their simulations based on simulators developed by their own research groups [24,25].

DeBoer et al [51], Breton et al [52], and Jacobs et al [44,45] carried out a clinical trial to evaluate their switching mode controller after obtaining FDA and institutional review board

approvals. Breton et al [52] and DeBoer et al [51] reported a reduction in hypoglycemic events in adolescents and adults, respectively, using HR in an activity-augmented control architecture. Jacobs et al [44] also achieved a reduction in time spent in hypoglycemia, but there was an increase in the time spent in hyperglycemia when the exercise-augmented control structure was used. Similar results were observed in the subsequent trial by Castle et al [45]. Overall, these randomized crossover trials were able to identify a reduction in hypoglycemia when the activity-augmented control structure was used. It is important to note that activity-augmented APS design might be compromised during different types of exercises (high-intensity training and resistance exercise), which has not been explored. Turksoy et al [39-41] focused on having a medical expert to review each insulin dose before the application and obtained institutional review board approval. They focused on integrating continuous inputs (EE and GSR) into the controller and developing submodules and conducted clinical trials for evaluation. They succeeded in improving the time in target range (70-180 mg/dL) to 76.75% with the integration of different submodules into the APS. The identified clinical trials (Table 4) focused on either adolescents, young adults, or adults. The trials comprised both normal closed-loop trials and randomized crossover trials, which evaluated different treatment types and typically ranged in duration from 1 to 4 days. Further longitudinal studies will be beneficial to ascertain the effects of sensor noise and unanticipated dropouts that might arise from the additionally introduced sensors. It is important to conduct trials encompassing all age groups (children, adolescents, and adults) to evaluate the robustness of the controllers because different age groups have different insulin sensitivities, which affects the controller's accuracy.

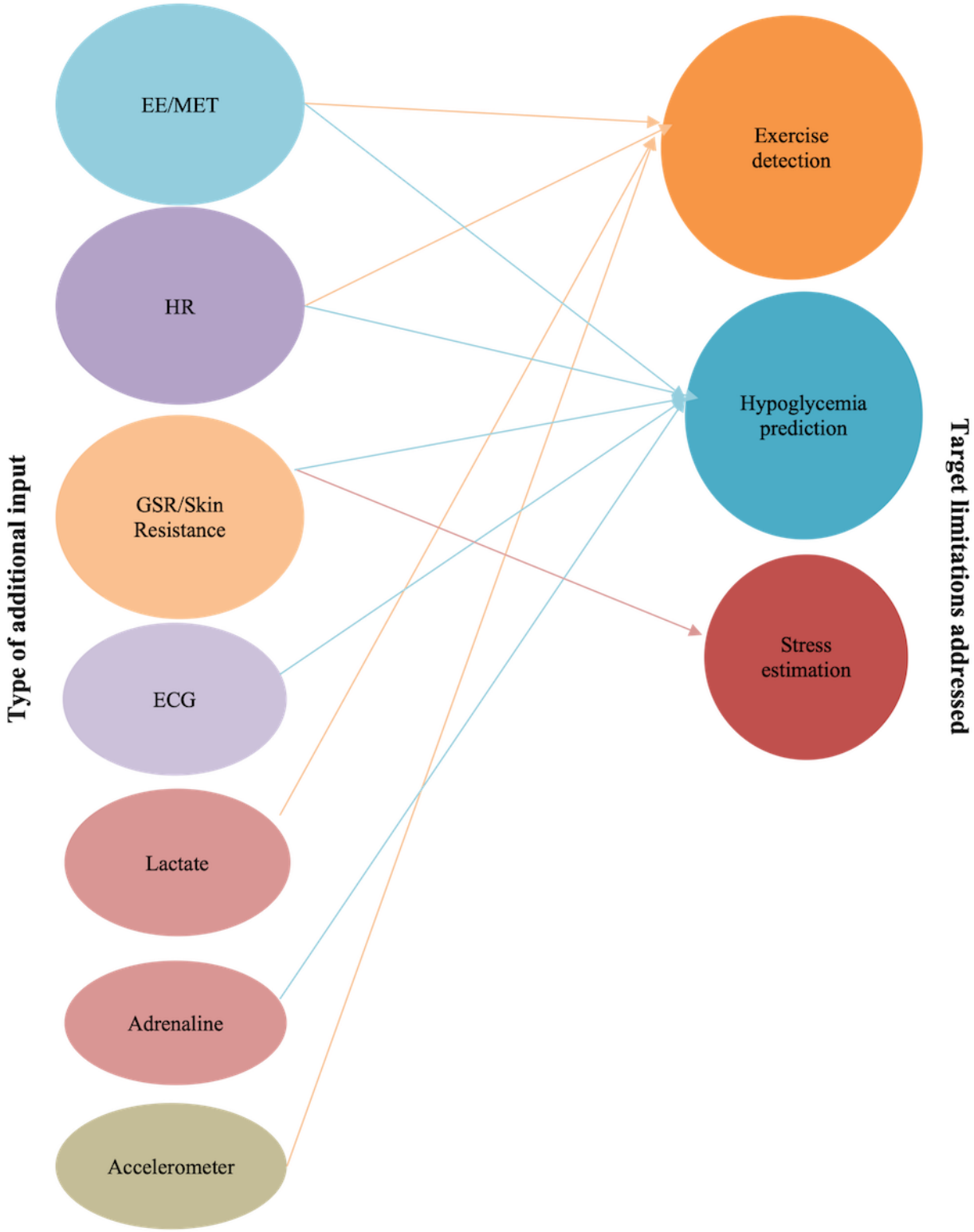
Discussion

Principal Findings

This survey focused on three main verticals: (1) identifying the types of additional input signals used, (2) analyzing different APS control methodologies, and (3) exploring MAPS validation methodologies. In this section, a summary of the findings based on these aspects, a discussion on the feasibility of MAPS, a comparison of clinical trial results, and limitations of the conducted survey are discussed.

Most of the identified inputs were noninvasive, captured through wearable devices. However, the effectiveness of invasive inputs has also been analyzed through simulations. Lactate and adrenaline were the identified invasive inputs used for exercise detection and hypoglycemia detection. EE (or MET) can be identified as the most frequent additional input used in APS development. EE is able to detect exercise, which helps mitigate the related APS limitations identified previously. Hypoglycemia prediction has been carried out through the use of inputs such as ECG, HR, skin resistance, EE, and GSR. GSR has also been used effectively as an indicator of stress. HR-, EE-, GSR-, and accelerometer-based studies have been evaluated through clinical trials mainly because of the easy access through wearable devices. The technological advancements in wearable devices would be beneficial for the development of MAPS. A summary of the distribution of different additional inputs used in the final APS design and their main focus aspects in the selected studies is provided in Figure 3.

Figure 3. Distribution of additional inputs used in the final artificial pancreas systems design and their main focus aspects. Only the additional inputs used in the final design are presented. Input variables used to synthesize the final inputs have been removed. ECG: electrocardiogram; EE: energy expenditure; HR: heart rate; GSR: galvanic skin response; MET: metabolic equivalent.



Most of the studies (8/11, 73%) focused on augmenting single-hormone APS compared with dual-hormone systems. Identifying additional inputs that can be used to address current limitations and directly integrating those inputs into the controller has shown promise. The development of submodules based on these limitations and switching the mode of the controller through activity detection can also be identified as effective approaches to MAPS design. Different control algorithms and architecture have been proposed in previous research. Adaptive model–based controlling methods have been frequently used for controller development.

Validations were carried out in the studies in silico (7/11, 63%) as well as in vivo (4/11, 36%). Both quantitative and qualitative metrics were used to evaluate the effectiveness of the proposed

systems. The time in hypoglycemia, euglycemia, and hyperglycemia ranges as well as the number of hypoglycemic events were some of these measures. However, comparison of the results is subjective because of the different physiological models used in the simulators and different protocols (exercise, meals, and age groups) used in the clinical studies. Furthermore, some of the studies included additional modules such as hypoglycemia alarms and meal detection, which were unrelated to the analyzed additional inputs in this study. This further limited a valuable interstudy statistical analysis to understand the impact of the proposed additional Inputs. However, an analysis of comparable studies within the same research group has been presented in the previous section. It is important to mention that 2 groups had focused on developing their own simulators [24,25] because currently available simulators did not have other multiple inputs incorporated. The rest of the studies had combined different physiological models in previous research to simulate the additional variables. At present, such a validated simulator is yet to be developed for MAPS. The development of an FDA-approved simulator for MAPS would be beneficial to test and compare different proposed control architectures to statistically evaluate their performance and the progress in this area. The studies analyzed in the survey have obtained FDA and institutional review board approvals to conduct clinical trials.

It is important to review the patents published related to APS to identify possible technological advancements. We conducted a search on Google Patents for the period January 2005 to May 2021 and identified 2 patents associated with MAPS (Multimedia Appendix 4 [73,74]). Both the patents were associated with the Illinois Institute of Technology research group identified in the previous section. Patent ID US8690820B2 [73] presented a device where a glucose sensor and physiological status–monitoring system communicate with an automatic controller for glucose control. The controller also included a module to predict future glucose levels. Patent ID US10646650B2 [74] introduced additional modules for recursive model identification of hypoglycemia and hyperglycemia early alert and alarm, plasma insulin concentration estimation, physical activity assessment, stress detection and assessment, sleep detection, and sensor and pump fault detection and diagnosis. The aforementioned proposed modules using physiological signals were identified in the previous section.

Feasibility of MAPS

Different additional inputs have been identified and used to address limitations identified in current generation APS. However, more signals and relationships need to be explored to address limitations such as meal and illness estimation. It is important to quantify the improvement of the APS through the integration of additional input signals. The benefits should outweigh the burden of using the external sensors.

The results of the proposed approaches can be analyzed based on their clinical trials, which provides a fairer interpretation compared with the simulations. However, it should be noted that comparison between trials is not straightforward because of the different protocols (meals and exercise) and the number of participants involved. The identified clinical trials improved the time in euglycemia range and showed a reduction in hypoglycemic events when additional inputs were used. However, further trials need to be conducted with larger cohorts and trial durations to ensure the effectiveness of the systems.

The noise and instability associated with wearable sensors also need to be evaluated because they could have a detrimental effect on the controllers. Precautionary measures should be set in place to ensure patient safety during such circumstances. It is also important to note that the real-world application of MAPS would be very complex. For example, a person with T1D might not wear additional wearables during sleep, which might require the controller to work in highly dynamic environments. Hence, it is important to evaluate such scenarios through simulations and clinical studies conducted for longer durations.

Conclusions and Comparison With Prior Work

Kudva et al [30] analyzed the clinical importance of incorporating additional signals, and Cinar [29] and Patek [31] analyzed the current limitations in APS design and the approach to MAPS development. In this survey, we analyzed existing APS designs to identify the types of input variables used, control techniques, architectures, and validation methodologies. This survey was restricted to studies that proposed APS. However, research studies exist that aim to identify relationships between various physiological signals and T1D. The identification of such relationships would be beneficial for the development of MAPS. Previous research has also focused on designing submodules such as meal detection [56], carbohydrate recommendation [57], and hypoglycemia prediction [55] modules for APS. Given the scope of this survey, such submodules were only identified and only the final integrated APS were evaluated. This survey mainly focused on the technical aspects of MAPS development. It is also important to explore and evaluate the corresponding practical aspects (eg, additional user burden, sensor failures, and psychosocial impact).

The integration of additional signals is an approach to mitigate the current limitations of the APS. Most of the integrated additional inputs in previous research are from wearables. The widespread availability of wearables could be seen as a factor facilitating MAPS. Past studies have mainly focused on using the additional inputs for detecting exercise (HR, accelerometer, and EE), hypoglycemia (ECG, HR, EE, and GSR), and stress (GSR). In future, these additional sensors might also be valuable in capturing other physiological changes such as illnesses, alcohol consumption, and seasonal variations. Previous randomized crossover studies were able to obtain lower time in hypoglycemia and improvements in the normal glycemic range when additional inputs were integrated. However, these systems need to be improved to obtain better time in target range for glucose to improve the quality of life of people with T1D. The lack of an FDA-approved simulator for testing the identified additional input can be identified as a major constraint regarding the development of MAPS. It is important to explore different additional inputs further to establish relationships with glucose regulation and use them to address the identified limitations. The practical complexities and psychosocial aspects associated with MAPS need to be evaluated to develop effective APS.

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Authors' Contributions

CH contributed to all aspects of this work and wrote the original manuscript. CH, ED, and HS were responsible for conceptualizing the study and served as the 3 independent reviewers. ED, HS, JD, CJN, and DON critically reviewed, commented on, and revised the manuscript. CJN, HS, and ED contributed to the oversight and leadership responsibilities for the research activity planning, resourcing, and execution.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Search query formulation.
[DOCX File , 24 KB - diabetes_v7i1e28861_app1.docx]

Multimedia Appendix 2
Quality assessment.
[DOCX File , 29 KB - diabetes_v7i1e28861_app2.docx]

Multimedia Appendix 3
Summary of additional inputs and simulation models.
[DOCX File , 26 KB - diabetes_v7i1e28861_app3.docx]

Multimedia Appendix 4
Patents associated with multi-input artificial pancreas systems.
[DOCX File , 25 KB - diabetes_v7i1e28861_app4.docx]

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Abbreviations

ANU: Australian National University
AP: artificial pancreas

APS: artificial pancreas systems
CGM: continuous glucose monitoring
CSII: continuous subcutaneous infusion of insulin
ECG: electrocardiogram
EE: energy expenditure
FDA: Food and Drug Administration
GSR: galvanic skin response
HR: heart rate
MAPS: multi-input artificial pancreas systems
MET: metabolic equivalent
MPC: model predictive control
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
T1D: type 1 diabetes

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Original Paper

Internet-Based Patient Education Materials Regarding Diabetic Foot Ulcers: Readability and Quality Assessment

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Abstract

Background: While diabetic foot ulcers (DFU) are a common complication of diabetes, little is known about the content and readability of online patient education materials (PEM) for DFU. The recommended reading grade level for these materials is grades 6-8.

Objective: The aim of this paper was to evaluate the quality and readability of online PEM on DFU.

Methods: A Google search was performed using 4 different search terms related to DFU. Two readability formulas were used to assess the readability of the included PEM. These included the Flesch-Kincaid grade level and the Flesch-Reading ease score. The DISCERN tool was used to determine quality and reliability.

Results: A total of 41 online PEM were included. The average Flesch-Reading ease score for all PEM was 63.43 (SD 14.21), indicating a standard difficulty level of reading. The average reading grade level was 7.85 (SD 2.38), which is higher than the recommended reading level for PEM. The mean DISCERN score was 45.66 (SD 3.34), and 27% (11/41) of the articles had DISCERN scores of less than 39, corresponding to poor or very poor quality.

Conclusions: The majority of online PEM on DFU are written above the recommended reading levels and have significant deficiencies in quality and reliability. Clinicians and patients should be aware of the shortcomings of these resources and consider the impact they may have on patients' self-management.

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KEYWORDS

diabetic foot ulcer; patient education; patient education materials; online resources; readability; diabetic foot; diabetes; online eduction

Introduction

Diabetes affects 1 in 10 people worldwide and disproportionately affects those who do not have regular access to health care [1,2]. Diabetic foot ulcers (DFU) affect 15-25% of people living with diabetes mellitus at some point in their life [2]. This not only leads to a decreased quality of life and functional limitations but also precedes most lower extremity amputations [3]. Patients with DFU have a 7% risk of amputation 10 years after their diagnosis [4]. As a leading cause of mortality globally, diabetes is 1 of 4 priority noncommunicable diseases targeted for action by the World Health Organization [5].

Patient education is imperative in preventing and managing DFU and subsequently lower extremity amputations [6-8]. Foot care practices include how to inspect and wash the feet when drying, choosing suitable socks and footwear, applying lotion to dry skin, cutting nails appropriately, and notifying a health

provider if a cut, blister, or sore develops [9]. Usually, patients and their families provide 95% of their diabetes foot care themselves [10].

Readability is an objective measure of reading skills required to comprehend written information [11]. These can include elements such as familiarity, legibility, typography, and complexity of words and sentences. Readability formulas attempt to assess written information based on word and sentence length as surrogates of text complexity [11]. Currently, the National Institutes of Health recommends that patient education material be written for a grade 6 level audience, the estimated reading level of the average North American adult [12]. The Canadian Medical Protective Association and the American Medical Association also recommended that patient education materials (PEM) be written for a grade 6 level audience [13].

The understandability, readability, and actionality of web-based information have been assessed for diabetes mellitus [14]. However, no study has been conducted investigating the quality and readability of online PEM regarding DFU. Since DFU are a common complication of diabetes mellitus, clinicians must evaluate the information patients access online about foot care. Self-management of diabetic foot ulcers is critical for clinical outcomes [3]. Patients often rely on a plethora of online information available to educate them on the self-management of DFU. Therefore, the objective of this study is to assess the quality and readability of online patient education material related to management and care for diabetic foot ulcers.

Methods

Search and Categorization

This study was exempt from the St. Michael's Hospital Research Ethics Board. The search was conducted using the Google (Google Inc) search engine, the most used search engine in Toronto, Ontario, on October 1, 2020. Four search terms were used, which were "diabetic foot ulcer care," "diabetic foot care," "diabetic wound care," and "foot care." The first 20 pages of the search were reviewed for this study. Although most internet users only review the first 20 search results, the search is normally broadened to offset variability in previous search history and location [15]. Before initiating the search, the browser was set to incognito mode. All search history, cookies, and cached data were erased from the browser, and location settings were disabled to prevent the search engine from showing personalized results.

All webpages and articles that were PEM about diabetic foot care were included. The exclusion criteria included websites that were not written in English, websites that had access restrictions, nontext media (including videos and audio), news articles, scientific webpages (eg, Science Direct and PubMed), websites that targeted medical professionals, webpages that contained less than 100 words, and websites that did not contain patient information on diabetic foot ulcer care and prevention.

The websites were divided into 6 main categories based on their origin: academic institutions, professional organizations, medical information websites, government websites, private clinics, and miscellaneous websites. The websites were categorized as originating from an academic institution if they are affiliated with a university or a medical center. Examples of professional organizations include the American Diabetes Association, Diabetes Canada, Wounds Canada, International Working Group on the Diabetic Foot, and Diabetes Action Canada. Examples of medical information websites include websites such as WebMD and Merck Manual. Miscellaneous websites include Wikipedia and patient testimonials. Categorization was completed in duplicate.

Outcome Measures

Readability Evaluation

All websites were downloaded into plain text using Microsoft Word (Microsoft Corp). Formatting elements found on webpages were removed. This was carried out to avoid skewing readability results as recommended by several groups [15-17]. PEM were evaluated for readability using an online readability calculator, Readable (Added Bytes Ltd), which performs the Flesch-Kincaid reading ease (FRE) and Flesch-Kincaid grade level (FKG) readability tests. Each of these tests uses variables such as sentence length, number of words, and number of syllables to estimate readability [18-20]. Multimedia Appendix 1 describes each instrument, the formula used to calculate the score, and the interpretation of the scores generated by each instrument. To be a Grade 6 level and under, the scores for the FKG needed to be 6 or lower. FRE scores ranged from 0 to 100, with a higher score corresponding to a text that is easier to read (Table 1). An FRE score between 60 and 70 corresponded to a standard reading level. The online calculator, Readable, was used by other peer-reviewed publications, and we used the validated readability formulas in Table 1 [21,22]. The FRE and FKG scores have been used to evaluate medical literature and are the most applicable readability formulas for health information [18,23-27].

Table 1. Flesch-Kincaid reading ease score interpretation.

Score	Interpretation
90 to 100	Very easy
80 to <90	Easy
70 to <80	Fairly easy
60 to <70	Standard
50 to <60	Fairly difficulty
30 to <50	Difficult
0 to <30	Very difficult

Quality of Patient Education Material

DISCERN is a tool designed for patients and health care providers to assess the reliability and quality of written material on treatment choices without the need for medical knowledge [28]. It is a 16-question survey that covers the reliability of a publication, treatment options, benefits, and risks of treatment options. Table 2 describes the interpretation of the total DISCERN scores. A higher score indicates a higher quality of the publications. The DISCERN scores were independently performed by a senior medical student who was trained in using the DISCERN tool. The DISCERN score has been used by other senior medical students in other peer-reviewed publications [29-31].

Table 2. DISCERN scores.

Score range	Quality rating
63-80	Excellent
51-62	Good
39-50	Fair
27-38	Poor
16-26	Very poor

Statistical Analyses

Categorical variables were reported using frequencies and proportions. Continuous variables are presented as means (SD) or medians and interquartile ranges. Separate analyses were conducted to determine if quality and readability differed depending on the origin of the PEM. These were compared using the Kruskal Wallis test, followed by the Dunn-Bonferroni post hoc tests. The Spearman correlation coefficients were used to assess the relationship between DISCERN scores and readability scores. Statistical analyses were performed using SPSS, version 26.0 (IBM Corp), with statistical significance set to $P<.05$.

Results

Search Results

A total of 80 webpages were retrieved from the search. After the removal of 4 duplicates and excluding 35 webpages, 41 webpages met the inclusion criteria. Moreover, 63% of the webpages originated from the United States (26/41) while 37% (15/41) originated from Canada. Of the included webpages, 2% (1/41) were from an academic institution, 17% (7/41) from a professional organization, 36% (15/41) were from a medical information website, 17% (7/41) were from a government website, 21% (9/41) were from private clinics, and 4% (2/41) were from miscellaneous websites. Of the excluded webpages, 2% (1/35) were from a blog, 17% (6/35) were from a scientific webpage, 25% (9/35) were from websites targeting medical professionals, and 45% (16/35) were websites without patient information pertaining to diabetic wound care.

Readability Evaluation

The FRE scores ranged from 0 to 100 with a higher score corresponding to a text that is easier to read (Table 1). An FRE score between 60 and 70 corresponds to a standard reading level. The mean FRE score for all included PEM was 63.43 (SD 14.21), indicating a standard difficulty with a range of 33.8-84.2. Moreover, 68% (58/85) had FRE scores below 60, indicating that they were “fairly difficult” to “very difficult” to read. The mean reading grade levels as determined by the FKG score was 7.85 (SD 2.38). When looking at PEM from different origins, PEM from government websites had the highest FRE scores. PEM from private clinics had the highest FKG scores (Table 3). PEM from the United States also appeared to have a higher reading level than Canadian PEM (Table 4).

Table 3. Mean readability scores according to each type of website (95% CI).

	Academic institutions (n=1)	Private clinics (n=15)	Professional organizations (n=7)	Medical information websites (n=7)	Government websites (n=9)	Miscellaneous (n=2)	Total (N=41)
FRE[a] score (SD)	71.9 (—[b])	55.4 (8.4)	68.9 (7.4)	61.69 (8.4)	73.19 (5.17)	55.1 (21.9)	7.85 (2.38)
FKG[c] score (SD)	6.7 (—)	8.63 (1.3)	7.54 (1.8)	8.15 (1.4)	6.46 (1.1)	8.6 (3.9)	63.43 (14.21)

[a]FRE: Flesch-Kincaid reading ease.

[b]Not applicable.

[c]FKG: Flesch-Kincaid grade level.

Table 4. Mean readability scores according to country of origin (95% CI).

	Canada	The United States
FRE[a] score (SD)	66.52 (6.7)	55.4 (5.7)
FKG[b] score (SD)	7.67 (1.1)	8.63 (1.0)

[a]FRE: Flesch-Kincaid reading ease.

[b]FKG: Flesch-Kincaid grade level.

Quality of Patient Education Material

The mean DISCERN score was 45.66 (SD 3.34) (Table 5). The weighted κ statistic for the total DISCERN scores was 0.95. The average scores for each item in the DISCERN instrument are displayed in Multimedia Appendix 1. Twenty-seven percent (11/41) of articles had total DISCERN scores of less than 39, indicating they were of “poor” or “very poor” quality. Table 6 demonstrates the DISCERN scores for the PEM based on their origin. PEM originating from medical information websites had significantly higher DISCERN scores (P=.01). There was no significant correlation between DISCERN score and FRE score (r=0.07, P=.67) or DISCERN score and the average reading grade level (r=-0.005, P=.97).

Table 5. Average score (95% CI) for each item in the DISCERN instrument.

Quality criterion	Value
Section 1: reliability, mean (SD)	
Are the aims clear?	3.1 (0.3)
Does it achieve its aims?	4.1 (0.3)
Is it relevant?	3.7 (0.3)
Is it clear what sources of information were used to compile the publication (other than the author or producer)?	2.6 (0.4)
Is it clear when the information used or reported in the publication was produced?	2.6 (0.5)
Is it balanced and unbiased?	2.7 (0.3)
Does it provide details of additional sources of support and information?	2.6 (0.3)
Does it refer to areas of uncertainty?	2.0 (0.4)
Total reliability score, mean (SD)	23.4 (1.8)
Section 2: quality, mean (SD)	
Does it describe how each treatment works?	3.4 (0.4)
Does it describe the benefits of each treatment?	2.8 (0.4)
Does it describe the risks of each treatment?	3.0 (0.9)
Does it describe what would happen if no treatment were used?	3.1 (0.4)
Does it describe how the treatment choices affect overall quality of life?	2.5 (0.3)
Is it clear that there may be more than one possible treatment choice?	3.1 (0.3)
Does it provide support for shared decision-making?	3.0 (0.4)
Total quality score, mean (SD)	19.2 (1.6)
Overall rating of sites, mean (SD)	3.0 (0.3)
Total DISCERN scores, mean (SD)	45.7 (3.3)

Table 6. Mean DISCERN score for patient education materials based on their origin.

PEM[a] origin	Value
Academic institutions, mean (SD)	42.00 (—[b])
Professional organizations, mean (SD)	41.57 (9.52)
Medical information websites, mean (SD)	53.53 (5.99)
Government websites, mean (SD)	42.43 (5.26)
Private clinics, mean (SD)	39.56 (15.83)
Miscellaneous, mean (SD)	41.50 (6.36)

[a]PEM: patient education materials.

[b]Not applicable.

Discussion

Principal Findings

On average, PEM on diabetic foot ulcer care were written at an approximate reading level of grades 7-8, which exceeds the 6th-grade reading level recommendation from the Canadian Medical Protective Association and the average reading level of a North American adult [14]. Furthermore, 68% had FRE scores below 60, indicating that they were “fairly difficult” to “very difficult” to read. Similar results have been found by other studies. Lipari et al conducted a study on the readability of online PEM on diabetes mellitus and found that 77% of PEM (10/13) were written above an 8th-grade reading level [14]. Furthermore, PEM from Diabetes Canada were written at about a 7th-10th grade reading level. This is an important finding as some may assume that material originating from credible sources such as academic institutions and professional organizations may be better for patient education. Our study found that PEM from professional organizations and an academic institution typically exceeded a 6th-grade reading level. This is in keeping with a previous study, which found that PEM on diabetes mellitus from US academic institutions and professional organizations were written for a reading level of above grade 10 [32].

PEM must also be reliable, comprehensive, and contain evidence-based information. This study attempted to assess reliability and quality through the DISCERN tool. Twenty-seven percent (11/41) of the articles had total DISCERN scores less than 39, indicating they were of "poor" or "very poor" quality. Similar studies on diabetic retinopathy have found that 73% (16/22) of PEM were of "poor" or "very poor" quality [33]. Interestingly, this study also found that academic institution and medical information websites had significantly higher reliability scores when compared with private clinics. These differences may be because academic institutions and medical information websites have access to several experts in their respective fields and may have more resources to produce more robust PEM. These findings may have important implications when physicians and other allied health professionals refer patients to online resources to learn more about diabetic foot ulcers.

This study performed a correlation analysis to determine the relationship between DISCERN scores and readability. A weak positive correlation was found between DISCERN scores and FRE scores, and a weak negative correlation was found between DISCERN scores and average reading grade level. Neither reached statistical significance. This implies that high-quality, more reliable PEM were not necessarily more readable. While the target audiences for these websites vary, these were the websites most readily accessible and targeted to patients. This has an important implication as easily accessible PEM that patients can easily comprehend may not necessarily be of high quality.

Limitations

This study has several limitations. Firstly, the search strategy in this study used the Google search engine with 4 different search terms to appropriately simulate how patients search the internet for health information. It is possible that patients could obtain different resources. However, Google is the most common search engine used and has been the sole search engine used in several other readability analyses [14,33,34]. Furthermore, it is not possible to predict which search terms patients will use. However, this study utilized 4 different search terms that are the most likely terms used by patients searching for diabetic foot ulcer care. We did not account for patients who do not use the internet to access PEM on diabetic foot ulcers or those who do not have access to a computer.

The correlation between readability scores and true reading comprehension cannot be considered perfect since readability scores have several limitations. Since these scores are based on variables such as the number of syllables or characters per word, they can be skewed by medical terminology such as "vasculature" or "neuropathy." Titles and headings can also mislead them as these may be interpreted as sentences. This study mitigates these limitations by using readability formulas most suited for medical literature and appropriately preparing the text from websites. It is important to note that readability scores are not measures of overall comprehension. Rather, readability scores reflect one of the many characteristics of reading skill and reading ease of materials [35,36]. Some suggestions for improving the readability of PEM include minimizing the use of complex words and decreasing the length of sentences or syllables per word. Readability scores should be considered with other indicators in assessing the overall comprehension of written PEM. Our study attempts to address this by using readability scores along with the DISCERN tool. Lastly, although the DISCERN tool has been validated and widely applied to patient information on treatment options, it does not directly evaluate the accuracy of the information contained within these PEM. Rather, DISCERN determines the readability and quality of public materials.

Conclusion

As the COVID-19 pandemic has placed a greater emphasis on digital health, it is important to assess the readability and quality of online information of DFU to ensure adequate and appropriate patient education. While the internet has allowed for ease of access to information for a breadth of patients, our study showed that online PEM on DFU care were far above the recommended reading level for patients. Physicians and other allied health professionals should be aware of the deficiencies in the quality and reliability of internet-based PEM that patients use to inform their care. In the future, PEM authors should consider using these tools to evaluate the readability and quality of their website.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Instruments and calculations used to assess readability.
[DOCX File , 13 KB - diabetes_v7i1e27221_app1.docx]

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Abbreviations

DFU: diabetic foot ulcers
FKG: Flesch-Kincaid grade level
FRE: Flesch-Kincaid reading ease
PEM: patient education materials

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Original Paper

Use of Health Information Technology by Adults With Diabetes in the United States: Cross-sectional Analysis of National Health Interview Survey Data (2016-2018)

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Abstract

Background: The use of health information technology (HIT) has been proposed to improve disease management in patients with type 2 diabetes mellitus.

Objective: This study aims to report the prevalence of HIT use in adults with diabetes in the United States and examine the factors associated with HIT use.

Methods: We analyzed data from 7999 adults who self-reported a diabetes diagnosis as collected by the National Health Interview Survey (2016-2018). All analyses were weighted to account for the complex survey design.

Results: Overall, 41.2% of adults with diabetes reported looking up health information on the web, and 22.8% used eHealth services (defined as filled a prescription on the web, scheduled an appointment with a health care provider on the web, or communicated with a health care provider via email). In multivariable models, patients who were female (vs male: prevalence ratio [PR] 1.16, 95% CI 1.10-1.24), had higher education (above college vs less than high school: PR 3.61, 95% CI 3.01-4.33), had higher income (high income vs poor: PR 1.40, 95% CI 1.23-1.59), or had obesity (vs normal weight: PR 1.11, 95% CI 1.01-1.22) were more likely to search for health information on the web. Similar associations were observed among age, race and ethnicity, education, income, and the use of eHealth services. Patients on insulin were more likely to use eHealth services (on insulin vs no medication: PR 1.21, 95% CI 1.04-1.41).

Conclusions: Among adults with diabetes, HIT use was lower in those who were older, were members of racial minority groups, had less formal education, or had lower household income. Health education interventions promoted through HIT should account for sociodemographic factors.

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KEYWORDS

health information technology; National Health Interview Survey; diabetes; Healthy People 2020; Healthy People 2030; mobile phone

Introduction

Background

Advances in technologies have introduced mechanisms that support effective and affordable health care delivery and education. In recent years, industries and health care systems have made significant efforts to expand health technology for people with diabetes. Mobile apps and web-based platforms provide many options for managing diabetes, including blood glucose tracking, insulin dosing, and diabetes education [1]. Web-based patient portals improve access to health information

and personal health records. Although these tools have shown promise, particularly by improving glycemic control and reducing hemoglobin A_{1c} levels, the effectiveness of these interventions at the population level is reliant on actual use by people with diabetes [2,3].

The Department of Health and Human Services has established the Healthy People initiatives to promote public health and well-being priorities across the United States by providing measurable, decade-long public health objectives [4]. Healthy People 2020 specified the objectives of using health information technology (HIT) to improve population health outcomes and health care quality and to achieve health equity [1]. These specific objectives included increasing the use of electronic personal health management tools (HIT Objective 5.1), increasing the use of the internet to communicate with their health providers (HIT Objective 5.2), and increasing web-based health information seeking (HIT Objective 9). In addition, the published Healthy People 2030 goals have since been built upon the established 2020 HIT goals. The new 2030 goals underscore a desire to increase the use of patient portals, particularly the proportion of adults who use information technology to track health care data or communicate with health care providers [5].

A study using data from the Health Information National Trends Survey (HINTS; 2014-2017) reported that 80% of survey participants went on the web to access the internet or to send and receive email, more than 70% had broadband access, and more than 65% had access via cellular network [6]. However, these statistics were not specific to health-related information seeking or communication. Little is known about the proportion of people with diabetes who use the internet to search for health information on the web and communicate with health care providers. In addition, less attention has been paid to how HIT use in people with type 2 diabetes compares to US National Public Health objectives. There is a need for this information, as people with diabetes often have complex management needs and potentially face barriers to HIT but may benefit greatly from eHealth services.

In addition, reporting the association between sociodemographic factors and HIT use by people with diabetes may provide new insight to better promote this technological approach to care. It is well-known that patients of older age, lower socioeconomic status, lower level of education, and racial or ethnic minorities are less likely to engage in eHealth activities, such as looking up health information on the web [1,7,8]. Patients with type 2 diabetes tend to be even more disadvantaged than those in the general population [9,10]. It is therefore important to understand the sociodemographic factors that influence HIT use in patients with diabetes to assist vulnerable populations and advance the progress of health equity.

Objective

The aim of this study is to examine the prevalence of HIT use in adults with diabetes in the United States, compare it with the goals set in Healthy People 2020, and identify factors associated with HIT use by analyzing data from the National Health Interview Survey (NHIS; 2016-2018), which provides a large, nationally representative sample.

Methods

Study Design and Setting

The NHIS provides data on the health status, health care access, and health behavior of the noninstitutionalized civilian population in the United States using a multistage probability sampling design. The data were collected by trained interviewers using a computer-assisted personal interviewing program and were based on self-reports from the respondents. Details regarding the study design, questionnaires, and procedures are available elsewhere [11].

We used data collected between 2016 and 2018 from a sample of NHIS adult participants who self-reported diabetes diagnosed after an age of 25 years and had a BMI ≥18.5 kg/m^2. As types of diabetes were not asked consistently in all survey years during 2016-2018, we were unable to completely distinguish between responders with type 1 and type 2 diabetes. However, because 90%-95% of all adults with diabetes are type 2, and type 1 is more commonly diagnosed at earlier ages, we are confident that the study participants in our sample most likely had type 2 diabetes [10,12].

Survey participants were asked whether they had ever used a computer in the last 12 months for any of the following tasks: (1) to look up health information on the internet, (2) to fill a prescription, (3) to schedule an appointment with a health care provider on the web, or (4) to communicate with a health care provider via email. We studied 2 primary outcomes: prevalence of participants who ever looked up health information on the web and prevalence of participants who ever used eHealth services. We categorized a patient as ever using eHealth services if the individual reported ever scheduling appointments, communicating with health care providers, or refilling prescription medications on the web [13]. The prevalence of using each of the 3 components of eHealth services was also examined.

In a separate question, survey participants were asked, “Do you use the Internet?” We conducted a subgroup analysis on HIT use only by adults with diabetes who indicated that they were internet users.

Sociodemographic variables of interest were age, sex, race and ethnicity, educational attainment, health insurance coverage status, and income to poverty ratio. Individuals were classified into 3 categories according to calculated BMI: normal weight (18.5 kg/m^2≥ BMI <25 kg/m^2), overweight (25 kg/m^2 BMI <30 kg/m^2), or obese (BMI 30 kg/m^2). BMI was calculated based on self-reported height and weight. The use of antidiabetic medications was assessed based on self-reports and was classified as no medication use, oral medication only, or any insulin use. Other self-report variables included history of chronic disease and having at least one visit to a doctor or health care professional in the past year.

Statistical Analysis

We pooled 3 years of data from 2016 to 2018 and created new design variables incorporating stratum, primary sampling unit, and sampling weight. This approach accounted for complex

sampling designs and weights and was limited to eligible adults with diabetes using the STATA (StataCorp LP) *subpop* command for correct SE estimation. Baseline characteristics according to HIT use were compared using chi-square tests for categorical variables (eg, age group, sex, race and ethnicity, educational attainment, and income). Multiple Poisson regression models were constructed to estimate prevalence ratios (PRs) and their 95% CIs and examine the association between BMI category, sociodemographic characteristics, and HIT use in adults with diabetes, adjusting for covariates.

All analyses were weighted to account for the complex survey design. All tests of significance were 2-tailed with an α level of .05. Analyses were performed using Stata 14 (StataCorp LLC).

Results

Overview

We identified 7999 individuals who reported diabetes diagnosed after the age of 25 years with BMI ≥18.5 kg/m^2. Overall, 41.2% of adults with diabetes looked up health information on the web, and 22.8% used eHealth services (14.7% filling a prescription on the web, 12.2% scheduling an appointment on the web, and 15% communicating with a health care provider via email). Non-Hispanic White and female adults with diabetes were more likely to search for health information on the web. Graded relationships were used to search for health information on the web across categories of age, education level, and income. Adults with obesity and those not on any medications were more likely to look up health information on the web.

For eHealth services use, higher proportions of non-Hispanic White and Asian populations used eHealth services than other racial and ethnic groups. Graded relationships also existed for using eHealth services across age groups, education levels, and income levels. There were no differences by sex, BMI, or antidiabetic medication status.

Compared with individuals who did not look up health information on the web, adults with diabetes who looked up health information on the web were more likely to be <65 years of age, female, and non-Hispanic White. They were more likely to be of higher education and higher income, more likely to have obesity and see or talk to health care providers in the past 12 months, and less likely to be on antidiabetic medications. They were also less likely to have cardiovascular disease and cancer (Table 1). The 2 groups did not differ by insurance status or arthritis status.

Table 1. Participant characteristics by health information technology use (National Health Interview Survey, 2016-2018; N=7999).

Characteristics	Look up web-based health information, % (SE)		*P* value	Use eHealth services, % (SE)		*P* value
	No (n=4706)	Yes (n=3293)		No (n=6174)	Yes (n=1825)	
Age group (years)			<.001			<.001
25-44	8.22 (0.6)	13.45 (0.8)		9.61 (0.56)	13.11 (1.03)	
45-64	42.13 (0.95)	53.67 (1.05)		45.2 (0.82)	52.86 (1.4)	
≥65	49.65 (0.92)	32.88 (0.94)		45.2 (0.79)	34.03 (1.31)	
Sex			<.001			.12
Male	54.71 (0.94)	49.61 (1.09)		51.87 (0.82)	54.56 (1.42)	
Female	45.29 (0.94)	50.39 (1.09)		48.13 (0.82)	45.44 (1.42)	
Race and ethnicity			<.001			<.001
Non-Hispanic White	52.53 (1.43)	69.52 (1.14)		55.21 (1.33)	74.01 (1.47)	
Non-Hispanic Black	16.55 (0.94)	12.17 (0.78)		16.48 (0.86)	9.08 (0.92)	
Non-Hispanic Asian	5.47 (0.54)	4.88 (0.55)		4.77 (0.45)	6.59 (0.9)	
Non-Hispanic others	3.54 (0.68)	2.87 (0.35)		3.68 (0.61)	1.93 (0.35)	
Hispanic	21.92 (1.33)	10.57 (0.87)		19.87 (1.17)	8.4 (0.96)	
Education level			<.001			<.001
Less than high school	27.85 (0.94)	6.9 (0.66)		23.56 (0.81)	4.38 (0.59)	
High school	33.13 (0.95)	21.49 (0.93)		31.18 (0.78)	18.74 (1.21)	
Some college	25.43 (0.83)	37.22 (1.11)		28.64 (0.8)	36.18 (1.45)	
College	8.53 (0.54)	19.77 (0.91)		10.1 (0.49)	23.34 (1.23)	
Above college	4.18 (0.34)	14.29 (0.76)		5.78 (0.36)	16.97 (1.09)	
Do not know	0.89 (0.21)	0.34 (0.17)		0.74 (0.17)	0.39 (0.23)	
Income to poverty ratio			<.001			<.001
Poor (<100% FPL[a])	17.17 (0.80)	8.64 (0.62)		15.95 (0.67)	5.99 (0.71)	
Near poor (100%-199% FPL)	25.25 (0.84)	14.59 (0.76)		24.04 (0.75)	10.31 (0.85)	
Middle income (200%-399% FPL)	26.94 (0.84)	27.92 (1.01)		27.54 (0.75)	26.81 (1.28)	
High income (≥400% FPL)	23.2 (0.89)	42.5 (1.22)		24.99 (0.79)	51.5 (1.51)	
Do not know	7.45 (0.55)	6.34 (0.57)		7.49 (0.48)	5.39 (0.74)	
BMI category			<.001			.005
Normal	12.81 (0.62)	10.46 (0.67)		12.03 (0.53)	11.1 (0.95)	
Overweight	31.93 (0.93)	26.77 (0.96)		30.8 (0.81)	26.37 (1.3)	
Obese	55.26 (0.98)	62.77 (1.04)		57.17 (0.84)	62.53 (1.37)	
Insurance			.48			.002
Insured	93.42 (0.57)	93.97 (0.61)		92.88 (0.51)	96.04 (0.73)	
Uninsured	6.58 (0.57)	6.03 (0.61)		7.12 (0.51)	3.96 (0.73)	
Hypertension			<.001			.02
No	24.81 (0.82)	29.65 (1.08)		26 (0.69)	29.62 (1.43)	
Yes	75.19 (0.82)	70.35 (1.08)		74 (0.69)	70.38 (1.43)	
CHD[b]			<.001			<.001
No	78.52 (0.72)	83.89 (0.77)		79.59 (0.63)	84.62 (1.05)	
Yes	21.48 (0.72)	16.11 (0.77)		20.41 (0.63)	15.38 (1.05)	

Characteristics	Look up web-based health information, % (SE)		*P* value	Use eHealth services, % (SE)		*P* value
	No (n=4706)	Yes (n=3293)		No (n=6174)	Yes (n=1825)	
Stroke			<.001			<.001
No	89.04 (0.61)	93.03 (0.51)		89.74 (0.52)	93.89 (0.62)	
Yes	10.96 (0.61)	6.97 (0.51)		10.26 (0.52)	6.11 (0.62)	
Arthritis			.13			.72
No	52.75 (0.96)	50.68 (1.01)		52.01 (0.84)	51.4 (1.45)	
Yes	47.25 (0.96)	49.32 (1.01)		47.99 (0.84)	48.6 (1.45)	
Cancer			.045			.02
No	84.48 (0.63)	82.54 (0.77)		84.28 (0.54)	81.7 (1.05)	
Yes	15.52 (0.63)	17.46 (0.77)		15.72 (0.54)	18.3 (1.05)	
Seen or talked to a general physician or specialist in the past 12 months			<.001			<.001
No	13.54 (0.67)	9.76 (0.63)		13.28 (0.59)	7.7 (0.74)	
Yes	86.46 (0.67)	90.25 (0.63)		87.72 (0.59)	92.3 (0.74)	
Antidiabetic medication status			.002			.62
No medication	13.37 (0.67)	16.92 (0.89)		15.17 (0.66)	14.02 (1.03)	
Oral medication only	57.35 (0.97)	55.88 (1.08)		56.48 (0.84)	57.45 (1.4)	
Insulin treatment	29.29 (0.88)	27.2 (0.94)		28.35 (0.73)	28.53 (1.26)	

[a]FPL: federal poverty level.

[b]CHD: coronary heart disease (includes coronary heart disease, angina, or heart attack).

Similar associations were seen when comparing adults with diabetes who used eHealth services to those who did not use eHealth services. However, those who used eHealth services were more likely to have insurance than those who did not use eHealth services. There were no significant differences between the users and nonusers of eHealth services by sex or antidiabetic medication use.

In the multivariable model that included age group, sex, race and ethnicity, education level, income to poverty ratio category, BMI category, prevalent chronic conditions, provider visit, insurance, and antidiabetic medication use, patients who were female (vs male: PR 1.16, 95% CI 1.10-1.24), had higher education (above college vs less than high school: PR 3.61, 95% CI 3.01-4.33), had higher income (high income vs poor: PR 1.40, 95% CI 1.23-1.59), or were obese (vs normal weight: PR 1.11, 95% CI 1.01-1.22), were more likely to search for health information on the web. Adults with diabetes who were >45 years or racial minorities were less likely to search for health information on the web (Table 2). Similar associations were observed between sociodemographic characteristics and the use of eHealth services. In contrast to the univariate analysis, in the multivariable model, patients on insulin were more likely to use eHealth services (on insulin vs no medication: PR 1.21, 95% CI 1.04-1.41) after considering other covariates. There were no significant differences between men and women and across BMI categories regarding the use of eHealth services (Table 2).

Table 2. Proportions and adjusted prevalence ratios (PRs; 95% CI) of health information technology use by sociodemographic characteristics, BMI category, and medication status (National Health Interview Survey, 2016-2018).

Characteristics	Look up web-based health information[a]		Use eHealth services[a]	
	Unadjusted % (SE)	Adjusted PR (95% CI)	Unadjusted % (SE)	Adjusted PR (95% CI)
Age group (years)				
25-44	55.06 (2.37)	1.00 (reference)	30.62 (2.16)	1.00 (reference)
45-64	48.83 (1.06)	0.82 (0.75-0.90)[b]	27.44 (1.02)	0.76 (0.66-0.88)[b]
≥65	33.16 (0.98)	0.55 (0.50-0.61)[b]	19.58 (0.83)	0.52 (0.44-0.61)[b]
Sex				
Male	40.45 (1.02)	1.00 (reference)	25.38 (1)	1.00 (reference)
Female	45.46 (1.08)	1.16 (1.10-1.24)[b]	23.39 (0.88)	1.01 (0.92-1.11)
Race and ethnicity				
Non-Hispanic White	49.79 (0.9)	1.00 (reference)	30.24 (0.94)	1.00 (reference)
Non-Hispanic Black	35.52 (1.79)	0.79 (0.72-0.87)[b]	15.12 (1.43)	0.61 (0.50-0.73)[b]
Non-Hispanic Asian	40.07 (3.28)	0.80 (0.68-0.94)[b]	30.9 (3.57)	0.99 (0.80-1.22)
Non-Hispanic others	37.79 (4.38)	0.83 (0.70-0.98)[b]	14.47 (3.1)	0.61 (0.43-0.86)[b]
Hispanic	26.54 (1.88)	0.71 (0.62-0.81)[b]	12.02 (1.4)	0.61 (0.49-0.77)[b]
Education level				
Less than high school	15.65 (1.41)	1.00 (reference)	5.67 (0.76)	1.00 (reference)
High school	32.7 (1.31)	1.79 (1.48-2.17)[b]	16.27 (1.04)	2.16 (1.61-2.88)[b]
Some college	52.29 (1.31)	2.64 (2.21-3.16)[b]	29.01 (1.27)	3.37 (2.57-4.41)[b]
College	63.5 (1.93)	3.20 (2.65-3.85)[b]	42.78 (1.97)	4.55 (3.43-6.03)[b]
Above college	71.9 (1.97)	3.61 (3.01-4.33)[b]	48.72 (2.34)	4.95 (3.74-6.54)[b]
Income to poverty ratio				
Poor (<100% FPL[c])	27.39 (1.83)	1.00 (reference)	10.84 (1.29)	1.00 (reference)
Near poor (100%-199% FPL)	30.21 (1.43)	1.06 (0.92-1.22)	12.18 (1.05)	1.03 (0.79-1.36)
Middle income (200%-399% FPL)	43.7 (1.38)	1.31 (1.15-1.50)[b]	23.94 (1.18)	1.62 (1.28-2.03)[b]
High income (≥400% FPL)	57.85 (1.34)	1.40 (1.23-1.59)[b]	40 (1.32)	2.02 (1.60-2.54)[b]
BMI category				
Normal	37.95 (1.9)	1.00 (reference)	22.99 (1.8)	1.00 (reference)
Overweight	38.58 (1.27)	1.03 (0.93-1.14)	21.69 (1.17)	0.97 (0.82-1.14)
Obese	45.97 (1)	1.11 (1.01-1.22)[b]	26.13 (0.87)	1.10 (0.95-1.26)
Antidiabetic medication status				
No medication	48.67 (1.92)	1.00 (reference)	23.02 (1.67)	1.00 (reference)
Oral medication	42.2 (0.97)	0.95 (0.88-1.03)	24.75 (0.88)	1.14 (0.98-1.31)
Insulin treatment	41.03 (1.32)	0.97 (0.89-1.06)	24.55 (1.13)	1.21 (1.04-1.41)[b]

[a]Models include BMI category, age group, sex, race and ethnicity, education level, income to poverty ratio category, prevalent chronic conditions, health care provider visit, and insurance.

[b]Statistically significant based on a 95% CI.

[c]FPL: federal poverty level.

Subgroup Analysis of Internet Users Only

We conducted a subgroup analysis of the 4805 adults (weighted percentage 62.3%, SE 0.83%, of all adults with diabetes) who reported using the internet.

Among internet users, 64.6% (SE 0.87%) reported looking up health information and 37.3% (SE 0.95%) reported using eHealth services, including 22.4% (SE 0.76%) who filled a prescription on the web, 18.5% (SE 0.75%) who scheduled a medical appointment on the web, and 23.2% (SE 0.85%) who communicated with a health care provider via email.

Table 3 shows associations between HIT use and individual characteristics among internet users with diabetes. Compared with internet users who did not search for health information on the web, users who searched for health information on the web were more likely to be <65 years old, female, non-Hispanic White, of higher education level and higher income, have obesity, and more likely to see or talk to providers. There were no associations with chronic conditions other than arthritis and antidiabetic medication use.

Table 3. Participant characteristics by health information technology use among internet users (National Health Interview Survey, 2016-2018; N=7999).

Characteristics	Look up web-based health information, % (SE)		*P* value	Use eHealth services, % (SE)		*P* value
	No (n=1720)	Yes (n=3085)		No (n=3071)	Yes (n=1734)	
Age group (years)			.004			.55
25-44	13.94 (1.17)	13.14 (0.8)		13.75 (0.91)	12.86 (1.03)	
45-64	48.08 (1.59)	54.21 (1.09)		51.31 (1.17)	53.28 (1.44)	
≥65	37.98 (1.44)	32.65 (0.96)		34.93 (1.01)	33.86 (1.35)	
Sex			<.001			.13
Male	58.63 (1.39)	49.76 (1.1)		51.82 (1.11)	54.71 (1.44)	
Female	41.37 (1.39)	50.24 (1.1)		48.18 (1.11)	45.29 (1.44)	
Race and ethnicity			<.001			<.001
Non-Hispanic White	62.22 (1.72)	70.05 (1.18)		63.2 (1.39)	74.15 (1.5)	
Non-Hispanic Black	12 (1.05)	11.66 (0.8)		13.36 (0.89)	9.12 (0.96)	
Non-Hispanic Asian	6.43 (0.92)	5.12 (0.58)		4.92 (0.6)	6.69 (0.92)	
Non-Hispanic others	2.96 (0.56)	2.92 (0.37)		3.5 (0.5)	1.99 (0.37)	
Hispanic	16.39 (1.34)	10.25 (0.88)		15.02 (1.09)	8.06 (0.95)	
Education level			<.001			<.001
Less than high school	11.55 (0.99)	6.32 (0.63)		10.81 (0.79)	3.73 (0.56)	
High school	29.25 (1.35)	21.01 (0.97)		27.13 (0.97)	18.53 (1.25)	
Some college	36.14 (1.4)	37.5 (1.15)		37.58 (1.15)	36.06 (1.51)	
College	14.92 (1.09)	20.14 (0.94)		14.98 (0.82)	23.87 (1.26)	
Above college	7.8 (0.76)	14.68 (0.78)		9.18 (0.62)	17.41 (1.12)	
Do not know	0.32 (0.14)	0.36 (0.18)		0.31 (0.15)	0.41 (0.24)	
Income to poverty ratio			.002			<.001
Poor (<100% FPL[a])	8.11 (0.78)	8.66 (0.65)		10.05 (0.7)	5.79 (0.73)	
Near poor (100%-199% FPL)	18.65 (1.12)	13.7 (0.76)		18.8 (0.9)	9.83 (0.83)	
Middle income (200%-399% FPL)	28.2 (1.3)	27.96 (1.04)		28.95 (1.04)	26.52 (1.32)	
High income (≥400% FPL)	38.09 (1.55)	43.39 (1.24)		35.05 (1.18)	52.38 (1.55)	
Do not know	6.95 (0.79)	6.29 (0.59)		7.14 (0.61)	5.48 (0.77)	
BMI category			.006			.16
Normal	10.6 (0.92)	10.41 (0.68)		10.21 (0.7)	10.93 (0.97)	
Overweight	31.75 (1.54)	26.67 (1)		29.7 (1.16)	26.39 (1.35)	
Obese	57.65 (1.63)	62.92 (1.07)		60.09 (1.2)	62.68 (1.43)	
Insurance			.66			.003
Insured	93.53 (0.92)	94 (0.63)		92.57 (0.7)	95.96 (0.77)	
Uninsured	6.47 (0.92)	6 (0.63)		7.43 (0.7)	4.04 (0.77)	
Hypertension			.33			.61
No	31.25 (1.39)	29.55 (1.14)		30.48 (1.07)	29.6 (1.46)	
Yes	68.75 (1.39)	70.45 (1.14)		69.52 (1.07)	70.4 (1.46)	
CHD[b]			.14			.17
No	82.43 (1.06)	84.33 (0.76)		82.93 (0.81)	84.88 (1.08)	
Yes	17.57 (1.06)	15.67 (0.76)		17.07 (0.81)	15.12 (1.08)	
Stroke			.86			.08

Characteristics	Look up web-based health information, % (SE)		*P* value	Use eHealth services, % (SE)		*P* value
	No (n=1720)	Yes (n=3085)		No (n=3071)	Yes (n=1734)	
No	93.08 (0.74)	93.24 (0.52)		92.59 (0.58)	94.17 (0.62)	
Yes	6.92 (0.74)	6.76 (0.52)		7.41 (0.58)	5.83 (0.62)	
Arthritis			<.001			.06
No	58.87 (1.42)	50.79 (1.04)		54.97 (1.09)	51.43 (1.49)	
Yes	41.13 (1.42)	49.21 (1.04)		45.03 (1.09)	48.57 (1.49)	
Cancer			.17			.06
No	84.42 (1.09)	82.56 (0.79)		84.13 (0.77)	81.69 (1.08)	
Yes	15.58 (1.09)	17.44 (0.79)		15.87 (0.77)	18.31 (1.08)	
Seen or talked to a general physician or specialist in the past 12 months			.004			<.001
No	13.01 (1.03)	9.73 (0.66)		12.82 (0.8)	7.64 (0.77)	
Yes	86.99 (1.03)	90.27 (0.66)		87.18 (0.8)	92.36 (0.77)	
Antidiabetic medication status			.17			.02
No medication	15.09 (1.13)	17.03 (0.93)		17.7 (1)	14.06 (1.07)	
Oral medication	59.57 (1.49)	56.24 (1.09)		57.25 (1.2)	57.69 (1.44)	
Insulin treatment	25.34 (1.33)	26.73 (0.95)		25.05 (0.99)	28.25 (1.29)	

[a]FPL: federal poverty level.

[b]CHD: coronary heart disease.

Compared with users who did not use eHealth services, users who used eHealth services were more likely to be non-Hispanic White, had higher education and higher income, were more likely to have insurance, were more likely to be taking antidiabetic medication, and were more likely to see a physician in the past 12 months. There were no associations between eHealth service use and age, sex, BMI category, or comorbidities.

In the multivariable model, being female or having higher education was associated with being more likely to search for health information on the web, whereas being ≥65 years, Hispanic, or near poor was associated with being less likely to search for health information on the web (Table 4).

Table 4. Proportions and prevalence ratios (PRs) of health information technology use by sociodemographic characteristics, obesity category, and antidiabetic medication status in internet users (National Health Interview Survey, 2016-2018).

Characteristics	Look up web-based health information[a]		Use eHealth services[a]	
	Unadjusted % (SE)	Adjusted PR (95% CI)	Unadjusted % (SE)	Adjusted PR (95% CI)
Age group (years)				
25-44	63.27 (2.49)	1.00 (reference)	35.74 (2.56)	1.00 (reference)
45-64	67.34 (1.21)	1.00 (0.92-1.09)	38.19 (1.34)	0.88 (0.76-1.02)
≥65	61.11 (1.38)	0.87 (0.79-0.95)[b]	36.58 (1.34)	0.75 (0.64-0.88)[b]
Sex				
Male	60.81 (1.21)	1.00 (reference)	38.58 (1.36)	1.00 (reference)
Female	68.94 (1.23)	1.14 (1.08-1.20)[b]	35.87 (1.25)	0.99 (0.90-1.08)
Race and ethnicity				
Non-Hispanic White	67.3 (0.96)	1.00 (reference)	41.11 (1.17)	1.00 (reference)
Non-Hispanic Black	63.97 (2.55)	0.93 (0.86-1.01)	28.87 (2.48)	0.73 (0.62-0.87)[b]
Non-Hispanic Asian	59.27 (4.3)	0.87 (0.75-1.01)	44.73 (4.67)	1.02 (0.83-1.25)
Non-Hispanic others	64.3 (4.8)	0.94 (0.82-1.07)	25.26 (4.45)	0.67 (0.49-0.93)[b]
Hispanic	53.35 (3.01)	0.85 (0.76-0.95)[b]	24.19 (2.67)	0.71 (0.57-0.88)[b]
Education level				
Less than high school	50 (3.39)	1.00 (reference)	17.02 (2.41)	1.00 (reference)
High school	56.76 (1.85)	1.13 (0.98-1.31)	28.9 (1.74)	1.49 (1.10-2.01)[b]
Some college	65.47 (1.4)	1.29 (1.12-1.47)[b]	36.34 (1.53)	1.78 (1.34-2.37)[b]
College	71.17 (1.97)	1.43 (1.25-1.65)[b]	48.66 (2.16)	2.26 (1.68-3.03)[b]
Above college	77.47 (1.98)	1.58 (1.37-1.83)[b]	53.02 (2.48)	2.41 (1.80-3.23)[b]
Income to poverty ratio				
Poor (<100% FPL[c])	66.12 (2.74)	1.00 (reference)	25.51 (2.83)	1.00 (reference)
Near poor (100%-199% FPL)	57.32 (2.18)	0.90 (0.81-0.99)[b]	23.73 (1.98)	0.92 (0.71-1.20)
Middle income (200%-399% FPL)	64.44 (1.58)	0.98 (0.89-1.08)	35.27 (1.62)	1.26 (1.01-1.57)[b]
High income (≥400% FPL)	67.56 (1.36)	0.97 (0.89-1.06)	47.06 (1.45)	1.47 (1.18-1.84)[b]
BMI category				
Normal	64.23 (2.45)	1.00 (reference)	38.9 (2.76)	1.00 (reference)
Overweight	60.57 (1.64)	0.96 (0.88-1.05)	34.59 (1.76)	0.92 (0.78-1.08)
Obese	66.61 (1.12)	1.01 (0.93-1.10)	38.29 (1.14)	1.01 (0.88-1.16)
Antidiabetic medication status				
No medication	67.35 (2.18)	1.00 (reference)	32.09 (2.31)	1.00 (reference)
Oral medication	63.32 (1.12)	0.96 (0.89-1.03)	37.49 (1.2)	1.14 (0.99-1.32)
Insulin treatment	65.64 (0.87)	1.00 (0.93-1.09)	40.15 (1.69)	1.26 (1.08-1.47)[b]

[a]Models include BMI category, age group, sex, race and ethnicity, education level, income to poverty ratio category, prevalent chronic conditions, health care provider visit, and insurance.

[b]Statistically significant based on a 95% CI.

[c]FPL: federal poverty level.

Similarly, having higher education or higher income was significantly associated with a higher likelihood of using eHealth services. Patients using insulin were more likely to use eHealth services. However, those who were ≥65 years, non-Hispanic Black, Hispanic, or other non-Hispanic races were less likely to use e-services. There were no associations between BMI category and searching for health information on the web or using eHealth services.

Discussion

Principal Findings

This study found that in adults with diabetes, those of younger age, higher income and education, and non-Hispanic White were more likely to search for information on the web and use eHealth services. Moreover, patients who had obesity were more likely to search for health information on the web and use eHealth services. Our study also found that patients on insulin were 21% more likely to use eHealth services compared with those not on medications.

Healthy People 2020 set a goal of 45% on the proportion of web-based health information seekers (HIT Objective 9) and a goal of 15% on the proportion of persons who use the internet to communicate with their health providers (HIT Objective 5.2) by the year 2020. Although Healthy People 2020 goals were set for the entire population and were not specific toward people with diabetes, our study indicated that adults with diabetes in the United States did not completely achieve these goals—41.2% of adults with diabetes were web-based health information seekers, and 15% of adults with diabetes used the internet to communicate with their health providers.

Comparisons With Prior Surveys

Chou et al [13], using the NHIS (2009-2013) data, reported that in adults with diabetes, the multivariate-adjusted prevalence of scheduling appointments, communicating with health care providers, refilling prescriptions on the web, and any eHealth service use were 3.9%, 5.8%, 9%, and 13.8%, respectively. Compared with earlier data, our report from the NHIS demonstrates an overall increase in HIT use in adults with diabetes.

Our study found that only 62.3% of adults with diabetes reported using the internet in 2016-2018 (based on subgroup analyses). The proportion of internet users with diabetes is lower than the statistics reported in the general adult population, which increased from 87% in 2016 to 89% in 2018 [14]. In addition, a study using HINTS (2003-2017) data reported an increase from 14.2% to 70.9% between 2008 and 2017 in adults who reported tracking of electronic personal health information [15]. Together, these data suggest that individuals with diabetes have lower HIT use. Similarly, adults with diabetes tend to be older, racial minorities, and have lower education or lower income; these factors contribute to the lower accessibility and adaptability of internet use. Nonetheless, it is important to note that the survey response rate in the HINTS study was approximately 30%; we cannot rule out the possible effects of response bias on study outcomes. Our study used a data set with a higher response rate of approximately 70%.

Graetz et al [16] showed that ethnic minorities living in lower socioeconomic status neighborhoods were significantly more likely to access web-based personal health records through a mobile device, and as high as 19% relied exclusively on smartphones for internet access. Electronic health records (EHRs) and web-based interventions that are only available via a computer would not be available in mobile-exclusive populations, which may be more likely to include people with diabetes. This is another possible explanation for the lower use observed in people with diabetes.

Closing the Digital Divide

Initiatives to assist internet access and awareness in older and underserved populations are needed to close the digital divide. Mobile access to web-based health services is increasingly being used by hospital systems and providers. SMS text messaging, a popular mobile media platform, is a possible candidate for health interventions. Mayberry et al [17] reported that interventions that use SMS text messaging services may be more accessible to people with diabetes when compared with internet-based platforms, as people with diabetes were found to use internet-dependent interventions less than those conducted through SMS text messages.

Consistent with earlier studies in adults with and without diabetes, lower HIT use was observed among adults who are older, racial minorities, less educated, and with lower income. A study in Norway analyzed eHealth use by patients with type 1 and type 2 diabetes mellitus and found a positive correlation between education level and search engine use [8]. These findings underscore that health education and interventions to promote HIT use in adults with diabetes must account for sociodemographic factors. Older adults with diabetes are more often unfamiliar with health technology and potentially adverse to HIT used in telemedicine and eHealth services [18]. Efforts to help older adults and ethnic or racial minorities improve their abilities to navigate and use the internet, and eHealth services may increase HIT use.

Using culturally tailored interventions to better prevent and manage diabetes among minority and underserved populations should be encouraged [1]. In addition, providing guidance on recognizing reliable web-based sources will likely increase their confidence in HIT use.

Moreover, peer-to-peer interactions and increased social media use are growing parts of daily life. Some evidence suggests that implementing social media and increasing the formation of web-based health communities that focus on healthy lifestyle practices may be effective methods to increase confidence in HIT and its use in people with diabetes [19]. Social media interventions have also been associated with hemoglobin A_{1c} reduction and an improved sense of diabetes awareness and empowerment [20]. However, although many patients may have access to the internet, they may not choose to use HIT resources. Positive patient engagement through a networking forum that disseminates reliable health information may help improve patient satisfaction with HIT and increase overall use.

Associations With Insulin Use and Obesity Status

A higher proportion of eHealth service use was found in patients receiving insulin treatment. Patients with diabetes receiving insulin treatment are likely to require more frequent clinical visits with endocrinologists in addition to primary care physicians and are likely to require more prescription refills for diabetes management. As such, the use of eHealth services may be higher in this subgroup because eHealth services facilitate patient accessibility and convenience of treatment.

Our study found slightly higher HIT use in adults with diabetes and obesity. These findings are in accordance with an earlier survey conducted in Chicago Southside 2012-2013, where Gopalan et al [21] reported that people with measured obesity were more likely to report both general and health-specific HIT use compared with adults with normal weight. Obesity has been associated with difficulties in mobility and other physical activities that may lead to a greater use of HIT. However, the cross-sectional design cannot elucidate the temporal relationship, so we cannot rule out that a greater use of HIT results in a further increase in BMI.

Limitations

Our study had some limitations. First, the NHIS data were self-reported. Nondifferential misclassifications of BMI categories and HIT use may underestimate the true associations. Second, the NHIS is a cross-sectional survey. It is not possible to draw conclusions about probable causal pathways between sociodemographic factors and HIT use with this study design. Third, as there are other behavior factors associated with HIT use that were not accounted for, it is possible that the significant associations observed in the study were due to unadjusted residual confounders. Fourth, the types of diabetes were not assessed consistently across all survey years; we were not able to fully distinguish patients with type 1 diabetes from those with type 2 diabetes. However, as 90%-95% of adults with diabetes are type 2, we are confident that our results most likely reflect the characteristics of patients with type 2 diabetes [10]. Nonetheless, our study used a large sample size and a national representative sample of the US population with an annual response rate of approximately 70%.

Finally, the Centers for Medicare and Medicaid Services EHR Incentive Program, also known as Meaningful Use, provided incentives to eligible physicians to accelerate the adoption of EHRs [22]. The program began in 2011 and evolved over 3 stages. Although our data overlapped with the Meaningful Use timeline, the NHIS survey questions reflected general adult patients' behaviors toward the use of eHealth services, not physicians' responsiveness. Our study was not able to infer the impact of Meaningful Use on HIT in the general population.

Goals for Healthy People 2030

Newly published goals for Healthy People 2030 have since modified the critical objectives of HIT use, the most relevant of which is to "increase proportion of adults who use information technology to track health care data or communicate with providers" (Health Communication and HIT Objective-7) to a target goal of 87.3% [5]. These goals demonstrate significant increases from the previous 2020 goals. Although these goals reflect the overall desire to increase technology use by the general population, it remains to be seen if individuals with diabetes will meet these standards. In the meantime, more research must be conducted on HIT use and access in people with diabetes to assist this population in achieving these national goals.

Conclusions

In conclusion, our study found that HIT use in adults with diabetes was slightly lower than the target goals of Healthy People 2020. HIT use differed by several sociodemographic factors. Implementing educational strategies and improving widespread technological accessibility can help ease the transition to HIT and reduce disparities among people with diabetes. It is anticipated that using HIT tools will effectively improve health care quality and increase health delivery efficiency, but further research is needed to delineate the degree of these health benefits translated from the trend of increasing HIT use and the time frame needed for this translation to happen.

Authors' Contributions

SYW formulated the research question, wrote and edited the manuscript, and contributed to the discussion. HCY evaluated the data, reviewed and edited the manuscript, and contributed to the discussion. AAS conducted the data analyses and contributed to the discussion. ERM formulated the research question, reviewed and edited the manuscript, and contributed to the discussion.

Conflicts of Interest

None declared.

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Abbreviations

EHR: electronic health record
HINTS: Health Information National Trends Survey
HIT: health information technology
NHIS: National Health Interview Survey
PR: prevalence ratio

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Original Paper

Mobile Virtual Reality Versus Mobile 360° Video to Promote Enrollment in the Diabetes Prevention Program Among Hispanic Adults: Pilot Study

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Abstract

Background: Hispanic adults are at increased risk of developing type 2 diabetes. The Diabetes Prevention Program (DPP) reduces the risk of developing type 2 diabetes; however, the rate of enrollment is very low.

Objective: The goal of this pilot project was to determine whether presenting brief motivational mobile videos in virtual reality vs 360° video has differential effects on risk perceptions and enrollment in the DPP.

Methods: Adults with prediabetes were recruited at a clinic serving a low-income Hispanic community. After consenting, the participants completed a baseline survey that collected information about demographics and risk perceptions. All participants then viewed 2 videos. Per random assignment, the videos were presented either using the participant's smartphone alone (360° video) or were viewed with their smartphone in a virtual reality (VR) cardboard headset. Two weeks later, a follow-up survey collected measures of enrollment in the DPP, risk perceptions, health literacy, the importance of contextual factors related to the decision of whether to enroll in the DPP (eg, distance to the class), and qualitative feedback on the interventions. We used logistic regression to determine whether enrollment in the DPP differed by intervention mode, while accounting for health literacy and contextual factors related to the DPP. We used unpaired *t* tests to examine differences in change in risk perceptions between groups. Paired *t* tests were used to examine within-subject changes in risk perceptions.

Results: A total of 116 participants provided complete data. Most participants were middle-aged (mean age 44.6 years; SD 11.9) Hispanic (114/116), female (79/116), with low health literacy (mean score 12.3/20; SD 3.4). Enrollment in the DPP was 44/116 (37.9%) overall but did not differ by group (odds ratio for enrolling in VR group 1.78, 95% CI 0.75-4.3; *P*=.19). Individuals who rated the distance needed to travel to attend the DPP as more important were less likely to enroll in the DPP (odds ratio 0.56, 95% CI 0.33-0.92; *P*=.03). Risk perceptions did not differ by group (mean change in 360° video group -0.07, mean change in VR group 0.03, *t*=0.6, *P*=.54) and did not change within subjects (mean 0.02, *t*=0.21, *P*=.83). Participant feedback suggested that the videos are emotionally engaging and educational.

Conclusions: The videos presented in 360° video and mobile VR had equal efficacy in promoting enrollment in the DPP. Future work to rigorously evaluate this intervention, its mechanism of action, and potential moderators of the efficacy are discussed.

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KEYWORDS

diabetes prevention; virtual reality; risk; perception; diabetes; type 2 diabetes; mobile phone; prediabetes; prevention; VR; enrollment; pilot study; video

Introduction

More than 42% of Hispanic adults in the United States have prediabetes, placing them at increased risk of type 2 diabetes mellitus (T2DM) [1]. Extensive evidence has demonstrated that moderate lifestyle changes can reduce the progression from prediabetes to T2DM by 58% [2]. To address this epidemic, the Centers for Disease Control and Prevention have established the national Diabetes Prevention Program (DPP) [3]. The DPP is a yearlong lifestyle change program and has been shown to be effective in reducing the risk of developing T2DM [4]. However, through 2019, only 0.4% of the 88 million adults in the United States with prediabetes have enrolled in the DPP [4], and only 8.6% of these enrollees are Hispanic [5]. Clearly, there is need for scalable interventions that increase enrollment in the DPP among Hispanic adults.

Currently, most individuals with prediabetes who enroll in the DPP are identified by their primary care provider (PCP), counseled regarding the benefits of the program, and then referred. Studies of provider referrals to the DPP have reported variable DPP enrollment rates, ranging from 8% to 19% [6-8]. While provider counseling and referral is a useful means to promote DPP enrollment, there are 2 significant limitations to this approach. First, most providers do not currently counsel their patients about lifestyle changes and weight loss [9,10]. Adding diabetes prevention counseling to PCPs' already heavy workload may only exacerbate their perceptions of lack of time. Additionally, many PCPs lack training in counseling, leading to missed opportunities [11,12]. Second, DPP enrollment program that is based on a clinical encounter will necessarily miss the many individuals who do not seek primary care in a given year [13], a problem that may be more prevalent among Hispanic adults who access primary care less frequently than adults of other ethnicities [14]. Thus, we sought to compare 2 approaches to promoting DPP enrollment that do not require provider counseling or referral.

In this pilot project, we compared the effects of mobile 360° video vs mobile virtual reality (VR) on participants' risk perceptions and enrollment in the DPP. The participants were randomized to 1 of the 2 following study groups: mobile 360° video and mobile VR. The participants in both groups viewed 2 videos that contained the same content in different delivery modalities. The videos demonstrate the possible negative future complications of diabetes. Those assigned to mobile 360° video watched the videos on their smartphone (the viewer moved their phone to "look around" the world of the movie) while those assigned to mobile VR watched the videos using their smartphone inside a cardboard VR headset with headphones. The goal of this project was to determine if there was a difference in DPP enrollment rates between those who watched the videos using mobile 360° technology vs mobile VR. While we expected that VR would lead to greater changes in risk perceptions and higher enrollment in the DPP than the same videos viewed as 360° video, the study was not designed to measure the possible mediators of that effect. Future studies are planned to examine this question.

The rationale for comparing mobile 360° video vs mobile VR is twofold. First, the question is largely unaddressed; prior research comparing 360° video and immersive VR is very limited [15,16] and has not addressed health risk presentation or risk perceptions in individuals at risk of chronic disease. Second and more importantly, information on any differential effects of these 2 modes of intervention delivery would be valuable in the design of future interventions to promote health behaviors, particularly those that seek to target low-income, at-risk communities. Mobile 360° videos are highly scalable (ie, could be texted to anyone with a smartphone) while VR requires a headset and headphones that many low-income individuals may not have access to or may not be comfortable using without assistance.

Methods

Conceptual Framework

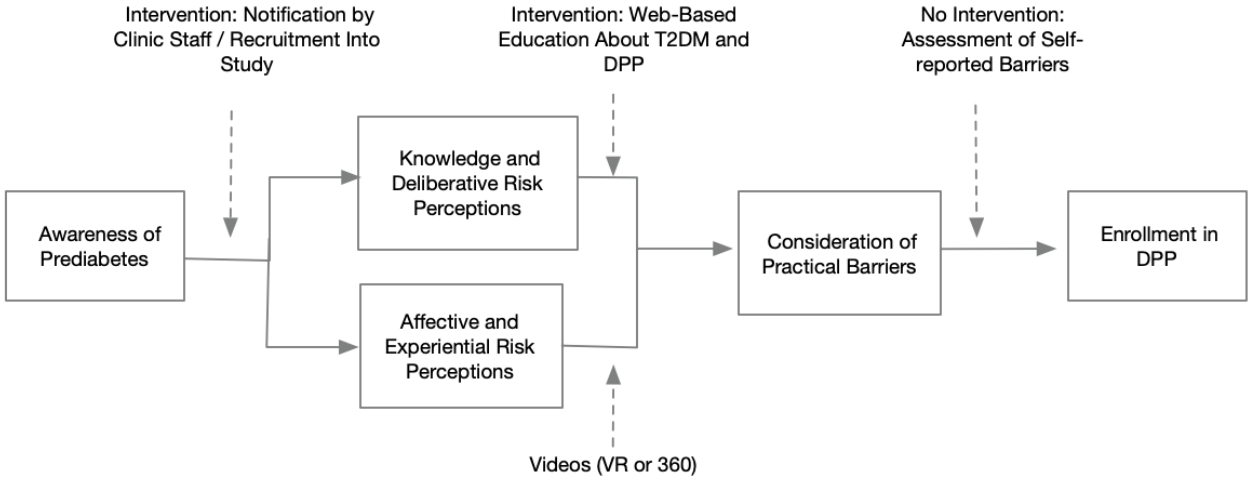
The reasons an individual may enroll (or not enroll) in the DPP are multifactorial. First, only 15% of Americans with prediabetes are aware they have this health condition [17]. Secondly, many individuals with prediabetes lack knowledge about appropriate health behavior changes (eg, increasing physical activity and weight loss) needed to prevent T2DM [17,18]. In addition, many individuals with prediabetes have an inaccurate understanding of the risks associated with developing T2DM and its complications [19]. Finally, even individuals who are aware that they have prediabetes and understand the risks may not enroll in the DPP because of practical barriers such as the cost of enrollment, limited time for participation (22 sessions over 12 months), and difficulty with travel to and from DPP sessions [20].

Our intervention addressed or measured (for use as a covariate) each of the factors shown in Figure 1. First, to address low awareness of prediabetes, all participants were called by the clinic's health coach, were informed that they have prediabetes, and were asked if they would like to participate in the study.

Second, to address low risk perceptions, individuals were randomized to either the VR or 360° version of our videos. The proposed mechanism of action for these videos was based on the tripartite model of risk perception [21], which divides risk perceptions into deliberative risk perceptions (ie, the individual's estimates of the likelihood of developing a condition), affective risk perceptions (ie, the individual's level of worry about a particular risk), and experiential risk perceptions (ie, how easy it is to imagine developing a condition). The videos were hypothesized to increase the participants' affective and experiential risk perceptions, and this would motivate them to

enroll in the DPP. Third, to address limited knowledge about prediabetes, T2DM, and the DPP, all participants were sent a link to a website [22], which includes the 3 following components: a self-assessment of risk (using the American Diabetes Association risk score, hypothesized to change deliberative risk perceptions), didactic pages about prediabetes and T2DM, and didactic pages about the DPP and its benefits. Finally, while this pilot study did not have the resources to intervene on the practical barriers to enrolling the DPP, we measured individuals' reports of these barriers (eg, cost and time for participation) for use as covariates when estimating the videos' efficacy.

Figure 1. Conceptual framework. DPP: Diabetes Prevention Program; T2DM: type 2 diabetes mellitus; VR: virtual reality.



Description of Videos

In this pilot project, all participants watched the same 2 immersive videos. These were developed by our research team after an extensive process of co-development with community members at risk of diabetes. The first video demonstrates how one's vision worsens over years with diabetic eye disease. The second video is a first-person narrative of an individual who progressively develops T2DM, oral health issues, and heart disease. Both videos conclude with a positive message that enrolling in the DPP may aid in preventing these potential negative outcomes. Both videos include a male or female voice-over in either Spanish or English (selected by the participant at the start of the video).

Ethical Considerations

The study protocol was approved by the University of Utah Institutional Review Board prior to study initiation (approval number: 00115941). Informed consent (in English or Spanish) was obtained from all participants, via consent cover letter, prior to data collection.

Recruitment and Settings

This project was conducted in partnership with the Midvale Community Building Community Clinic. This clinic serves a primarily low-income Hispanic population in Midvale, Utah. This clinic offers the DPP to its patients at no cost.

Procedures

Potential participants were identified in the clinic's electronic health record by the clinic's health coach (using hemoglobin A_{1c} values 5.7-6.4). They were then informed via telephone that they have prediabetes and asked if they were willing to participate in the study. During this call, individuals were screened to ensure they owned a smartphone, which was required for study participation.

Individuals who agreed to participate were contacted by the research assistant to meet in person at the clinic. During the in-person meeting, the study was explained, and the participant underwent informed consent. All study materials and the videos were provided in either English or Spanish according to the participant's preference.

The baseline questionnaire collected information on demographics and a yes or no question on whether the individual had prediabetes (a check on whether they understood the notification from the clinic's health coach); it also included an 18-item validated measure of risk perception [23]. After completion of the baseline questionnaire, the participants were randomized to receive either the mobile 360° video or the mobile VR experience. Individuals in the VR group were provided with a cardboard headset and headphones and watched the videos privately in the clinic conference room. Individuals in the mobile 360° video group watched the videos on their smartphone, privately in the clinic conference room. Technical issues that the participants experienced with either platform were noted for future refinement of the intervention. Prior to leaving the clinic, the participants were given a flier for the DPP offered by the clinic, which included enrollment instructions. Within 2 days of the baseline meeting, each participant was sent an SMS message with a link to the "doihaveprediabetes" website [22],

an educational website that provides information on prediabetes, T2DM, and the DPP.

Two weeks later, the participants were sent a follow-up survey to their mobile phone, which included questions about whether they enrolled in the DPP, a repeat assessment of their risk perceptions, qualitative feedback about the videos (VR or 360) and informational website, as well as a standardized measure of health literacy [24]. The questionnaire concluded with a set of 8 Likert-type questions about the importance of practical barriers or facilitators to enrollment in the DPP, including the following: language the DPP is offered in; availability of childcare at the DPP; accessibility of the DPP in terms of location; time requirements and scheduling [25]; and the desire to participate in the DPP if it were delivered by internet. To compensate for participation in this trial, the participants were emailed a US $75 electronic gift card.

Analysis

To test whether there were significant differences in the distributions of the participants' demographics for completers (participants who at least provided data on DPP enrollment in the follow-up survey) vs noncompleters (participants who did not start the follow-up survey) and between completers randomized to VR vs 360° video, we used chi-squared tests for categorical variables and *t* test for continuous variables.

The primary outcome of interest was self-reported enrollment in the DPP. We used logistic regression to compare the effects of the 2 modalities of video delivery on the likelihood of enrollment in the DPP. This model adjusted for any baseline difference in demographics between groups, a dichotomous variable that indicated whether the individual was aware that they had prediabetes, and the participants' rating of the importance of practical factors that affected their decision of whether to enroll as covariates.

To test whether the videos caused changes in risk perception, we first used paired *t* tests to determine whether there were significant within-subject changes in risk perceptions. We then used an unpaired *t* test to compare changes in risk perception by intervention modality. An exploratory mediation analysis was planned if there had been significant changes in risk perceptions. All analyses were conducted using statistical programming language R (R Foundation for Statistical Computing) [26].

Results

Participation

Approximately 240 patients were contacted by the clinic's health coach and notified that they had prediabetes. A total of 209 consented and participated in baseline assessments, and 116 participants provided complete follow-up data. The majority of the loss to follow-up occurred in the first few months of data collection because we originally compensated participants with a gift card at the end of the baseline assessment rather than after the follow-up assessment. Some data were also lost because some questions were not mandatory in the online follow-up questionnaire (both issues were addressed about half of the way through the pilot).

Table 1 provides the measured demographics of individuals who were randomized to VR vs 360° video; there were no significant differences in demographics between the groups.

Table 1. Demographics of participants by intervention group among those who completed baseline and follow-up interviews.

Characteristics	Values			
	VR[a] group	360° group	Statistic	*P* value
Sex (baseline survey), n (%)			1.9[b]	.38
Female	36 (64)	43 (72)		
Male	20 (36)	16 (27)		
Prefer not to answer	0 (0)	1 (1.7)		
Language (baseline survey), n (%)			0.8[b]	.36
English	12 (21.4)	8 (13.3)		
Spanish	44 (78.6)	52 (87.7)		
Race (baseline survey), n (%)			7.7[b]	.10
White	44 (78.6)	33 (55)		
African American	0 (0)	2 (3.3)		
Native American	0 (0)	0 (0)		
Asian	0 (0)	1 (1.7)		
Pacific Islander	0 (0)	1 (1.7)		
Other	12 (21.4)	24 (40)		
Ethnicity (baseline survey), n (%)			2.0[b]	.36
Hispanic/Latino	55 (98.2)	59 (98.3)		
Not Hispanic/Latino	1 (1.8)	1 (1.7)		
Aware of prediabetes (follow-up survey), n (%)			0.03[b]	.98
Yes	48 (85.7)	53 (88.3)		
No	6 (10.7)	6 (10)		
I don’t know	2 (3.6)	1 (1.7)		
Health literacy score (follow-up survey), mean (SD)	12.7/20 (3.4)	11.9/20 (3.4)	-1.2[c]	.22
Age (baseline survey) (years), mean (SD)	43.9 (13.6)	45.2 (10.3)	-0.57[c]	.56

[a]VR: virtual reality.

[b]Chi-square test.

[c]*t* test.

DPP Enrollment

A total of 116 participants provided data on DPP enrollment; overall enrollment in the DPP was 44/116 (37.9%). Enrollment among those randomized to VR was 25/56 (44.6%), while enrollment among those randomized to the 360° video was 19/60 (31.6%). To determine if the presentation modality was associated with differential enrollment rates after adjusting for relevant covariates, we created a logistic regression model with enrollment as the outcome and intervention modality, awareness of prediabetes (a check on whether they understood the notification from the clinics health coach), and participants’ ratings of the importance of factors that might affect their decision of whether or not to enroll (“which factors were important in your decision of whether or not to enroll in the DPP?” distance, time cost, etc) as covariates. Table 2 shows the results of that model.

Table 2. Model results from logistic regression predicting Diabetes Prevention Program enrollment.

Criteria	Odds ratio	Lower 95% CI	Upper 95% CI	*P* value
VR[a]	1.78	0.75	4.30	.19
Health literacy score	1.08	0.95	1.24	.22
Aware of prediabetes	2.06	0.54	9.20	.30
Importance of language DPP[b] is offered in	0.78	0.49	1.23	.30
Importance of distance to DPP	0.56	0.33	0.92	.03
Importance of time required for DPP	1.55	0.94	2.66	.09
Importance of availability of DPP via internet	1.00	0.56	1.71	.98
Importance of cost of DPP	1.05	0.64	1.73	.83
Importance of availability of childcare through DPP	1.14	0.73	1.80	.56
Importance of motivation to change lifestyle	0.73	0.42	1.24	.25

[a]VR: virtual reality.

[b]DPP: Diabetes Prevention Program.

Risk Perceptions

Complete pre-post risk perception data were available for 96 people. Table 3 shows the prevideo and postvideo scores for total risk perception score, and for each component of the risk perception scale. Neither the total risk perception score nor its components changed significantly. *T* tests comparing the changes by intervention modality found no significant difference in risk perception changes between groups: total risk score (*t*=-0.6; *P*=.54), deliberative risk score (*t*=-0.6; *P*=.54); affective risk score (*t*=0.44; *P*=.65); and experiential risk score (*t*=-1.6; *P*=.10)

Table 3. Risk perception pre video and post video by intervention group.

Risk perception score component	VR[a] group (n=49)		360° video group (n=47)	
	Previdео, mean (SD)	Postvideo, mean (SD)	Previdео, mean (SD)	Postvideo, mean (SD)
Total score	3.43 (0.74)	3.46 (0.76)	3.61 (0.75)	3.54 (0.70)
Deliberative component score	2.98 (0.87)	2.98 (0.86)	2.85 (0.96)	2.75 (0.84)
Affective component score	3.63 (1.63)	3.60 (1.72)	4.12 (1.72)	4.12 (1.80)
Experiential component score	3.69 (0.69)	3.82 (0.75)	3.86 (0.72)	3.74 (.73)

[a]VR: virtual reality.

Qualitative Feedback

In the follow-up survey, depending upon the video modality they received, the participants were asked “What did you think of the VR/Mobile 360° video?” Many participants provided extremely short feedback such as “good” or “educational.” Textbox 1 provides a sampling of the more detailed comments that were provided, divided into those that were positive and negative in tone.

Textbox 1. Feedback from participants on the videos.

Positive response to the videos

- "Very interesting, it helped me to reflect."
- "They are very interesting to became conscious on this disease of diabetes."
- "I was informed with the video, something that I have not seen before. I learned to take care of myself and eat healthy."
- "It's a good video on showing the difference on a person having higher risk on diabetes."
- "Very good information about diabetes prevention."
- "It is very interesting how I interacted with the program."
- "I learned to eat healthy to prevent diabetes."
- "I liked them. They are awesome!"
- "They are very descriptable (sp) about the risk for having high blood sugar."
- "It really open my eyes."
- "I thought of how we could lose our sight and even our lives if we do not take care of ourselves adequately, our eating habits and our children's eating habits. And value our health and our family's health. The consequence of our addictive lifestyle of not eating healthy. Our families and ourselves must take care of our health. I would like to learn more."
- "It was amazing how realistic it made me understand the importance of my health and keeping diabetes at bay."

Negative feedback on the videos

- "They are creative but over dramatics."
- "Scary."
- "It was nice but it did hurt my head a bit."

Discussion

Summary of Project and Primary Findings

In this pilot study, we tested whether the presentation of 2 brief motivational mobile phone videos delivered via mobile 360° vs mobile virtual reality had differential effects on risk perceptions and enrollment in the DPP. We found an absolute difference in the enrollment of 13% between groups that, while not statistically significant in this project, might be practically important. We also found that risk perceptions did not differ by modality and did not change for individuals in either group. We believe these results suggest several avenues for further investigation.

While we are unaware of prior research comparing the efficacy of VR to 360° Video on changing individuals' health beliefs and behaviors, a few studies have tested the use of VR for health behavior change [27]. For example, Ahn et al [28,29] compared the effects of a pamphlet on the health risks of sugary drink consumption alone with a VR simulation of a virtual person gaining weight as a result of regularly consuming soft drinks, with both interventions combined. They found that the combined intervention was more effective than either alone, leading to lower self-reported consumption of soft drinks. Interestingly, they found that the risk perceptions of participants who experienced the VR increased. By contrast, in this study, we found that our immersive videos did not lead to changes in risk perception. Clearly, further research is needed to understand the mechanism of action of immersive videos intended to change beliefs and behaviors.

There are several strengths to this study. First, this study addressed the pragmatic question of whether the greater immersiveness of VR is needed (vs 360° video) for persuasive videos to affect individuals' health beliefs and behaviors. Second, the study interventions sought to isolate the effect of the mode of video delivery on enrollment by addressing other factors that might affect enrollment. We notified all individuals of their prediabetes to address low awareness of prediabetes; we also sent all participants a website URL to educate them to address their lack of understanding of prediabetes, T2DM, and the DPP. Finally, we measured contextual factors related to the decision about whether to enroll in the DPP (eg, ratings of importance of travel, distance, and cost) for use as covariates in estimating the effect of the intervention.

This study has several limitations. First, our measure of DPP enrollment was based on self-report, leading to the potential for social desirability bias in our results. In addition, we only measured whether people signed up for the DPP, not whether they engaged with the program. In future work, we plan to collect objective data from the DPP program on both enrollment and engagement. Second, this study was an uncontrolled pilot study; therefore, it is possible that simply informing people that they have prediabetes and educating them about the DPP led to their enrollment, independent of the video interventions. However, prior research on notifying individuals that they have prediabetes and educating them about the DPP has found much lower rates of enrollment than we found in this study. For example, as part of a large trial of community-based DPPs, investigators contacted 7500 community members with a letter notifying them that they have prediabetes and educating them about the DPP; they found that that only 1.7% of those who

were contacted enrolled in the DPP [7]. The true magnitude of the efficacy of our videos will need to be tested in a controlled trial.

Based on the results of this pilot, we are planning a trial that will compare the efficacy of notification or education alone vs notification or education + VR videos vs notification or education + 360° on objectively measured enrollment and engagement in the DPP among individuals with prediabetes. Future work will also assess multiple potential mechanisms of action for the videos, assessing whether risk perceptions [23], narrative transportation [30], and immersion [31] are associated with the videos' efficacy and whether the effects of the intervention are moderated by the individuals' health literacy, numeracy, or practical barriers to enrolling.

Conclusions

Increasing enrollment in the evidence-based DPP is a national priority. We present a comparison of the presentation of brief motivational mobile phone videos in virtual reality vs 360° video on risk perceptions and enrollment in the DPP. Our results suggest that further work is warranted to determine the replicability of our findings in other populations, to examine the mechanism of action of the videos, and to assess any moderators of their efficacy.

Conflicts of Interest

None declared.

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Abbreviations

DPP: Diabetes Prevention Program
PCP: primary care provider
T2DM: type 2 diabetes mellitus
VR: virtual reality

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Original Paper

Virtual Endocrinology Care Emphasizing Data-Driven Insights and Continuous Engagement and Its Impact on Glycemic Outcomes in Patients With Uncontrolled Diabetes: A Real-world Retrospective Case Series

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Abstract

Background: Steady Health's novel virtual care model incorporates continuous glucose monitoring (CGM) and a multidisciplinary approach to timely person-centered diabetes care.

Objective: This real-world retrospective case series explores the early glycemic outcomes of its patients with uncontrolled diabetes.

Methods: All patients of Steady Health who had an initial time in range (TIR) below 70% from their first 4 weeks of available CGM data and who had completed onboarding by February 2021 were included in this analysis. We compared the change in TIR, time below range, and average blood glucose from their first 4 weeks with their latest 4 weeks of available CGM data. Hemoglobin A_{1c} (HbA_{1c}) values at baseline and at the end of the study were also compared. Patients completed a questionnaire assessing their satisfaction with Steady Health's intervention.

Results: A total of 53 patients (n=35, 66% with type 1 diabetes; n=44, 83% treated with insulin) were included in this analysis. This cohort had a median baseline TIR of 53.0% (IQR 40.9%, 61.7%) and saw a median change in TIR of +16.6% (IQR +6.0%, +27.9%; *P*<.001) over a median duration of care of 11 months, amounting to nearly 4 more hours spent between 70 to 180 mg/dL a day. Of the 27 patients who had both baseline and follow-up HbA_{1c} results, their median baseline HbA_{1c} was 8.6% (IQR 7.5%, 11.4%; 70 mmol/mol), while their median change in HbA_{1c} was –1.2% (IQR –2.6%, –0.2%; *P*=.001). Importantly, these glycemic improvements were achieved with a median decrease in the time below range by –0.3% (IQR –1.1%, 0.0%; *P*<.001), regardless of whether patients were started on an automated insulin delivery system. A total of 40 (75.5%) patients improved TIR by ≥5%, and 27 (50.9%) achieved TIR≥70% by the end of the study. Glycemic improvements were greatest among patients with the lowest baseline TIR and those who collaborated most intensively with Steady Health's clinicians. A total of 25 of these patients responded to a questionnaire assessing levels of satisfaction with their care, and all of them agreed that Steady Health had a positive impact on their diabetes management.

Conclusions: Our findings suggest that patients with uncontrolled diabetes can achieve significant glycemic improvements by working with a virtual multidisciplinary care team that uses CGM to provide continuous clinical feedback and support.

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KEYWORDS

continuous glucose monitoring; connected care; digital health; telemedicine; type 1 diabetes; type 2 diabetes

Introduction

Diabetes currently affects more than 10% of the US population [1], and its prevalence is projected to double by 2060 [2]. As the seventh leading cause of death in the United States [3] and a major driver of cardiovascular disease, kidney failure, and blindness, diabetes imposes the greatest economic burden of any chronic condition [4,5], to say nothing of its immeasurable impact on quality of life and well-being. Even though optimal glycemic control can prevent and delay diabetes complications, only about half of US adults with diabetes meet recommended hemoglobin A_{1c} (HbA_{1c}) treatment targets [6].

Unfortunately, current treatment paradigms fail to meet the complex and dynamic demands of this unrelenting disease. People with diabetes make daily, even hourly, decisions to manage their condition, but they are poorly supported by the conventional care model that consists of 1 to 4 visits a year with a health care provider. Limited time and resources prevent most providers from reviewing more than a HbA_{1c} level and a summary of blood glucose (BG) data, and opportunities to address mental health and promote effective lifestyle modification are often missed. Moreover, access to specialized care remains restricted amid a substantial shortage of diabetes providers, with patients with diabetes outnumbering diabetes educators by more than 1600:1 [7] and three-quarters of US counties not having an endocrinologist [8].

Meanwhile, technologies and therapies aimed at improving diabetes care are advancing at a substantial pace. We have more treatment options than ever before: medications targeting specific pathophysiological defects, both faster- and longer-acting insulins, and automated insulin delivery systems. Continuous glucose monitoring (CGM) deserves special mention as an excellent complement to HbA_{1c} when assessing glycemic control. By capturing a complete BG profile throughout the day, CGM can more immediately inform treatment decisions and lifestyle modifications. Unfortunately, these advances can improve outcomes only if they reach the patients with diabetes who need them. Many providers struggle to keep up with the rapidly changing landscape of diabetes treatment options. Other complicating factors include high treatment costs, lack of access to care, therapeutic inertia, and inadequate patient education and support. Indeed, ongoing efforts have yet to translate into better clinical outcomes as the percentage of patients with diabetes achieving glycemic targets remains stagnant over time [6,9].

There are no neat solutions that overcome all these challenges at once, but we believe that the way we deliver care to people with uncontrolled diabetes needs an overhaul. Patients with diabetes benefit from a comprehensive assessment by an endocrinologist, who can identify gaps and deficiencies in diabetes self-management, connect patients with diabetes with the best tools and resources, and put in motion a care plan tailored to their specific needs. Diabetes care and education specialists (DCESs) can provide essential education to patients with diabetes, train them to use new technology, coach them on nutrition and exercise, and answer day-to-day questions regarding diabetes management. Geographic barriers are minimized, and multidisciplinary care becomes convenient and continual when it is provided over telemedicine and messaging. CGM data can be remotely monitored and analyzed alongside details of the patient's lifestyle, and insights derived from that data can foster learning and self-improvement, and guide timely clinical interventions. We present a novel virtual diabetes care model that incorporates all these components and explore its early efficacy in patients with uncontrolled diabetes.

Methods

Ethical Considerations

The study was evaluated by the Advarra Institutional Review Board (Pro00061557) and approved for exemption from IRB oversight. All patient data was anonymized prior to analysis and no identifiable protected health information was included in this publication.

Steady Health

Steady Health is a virtual endocrinology clinic currently available to patients with diabetes in California and Washington (with plans to expand nationwide), with a monthly membership fee. Steady Health leverages CGM and telemedicine to provide personalized, data-driven care and features a multidisciplinary team approach led by endocrinologists, DCESs, and care coordinators.

All care is provided exclusively through the Steady Health app. Patients can exchange messages (responses are provided within 24 hours on weekdays) and schedule telemedicine visits with their care team within a few days. As a data collection tool, the Steady app allows for sharing of meals, insulin dosing, exercise, notes, and CGM data. These inputs are consolidated into a single view within the Steady Health software platform for clinicians to analyze in detail. Patients can view and learn from the BG profile associated with each logged event in the app, as well as access their clinical reports and visit note summaries.

Onboarding and Engagement

The onboarding process involves two visits with an endocrinologist and a "tracking period" in between. The first visit is an opportunity to gather and thoroughly understand the patient's medical history, which serves as the foundation for future care; the tracking period meticulously explores how the patient manages their diabetes day to day; and the tracking review visit takes the form of an open discussion, in which insights are highlighted and used to craft a long-term care plan.

During the first visit, a routine assessment is performed, with added emphasis on the patient's mental health and current struggles. Patients are asked to complete the Problem Areas in Diabetes questionnaire, and their responses are reviewed during the visit; if the patient agrees they might benefit from working with a mental health professional, a referral is made to one of several partnering psychologists specializing in diabetes distress. If patients are not already using one, they are prescribed a CGM and instructed on how to use the device and interpret readings. Data from Dexcom Clarity are obtained via a web application programming interface, whereas the raw data from LibreView and CareLink are periodically downloaded then uploaded to

Steady Health's software platform. Once CGM use is initiated and BG data are shared wirelessly, patients complete a 7-day tracking period. This includes photo journaling their meals and logging their exercise, insulin, and notes, which together with their BG data establish a diagnostic baseline of their diabetes management. Patients then have a 1-hour follow-up visit with their endocrinologist to review learnings from their tracking period and set personalized goals and projects to improve their diabetes management.

As part of ongoing care, DCESs provide education and coaching tailored to each patient's needs and schedule. Patients receive a monthly report from their endocrinologist that includes a summary of their BG statistics and a personalized message reviewing their progress. Patients may also receive biweekly notifications if they meet or dip below their self-identified time in range (TIR) goals. These built-in touch points allow Steady Health to proactively reach out and continuously engage with patients about their diabetes.

Steady Health's care model allows clinicians to start patients with diabetes on CGM, smart pens, and pumps completely remotely. Steady Health's clinicians have a deep knowledge of the latest diabetes advancements and recommend the best tools for meeting each patient's unique needs. Although the training for these devices is conventionally provided in person, Steady Health has developed online instructional material and offers one-on-one video appointments to ensure a smooth transition.

With greater shared insight into BG and lifestyle data, Steady Health empowers patients with a deeper understanding of the factors that impact BG, so they may play a more active role in their diabetes management. As they work with patients on educational topics, medication adjustments, and behavioral modification, Steady Health's clinicians emphasize meeting patients where they are in their journey, rather than going through a prescribed program. The clinic has a general framework for onboarding and follow-up, but patients have personalized plans for improvement projects and can engage with their clinicians as often as they like.

Study Design and Participants

This study was conducted in accordance with the Helsinki Declaration. A database review was performed in February 2021 to identify all Steady Health patients with uncontrolled diabetes who had completed onboarding. Patients came to the clinic either through the website or word of mouth, or they were referred by their health care provider between October 2019 and December 2020. Patients with uncontrolled diabetes were defined as having a TIR below 70% during their first 4 weeks of available CGM data. International consensus describes TIR as the percentage of time spent within a target BG range of 70 to 180 mg/dL and recommends a goal TIR>70% for patients with type 1 and type 2 diabetes [10]. Several studies suggest an association between TIR and the risk for microvascular complications [11-15].

For patients meeting inclusion criteria, the TIR, time below range (TBR), and average BG from their first 4 weeks of available CGM data were collected and used to define their baseline glycemic control. TBR refers to the percentage of time spent below 70 mg/dL, and international consensus recommends a goal TBR<4% for patients with type 1 and type 2 diabetes [10]. As a comparison to evaluate the impact of Steady Health's intervention, TIR, TBR, and average BG from the latest 4 weeks of available CGM data were used to quantify glycemic control at the study's end. Demographic characteristics and clinical data, including HbA_{1c} results, were obtained by a review of the medical record.

Because many patients were able to achieve and maintain glycemic improvements after a focused but variable period of active engagement with their care team (often resulting in lasting changes in lifestyle or therapy), we chose to focus on the intensity of these interactions. Maximal engagement was therefore quantitatively assessed by the number of clinically relevant encounters or messages exchanged over a period of 4 weeks at any point during each patient's care, and categorized as high (≥10), moderate (5-9), or low (<5).

Lastly, to assess levels of satisfaction with Steady Health's role in their ongoing diabetes care, an anonymous 9-question questionnaire (using a 5-point Likert scale) was sent to these 53 patients.

Statistical Analysis

Baseline characteristics of participants were presented using means and SDs or medians and IQRs for continuous measures (depending on normality) and counts and percentages for categorical measures. Absolute change in the outcome measures (TIR, TBR, HbA_{1c}, average BG) were reported as median and IQR given skewed distributions, and the Wilcoxon signed rank tests were used to determine whether study outcomes changed between enrollment and the study's end. Linear regression models were used to determine the associations between levels of maximal engagement and absolute change in TIR, TBR, HbA_{1c}, and average BG, adjusted for age, sex, diabetes type, and insulin type. Covariates were selected a priori based on the understanding of the causal network relating treatment to outcome. The appropriateness of treating levels of maximal engagement as a continuous variable (as opposed to an ordinal variable) was assessed with likelihood ratio tests for all models. All analyses were performed with STATA 15.1 software (StataCorp).

Results

A total of 53 patients met inclusion criteria and are described in Table 1. The mean duration of care was 11 (range 3-27) months.

Table 1. Baseline characteristics.

	Patients (N=53)
Age (year), mean (SD)	39.8 (11.7)
Female, n (%)	24 (45.3)
Ethnicity, n (%)	
Caucasian	36 (67.9)
Asian	8 (15.1)
Hispanic/Latinx	6 (11.3)
African American	3 (5.7)
Diabetes type, n (%)	
Type 1	35 (66.0)
Type 2	18 (34.0)
Commercially insured, n (%)	52 (98.1)
Complications, n (%)	20 (37.7)
Peripheral neuropathy	10 (18.9)
Diabetic retinopathy	11 (20.8)
Nephropathy	7 (13.2)
Cardiovascular disease	1 (1.9)
Duration of care (months), median (IQR)	11 (5, 18)
HbA_{1c}[a] (%; n=41), median (IQR)	8.5 (7.5, 11.2)
<8%, n (%)	17 (41.5)
8%-10%, n (%)	10 (24.4)
>10%, n (%)	14 (34.1)
Time in range[b] (%), median (IQR)	53.0 (40.9, 61.7)
0%-30%, n (%)	11 (20.8)
30%-50%, n (%)	12 (22.6)
50%-60%, n (%)	13 (24.5)
60%-70%, n (%)	17 (32.1)
Time below range[c] (%), median (IQR)	0.9 (0.2, 2.5)
0%-1%, n (%)	28 (52.8)
1%-4%, n (%)	18 (34.0)
>4%, n (%)	7 (13.2)
Treatment with insulin, n (%)	44 (83.0)
Injection	25 (56.8)
Pump	19 (43.2)

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

[b]Time in range defined as % of time glucose falls between 70-180 mg/dL over 28 days.

[c]Time below range defined as % of time glucose falls below 70 mg/dL over 28 days.

Improvements in Glycemic Outcomes

Initial values of TIR, TBR, HbA_{1c}, and average BG, and the absolute change in each glycemic metric by the end of study are shown in Table 2. Comparing glycemic parameters at baseline and at the end of the study, 40 (75.5%) patients increased their TIR by at least 5%, and 34 (64.2%) improved their TIR by 10% or more. Meanwhile, 36 (67.9%) patients simultaneously increased their TIR while maintaining or reducing their TBR, and 27 (50.9%) achieved TIR of 70% or greater (Figure 1, left). Although 7 patients had an initial TBR exceeding 4%, only 2 of these had a TBR greater than 4% at the end of the study. The greatest reduction in TBR was seen

among patients on multiple daily insulin injections (Figure 1, middle).

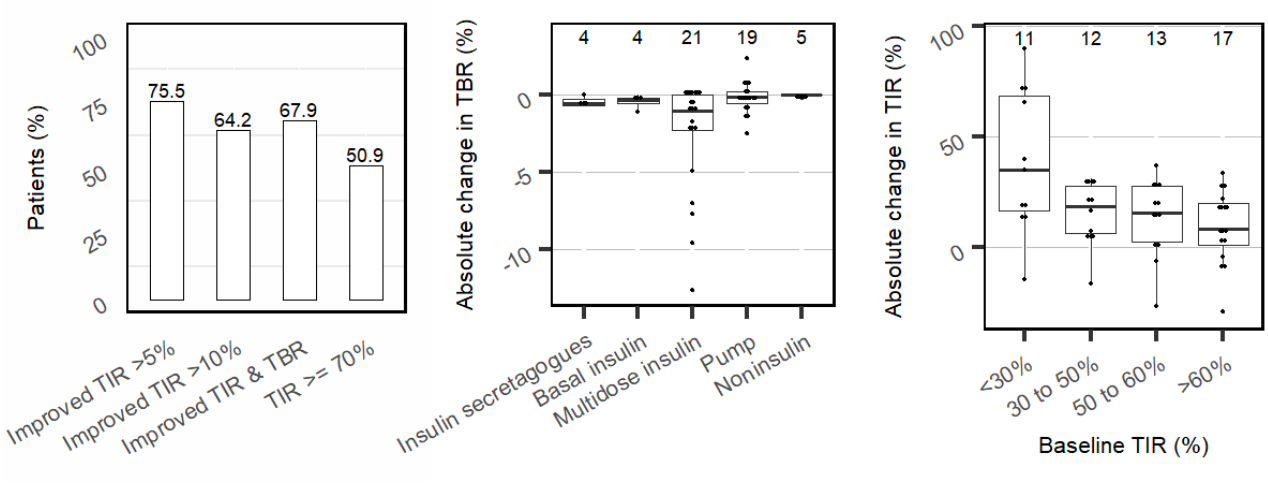
Table 2. Glycemic outcomes.

	Initial values, median (IQR)[a]	Δ (end of study), median (IQR)[a]	*P* value
Time in range (%)	53.0 (40.9, 61.7)	+16.6 (+6.0, +27.9)	<.001
Time below range (%)	0.9 (0.2, 2.5)	–0.3 (–1.1, 0.0)	<.001
HbA_{1c}[b] (%; n=27)	8.6 (7.5, 11.4)	–1.2 (–2.6, –0.2)	.001
Average glucose (mg/dL)	180 (163, 193)	–21 (–34, –6)	<.001

[a]Values are reported as medians (IQR) for these outcomes with skewed distribution. Wilcoxon signed rank tests were used.

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

Figure 1. The percentage of patients in this cohort who improved TIR by ≥5%, improved TIR by ≥10%, simultaneously improved TIR while maintaining or lowering TBR, and achieved TIR≥70% by end of the study are shown in the graph on the left. The absolute change in TBR by type of therapy (insulin secretagogues, basal insulin injections only, multiple daily insulin injections, insulin pump, and no insulin use whatsoever) is shown in the middle graph. The absolute change in TIR based on the baseline TIR category is shown in the graph on the right. All box plots are shown with median, IQR, and individual data points. The number on top in the middle and right graphs denote the number of patients in each category described. TBR: time below range; TIR: time in range.



Change in TIR by Baseline TIR Category

There was a progressively greater increase in TIR with lower baseline TIR (Figure 1, right). Those patients with a baseline TIR below 30% had the greatest increase in TIR of 35.1% (IQR 16.8%, 68.4%), equating to 8.4 additional hours spent in range, while those patients with a baseline TIR of 60.1%-69.9% had an increase in TIR of 8.2% (IQR 1.1%, 19.8%).

Remote Initiation of Diabetes Treatments

Of the 53 patients, 20 (37.7%) transitioned to either a new insulin pump or algorithm, 4 (7.5%) began using a smart pen, and 3 (5.7%) initiated inhaled insulin during their care. Of these 27 patients who successfully switched to a new mode of insulin delivery, 23 (85.2%) saw improvements in their TIR, and 2 more who had been experiencing excess hypoglycemia meaningfully reduced their TBR by more than 2.1% or 30 minutes a day. In addition, we performed a sensitivity analysis to examine the outcomes in those who transitioned to an automated insulin delivery system (17/53 patients) during this study and those who did not (36/53 patients). We found that the absolute changes in TIR, TBR, HbA_{1c}, and average BG did not differ significantly between these two groups.

Glycemic Improvements by Level of Maximal Engagement

Greater levels of maximal engagement were associated with more substantial reductions in HbA_{1c} and average BG, and increases in TIR, without an increase in TBR (Tables 3 and 4). These relationships strengthened with the adjustment for age, sex, diabetes type, and type of insulin therapy. For every level up in maximal engagement, there was an average increase in TIR by 13.5% (adjusted *P*=.01) and an average decrease in HbA_{1c} by 1.3% (adjusted *P*=.03).

Table 3. Levels of maximal engagement and changes in glycemic outcomes (simple linear regression).

	Coefficients[a] (simple linear regression)							
	Δ TIR[b] (%)	*P* value	Δ TBR[c] (%)	*P* value	Δ A_{1c}[d] (%)	*P* value	Δ aBG[e] (mg/dL)	*P* value
Maximal engagement	+8.61	.04	–0.00	.99	–0.97	.06	–17.50	.01
R^2	0.08		0.00		0.14		0.11	
F (*df*)	4.33 (1,51)		0.00 (1,51)		3.83 (1,24)		6.39 (1,51)	

[a]Coefficients referred to a change in outcome per level up in maximal engagement (low, medium, high).

[b]TIR: time in range.

[c]TBR: time below range.

[d]A_{1c}: hemoglobin A_{1c}.

[e]aBG: average blood glucose.

Table 4. Levels of maximal engagement and changes in glycemic outcomes (multiple linear regression).

	Coefficients[a] (multiple linear regression[b])							
	Δ TIR[c] (%)	*P* value	Δ TBR[d] (%)	*P* value	Δ A_{1c}[e] (%)	*P* value	Δ aBG[f] (mg/dL)	*P* value
Maximal engagement	+13.51	.002	–0.15	.77	–1.34	.01	–25.16	.001
R^2	0.36	.01	0.23	.13	0.59	.03	0.38	.005
F (*df*)	3.16 (8,44)		1.66 (8,44)		3.01 (8,17)		3.34 (8,44)	

[a]Coefficients referred to a change in outcome per level up in maximal engagement (low, medium, high).

[b]Multiple linear regression model adjusted for age, sex, diabetes type, and insulin type.

[c]TIR: time in range.

[d]TBR: time below range.

[e]A_{1c}: hemoglobin A_{1c}.

[f]aBG: average blood glucose.

Measures of Patient Satisfaction

Of the 53 patients surveyed, 25 (47.2%) responded. Of these 25 respondents, 23 (92%) strongly agreed and 2 (8%) agreed that Steady Health had a positive impact on their diabetes management. Meanwhile, 18 (72%) respondents strongly agreed and 5 (20%) agreed that they felt supported by Steady Health between visits. All respondents strongly agreed or agreed that it was easy and convenient to arrange a visit with their provider in a timely manner, and 23 (92%) would be very or somewhat disappointed if they could not use Steady Health. Of the 23 respondents who were started on a new device or injectable/inhaled medication, 21 (91.3%) strongly agreed or agreed that they had received the training or support they needed.

Discussion

Principal Results

This is the first report to our knowledge to explore the implementation of a ground-breaking digital diabetes care model that features universal CGM use among its patients, early and intensive patient engagement by an endocrinologist, and a program of ongoing guidance and accountability to individualized goals between endocrinology visits. Steady Health attempts to address some of the shortcomings of conventional diabetes care by expanding care and support to be continuous rather than episodic, offering telemedicine visits with diabetes specialists without the need for travel or extended wait times, devoting attention to mental health, and encouraging the adoption of transformative diabetes technologies when appropriate. Major innovations include the decoupling of data analysis from visits and a software platform that puts the patient's daily BG profile into the context of the meals, activities, and therapies that shape it, such that the reviewing clinician has both the time and tools to uncover deeper, less apparent associations within the data. This process of data discovery allows for actionable insights to be presented and discussed with patients over video and messaging to empower them with the knowledge and agency to better manage their diabetes.

The real-world data presented in this analysis suggest that virtual diabetes care that integrates enhanced analysis of CGM and continual close collaboration with endocrinologists and DCESs can be associated with significant improvements in TIR and HbA_{1c} for patients with uncontrolled diabetes. These improvements were notably seen without increasing TBR and were greatest in the patients least able to maintain adequate glycemic control at baseline. Current CGMs provide 96 or 288 BG readings per day, which serve as valuable input for driving behavioral change and guiding treatment decisions, and there is a growing body of literature supporting the use of CGM in patients with type 1 and type 2 diabetes [16-20]. However, not

all studies demonstrate meaningful gains [21,22], suggesting that an abundance of BG data alone may not always translate into better glycemic outcomes. Although many of the patients in this study saw a durable improvement in their glycemic control under Steady Health's care, those who were most engaged with the care team tended to see the greatest improvement overall. The specific interventions that proved successful were diverse and included diet and lifestyle modification, connecting patients with diabetes-focused mental health specialists, premeal bolusing, fine-tuning of insulin dosing (as frequently as daily), and the introduction of new therapies and devices. Importantly, better glycemic control was achieved whether or not an automated insulin delivery system was initiated. Not only did glycemic outcomes improve, but these patients also expressed high levels of satisfaction with the impact of Steady Health's intervention, the support provided between visits, and the ease of arranging visits with their providers in a timely manner.

The positive findings seen among this cohort of patients also strongly affirm the notion that the education, training, and support for CGM, smart pens, insulin pumps, algorithms, and inhaled insulin can be delivered both safely and effectively in a virtual care setting. A thorough discussion of the risks and benefits of each technology or therapy, an assessment of readiness, and guided instruction on proper use were prerequisites to initiation of each product, and all these interactions were routinely conducted over telemedicine visits. All patients new to CGM were able to self-start with instructional videos and messages, corroborating prior accounts that CGM can be feasibly initiated without in-office training [23]. Most patients also saw improvements in their glycemic control because of these interventions and expressed high levels of satisfaction with the relevant training and support provided by Steady Health.

Comparison With Prior Work

Another virtual diabetes care model partially incorporating CGM use and clinical support has been previously described [24]: significant improvements in HbA_{1c} were seen among 740 early participants in their telehealth program over a median follow-up period of 4.2 months. The noteworthy differences between these approaches are also relative strengths of this study in that it includes a large proportion of patients with type 1 diabetes, comprehensive CGM use, initiation of smart pens and insulin pumps when appropriate, and the reporting of CGM glycemic outcomes in addition to HbA_{1c}. Indeed, an HbA_{1c} value representing lower average glycemia may belie a greater frequency and severity of hypoglycemia, which should not be overlooked, given growing awareness for the short- and long-term consequences of hypoglycemia [25-27]. In this study, most patients were able to achieve greater TIR without increasing TBR, and half achieved the recommended TIR target of 70%.

Limitations

There were several limitations to this study, including small sample size, self-selection bias, and the lack of a control group. Most of Steady Health's patients are commercially insured or able and motivated to afford the added cost of CGM and membership. Moreover, because our cohort was relatively young and a majority had type 1 diabetes, these findings may not be generalizable to the greater population of patients with diabetes. There were some patients who saw an initial improvement in glycemic control followed by a deterioration, or vice versa, with subsequent fluctuations over time; arbitrarily defining the comparison end-of-study period as February 2021 did not fully convey the variability in glycemic control seen over longer periods of care. Moreover, the first 4 weeks of available CGM data did not always reflect true baseline glycemic control, as patients were unblinded to their BG readings and often made behavioral changes in response to the patterns seen. Meanwhile, treatment decisions were sometimes made within the first 4 weeks based on clinical judgment to avoid extreme hyperglycemia or hypoglycemia. There were also challenges obtaining a follow-up HbA_{1c} test for many of these patients. Most patients joining Steady Health have a baseline TIR>70% (and a fraction of these patients have prediabetes); their outcomes are not reported here. Longer term data on these and other patients being seen by Steady Health are being collected, and those findings will hopefully be published in the future.

Conclusions

Patients with uncontrolled diabetes can achieve significant glycemic improvements with a virtual care model that meets them where they are, helps them make the most of their CGM data, and provides continuous multidisciplinary care and support, even between visits.

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Authors' Contributions

CCW wrote the manuscript and researched data. KCW performed the statistical analysis and reviewed/edited the manuscript. ASJ wrote the manuscript. NN wrote the manuscript.

Conflicts of Interest

CCW, ASJ, and NN are current employees of Steady Health Inc. KCW has nothing to disclose.

Editorial notice: This study was retrospectively exempted from institutional review board (IRB) oversight as the authors were not aware that an IRB review was required for their study type. After an extended editorial review, the editor recommended they apply for an exemption as it would be appropriate for the study type and data used in their research.

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Abbreviations

BG: blood glucose
CGM: continuous glucose monitoring
DCES: diabetes care and education specialist
HbA_{1c}: hemoglobin A_{1c}
TBR: time below range
TIR: time in range

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Original Paper

Comparison of Daily Routines Between Middle-aged and Older Participants With and Those Without Diabetes in the Electronic Framingham Heart Study: Cohort Study

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Abstract

Background: Daily routines (eg, physical activity and sleep patterns) are important for diabetes self-management. Traditional research methods are not optimal for documenting long-term daily routine patterns in participants with glycemic conditions. Mobile health offers an effective approach for collecting users' long-term daily activities and analyzing their daily routine patterns in relation to diabetes status.

Objective: This study aims to understand how routines function in diabetes self-management. We evaluate the associations of daily routine variables derived from a smartwatch with diabetes status in the electronic Framingham Heart Study (eFHS).

Methods: The eFHS enrolled the Framingham Heart Study participants at health examination 3 between 2016 and 2019. At baseline, diabetes was defined as fasting blood glucose level ≥126 mg/dL or as a self-report of taking a glucose-lowering medication; prediabetes was defined as fasting blood glucose level of 100-125 mg/dL. Using smartwatch data, we calculated the average daily step counts and estimated the wake-up times and bedtimes for the eFHS participants on a given day. We compared the average daily step counts and the intraindividual variability of the wake-up times and bedtimes of the participants with diabetes and prediabetes with those of the referents who were neither diabetic nor prediabetic, adjusting for age, sex, and race or ethnicity.

Results: We included 796 participants (494/796, 62.1% women; mean age 52.8, SD 8.7 years) who wore a smartwatch for at least 10 hours/day and remained in the study for at least 30 days after enrollment. On average, participants with diabetes (41/796, 5.2%) took 1611 fewer daily steps (95% CI 863-2360; *P*<.001) and had 12 more minutes (95% CI 6-18; *P*<.001) in the variation of their estimated wake-up times, 6 more minutes (95% CI 2-9; *P*=.005) in the variation of their estimated bedtimes compared with the referents (546/796, 68.6%) without diabetes or prediabetes. Participants with prediabetes (209/796, 26.2%) also walked fewer daily steps (*P*=.04) and had a larger variation in their estimated wake-up times (*P*=.04) compared with the referents.

Conclusions: On average, participants with diabetes at baseline walked significantly fewer daily steps and had larger variations in their wake-up times and bedtimes than the referent group. These findings suggest that modifying the routines of participants with poor glycemic health may be an important approach to the self-management of diabetes. Future studies should be designed to improve the remote monitoring and self-management of diabetes.

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KEYWORDS

diabetes; mobile health; smartwatch; daily physical activities; daily routine pattern; sleep; step counts; diabetes self-management; mobile phone

Introduction

Background

Diabetes affects millions of people worldwide. It is estimated that >30 million people currently have diabetes in the United States, with that number expected to rise to 44.1 million by 2034 [1]. From 2015 to 2016, the annual diabetes-related health care costs increased from US $43.9 billion to US $51.5 billion in the United States [1]. As diabetes is associated with increased morbidity and mortality, and it ultimately predisposes the patient to heart disease, stroke, and kidney disease [2], lifestyle management should be a fundamental aspect of diabetes care in addition to medication treatment [3]. Healthy eating, more exercise, a regular sleep habit, smoking cessation, and stress management are 5 essential factors in diabetes lifestyle management [4]. Among these 5 factors, lack of exercise is a significant predictor of incident diabetes, which is independent of obesity [5,6]. In contrast, lack of exercise leads to obesity and being overweight, and excess body fat results in insulin resistance [7,8]. Therefore, the adoption and maintenance of physical activity are critical for the management of healthy weight and blood glucose levels in individuals with poor glycemic health [4,9]. In addition, previous studies have shown that sleep disturbance, which is similar to several traditional risk factors, is also a significant risk factor for diabetes [10], and chronic circadian disruption caused by sleep–wake cycle irregularities increases the risk of metabolic syndrome and diabetes [11,12]. Given the important roles of exercise and sleep in diabetes risk, self-monitoring of daily routine patterns may motivate people to adopt and maintain healthy lifestyles and, therefore, improve glycemic health in participants with diabetes.

Most previous studies that investigated daily routine patterns, for example, sleep patterns and physical activities, collected data using traditional epidemiological research methods such as self-reported questionnaires or surveys [13-15]. These traditional methods often collect data at a single time point or a few time points. In addition, these traditional methods are costly (eg, in-person interviews with a large number of participants) and are more likely to be subject to recall bias [16,17]. In the past few years, an accelerometer or pedometer has been used to access daily step count, although most accelerometer or pedometer studies only collect step counts within a few days or a couple of weeks [18]. Mobile health (mHealth) is an emerging technology that is increasingly being used worldwide [19]. mHealth enables continuous ambulatory monitoring of the health status and daily activities of users [20], making it possible to collect reliable daily routine patterns in large cohort studies with long-term follow-up. One of the early application areas of mHealth is diabetes remote monitoring and self-management [21]. mHealth provides a convenient and effective way of engaging people in digital diabetes care and self-management, including physical exercise management, insulin dosage calculation, and so forth [22-24]. However, the application of mHealth in diabetes self-management in community-based cohorts remains to be studied.

Objective

The electronic Framingham Heart Study (eFHS) is a cohort study in which participants were provided smartwatches and instructed to wear them each day. mHealth technology has allowed the participants in the eFHS to document their daily routine patterns in a relatively inexpensive and convenient way. On the basis of previous findings, this study aims to investigate the associations of daily routine patterns with diabetes status in the eFHS. We include 796 participants returning daily steps and heart rates for at least 1 to 36 months via smartwatches (average return 9.6 months). The sleep routine patterns included several smartwatch-derived proxy measures for wake-up times, bedtimes, and sleep durations. We perform association analyses of daily routine patterns (step counts and sleep pattern variables) with diabetes status. We hypothesize that, compared with the referents, participants with diabetes and prediabetes walk fewer steps per day and have higher variability in their daily sleep patterns, which were measured by the smartwatch.

Methods

Study Sample

The eFHS is nested in the Framingham Heart Study (FHS), a community-based, prospective study that was initiated in 1948 in the town of Framingham, Massachusetts [25-27]. The study sample included participants in three cohorts—the third-generation cohort (generation 3), a cohort of multiple

ancestries (omni 2), and a cohort of new offspring spouses (NOS)—who attended their third research center examination in person [25]. In the eFHS, we developed a smartphone app that included electronic consent and health questionnaires and integrated both a wireless blood pressure cuff and a smartwatch. The eFHS recruited approximately 2100 FHS participants who owned a smartphone (iPhone 4S or newer iPhone with at least an iOS 8.2 or Android phone), attended an FHS health examination in person between 2016 and 2019, and consented to participate in eFHS. For this study, we included participants with iPhones, who were offered a study smartwatch (Apple Watch v.0 [Apple Inc]) to record vital data (step and heart rate data). The participants who owned an Apple Watch were allowed to use their own smartwatches. The participants in the eFHS were invited to download the eFHS smartphone app and were provided a written protocol that included information on how to download the app, enter the registration information, sign the consent forms, enable notifications on their phones, and set up the smartwatches. Daily battery charging was needed for this version of the Apple Watch. To maximize the data collection during the daytime, the participants were instructed to wear the smartwatch after waking up in the morning and take off the smartwatch at bedtime to charge the smartwatch battery.

A total of 1127 participants who enrolled in the eFHS chose to use a smartwatch (1010/1127, 89.62% from generation 3, 17/1127, 1.51% from NOS, and 100/1127, 8.87% from omni 2). These participants returned heart rate and step data from the smartwatch for up to 3 years. Participants who developed cardiovascular disease may have had severe health issues and may have confounded the association analyses in this study. The main aim of this study was to access long-term daily routine patterns in relation to diabetes status. Therefore, of the 1127 participants, we excluded a total of 331 (29.37%) participants (Multimedia Appendix 1). The excluded participants had cardiovascular conditions at the third FHS health examination (39/331, 11.8%), wore the smartwatch for <10 hours per day (43/331, 12.9%; see the *Outcome Variables* section), or returned smartwatch data for <30 days (249/331, 75.2%).

The Boston University Medical Campus institutional review board reviewed and approved the study, and all participants provided informed consent via the eFHS.

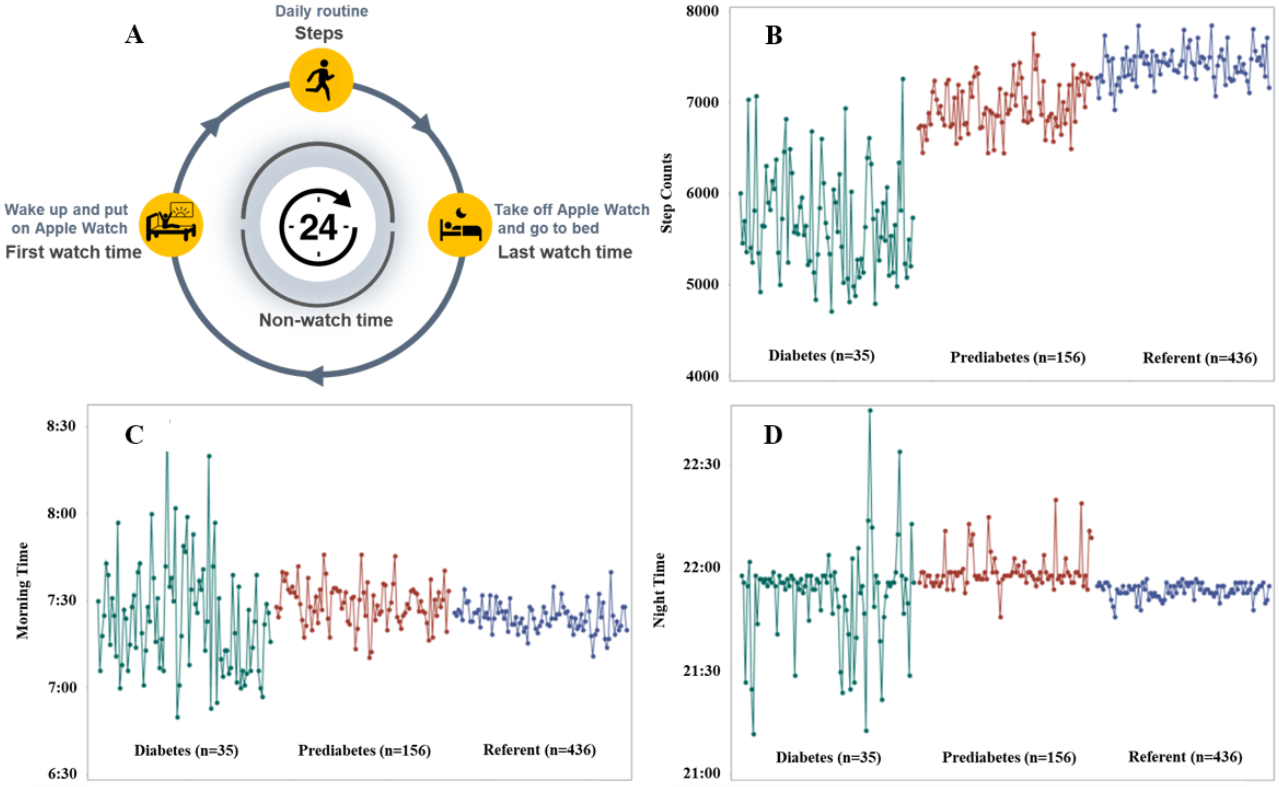
Outcome Variables

The participants in the eFHS were instructed to wear the smartwatch after waking up in the morning and remove the watch before bedtime. *Watch time* was the time during which any heart rate or step data were detected by the smartwatch. Therefore, on a calendar day, it was reasonable to assume that the first watch time (referred to as first watch time) reflected a participant's wake-up time. Similarly, the last watch time (referred to as last watch time) reflected a participant's bedtime (Figure 1**)**. However, it was difficult to determine whether a time detected by the watch was from the previous day or the following day if it occurred very late in the night or early in the morning (eg, after 12 AM and before 4 AM). We examined the distribution of the first watch time and last watch time on all calendar days. We found that 86% of the first watch time occurred after 4 AM on any calendar day and that 90% of the last watch time occurred after 7 PM on any calendar day (Multimedia Appendices 2 and 3). Therefore, we identified the first watch time if it occurred between 4 AM and noon (12 PM) on a given day. We excluded any person's day if the participant's first watch time was beyond this time interval. Similarly, we identified the last watch time if it occurred between 7 PM and midnight (ie, 12 AM), provided that a participant's first watch time occurred after 4 AM the following day. We excluded any person's day if the last watch time was beyond this time interval. The identified first watch time and last watch time were used as proxy measures to estimate wake-up times and bedtimes, respectively, on each day. For any 2 consecutive watch days, we calculated the non–watch time as the total time between the last watch time on a given watch day and the first watch time on the next watch day. Non–watch time was used as a proxy measure to estimate a participant's time spent asleep. To study the irregularity of daily routines for every participant, we calculated the mean value of the first watch time using the data collected during the entire eFHS study.

Next, we calculated the absolute deviations between the observed first watch times and the mean value on all follow-up days for each participant. Similarly, we calculated the absolute deviations for the last watch times and non–watch times for each participant on all follow-up days. The absolute deviations of the times for the 3 watch variables reflected the intraindividual variation of each watch time variable during the entire follow-up period. These repeated absolute deviations of the 3 watch time variables were used as outcome variables in association analyses with diabetes status.

In addition, we used repeated daily step counts collected from the smartwatch as an outcome variable for physical activity in association analyses with diabetes. Daily steps largely reflect people's routine daily physical activities, and previous studies support the use of daily step count as a measurement for assessing the association of physical activity with diabetes [13,28]. The Apple Watch used a built-in accelerometer to track users' wrist motion and then estimated the step counts [29]. We used repeated daily step counts collected from the smartwatch as an outcome variable for physical activity in association analyses with diabetes.

Figure 1. Daily routine pattern and observational measures of smart watch variables within 90 days of follow-up. (A) Variables of daily routine pattern of a participant. (B) The median values of daily step counts from participants in 3 diabetes categories within 90 days. (C) The median values of first watch time from participants in 3 diabetes categories within 90 days. (D) The median values of last watch time from participants in 3 diabetes categories within 90 days. The y-axis is the median value of daily steps (B), first watch time (C), and last watch time (D) using a 24-hour format.



Diabetes, Prediabetes, and Covariates at FHS Health Examination

At each health examination, blood samples were obtained after an overnight fast (approximately 10-12 hours), and plasma samples were immediately processed and kept at –80°C until assayed [25,30]. Glucose levels were measured in blood plasma [25,30]. We defined a 3-level categorical diabetes variable to classify participants with diabetes, prediabetes, or normal fasting blood glucose levels (ie, the referents). Diabetes was defined as a fasting blood glucose level ≥126 mg/dL or whether the participant was taking any blood glucose-lowering medications [31]. Prediabetes status was defined as a fasting blood glucose level of 100-125 mg/dL [31]. The referents were participants without diabetes or prediabetes. This 3-level diabetes category variable was used as the independent variable in all the statistical analyses.

Statistical Analyses

The baseline characteristics of the participants were described as means and SDs for continuous variables and frequencies (percentages) for categorical variables. We further compared the proportions of the remaining eFHS participants with diabetes and prediabetes with the referents at 30-, 60-, 90-, and 180-day windows.

After exclusion, we included the rest of the observations from the remaining participants in the association analysis. We applied a linear mixed regression model to investigate the associations between the outcome variables and diabetes category variables. The outcome variables were the repeated daily absolute deviations of the 3 watch time variables and repeated daily step counts.

We conducted 3 models. In the primary model, model 1, the covariates included sex, age, and self-reported race or ethnicity. Model 2 included BMI (kg/m^2) in addition to the covariates in model 1. Model 3 was further adjusted for current smoking and current alcohol consumption. Age, current smoking, and current alcohol consumption were collected in person during the third health examination.

In the analysis of steps as the outcome variable, we added the daily smartwatch wearing time as an additional covariate in the 3 models, as daily smartwatch wearing time was expected to be strongly associated with the number of daily steps.

All statistical analyses were performed using the SAS software (version 9.4; SAS Institute Inc). We used a 2-tailed P<.05 for significance.

To further investigate the daily step counts and the variation of the first watch time and last watch time from participants with diabetes and prediabetes versus referents during the study, we calculated and plotted the median value of each outcome variable per day from participants in each of the 3 diabetes categories. The number of participants (41/796, 5.2%) with diabetes was much smaller than the number of participants with prediabetes and the number of referents. To make a fair comparison, we performed a sampling procedure to randomly select 41 participants from the prediabetes and referent groups and plotted the median value of each outcome in the 3 diabetes categories.

Results

Characteristics of Study Participants

We excluded 331 participants (mean age 52.7, SD 8.5 years; 214/331, 64.7% women) who wore a smartwatch for <5 hours/day or remained in the study for <30 days. Of the 331 excluded participants, 19 (5.9%) had diabetes, 80 (24.6%) had prediabetes, and 226 (69.5%) had neither diabetes nor prediabetes (Multimedia Appendix 4). A total of 796 participants (710/796, 89.2% in generation 3, 12/796, 1.5% in NOS, and 74/796, 9.3% in omni 2) were included in the study. The median follow-up period of the participants in this study was 219 days (first quartile to third quartile: 109-377 days). Of the 796 participants, the study sample included 41 (5.2%) participants with diabetes, 209 (26.2%) with prediabetes, and 546 (68.6%) referents. The median follow-up duration for the participants in the 3 diabetes categories was not significantly different (Kruskal–Wallis test, *P*=.28). The participants with diabetes and prediabetes remained in the study for similar durations when we evaluated the 30-, 60-, 90-, and 180-day windows compared with the referents (Multimedia Appendix 5). For example, in the 90-day window, 85% (35/41) of participants with diabetes, 74.6% (156/209) of participants with prediabetes, and 79.9% (436/546) of referents remained in the study.

Compared with the referents (mean age 51.5, SD 8.7 years; 153/546, 28% men), participants with diabetes (mean age 57.4, SD 7.8 years; 24/41, 59% men) or prediabetes (mean age 55.3, SD 8.2 years; 125/209, 59.8% men) were older and tended to be men. In addition, as compared with referents, participants with diabetes or prediabetes had a higher BMI (33.4 kg/m^2 and 30.2 kg/m^2, respectively, vs 26.9 kg/m^2), a lower proportion of graduate or professional degrees (10/41, 24% and 50/209, 23.9%, respectively, vs 182/546, 33.3%), and a higher proportion of current smoking (2/41, 5% and 14/209, 6.7%, respectively, vs 19/546, 3.5%; Table 1). Participants with diabetes were less likely to drink alcohol than the referents (27/41, 66% vs 453/546, 83%; Table 1).

Table 1. Characteristics of the electronic Framingham Heart Study participants in this study (N=796).

Characteristics	Diabetes[a] (n=41)	Prediabetes[a] (n=209)	Referents (n=546)
Age (years), mean (SD)	57.4 (7.8)	55.3 (8.2)	51.5 (8.7)
Women, n (%)	17 (41.5)	84 (40.2)	393 (72)
Alcohol drinking (yes), n (%)	27 (65.9)	175 (83.7)	453 (83)
Smoking (yes), n (%)	2 (4.9)	14 (6.7)	19 (3.5)
Education, n (%)			
High school or less	7 (17.1)	21 (10)	33 (6.1)
Completed some college	13 (31.7)	51 (24.4)	116 (21.2)
Bachelor's degree	11 (26.8)	86 (41.1)	214 (39.2)
Graduate or professional degree	10 (24.4)	50 (23.9)	182 (33.3)
BMI (kg/m^2), mean (SD)	33.4 (6.4)	30.2 (5.0)	26.9 (5.1)
Daily step (step counts), mean (SD)	6216 (3634)	7980 (3851)	8120 (3902)
Variation of first watch time[b], mean (SD)	67 (57)	58 (53)	57 (51)
Variation of last watch time[b], mean (SD)	52 (39)	46 (37)	46 (37)
Variation of non–watch time[b], mean (SD)	77 (65)	66 (57)	66 (57)

[a]Diabetes was defined as fasting blood glucose ≥126 mg/dL or use of blood glucose-lowering medications. Prediabetes status was defined as a fasting blood glucose value between 100 and 126 mg/dL.

[b]Refer to Figure 1A and the *Methods* section for definitions. The unit for variation was minute.

We also compared the median daily smartwatch wearing time for participants in the 3 diabetes categories. The median daily watch-wearing time was the same: 14 hours (first quartile to third quartile: 13-15 hours; Kruskal–Wallis test for median daily smartwatch wearing times, *P*=.11) for the participants in all 3 groups.

We further compared the characteristics of participants in eFHS with the rest of the participants who were not enrolled in the eFHS but attended the third in-person FHS health examination. On average, the participants in this study were younger (mean age 52.8, SD 8.7 years) and had a better education (242/796, 30.4% had graduate or professional degrees) than those who were not in eFHS (mean age 56.8, SD 9.6 years; 252/1500, 16.8% had graduate or professional degrees). In addition, the eFHS participants appeared to be healthier. For example, this study included 5.2% (41/796) of participants with diabetes. In contrast, the participants who did not participate in the eFHS included 186 (186/1500, 12.4%) participants with diabetes (Multimedia Appendix 4).

Association Analyses of Daily Steps and Diabetes Status

We first visualized the median daily step count between the participants with diabetes and the referents at the 90-day window (Figure 1B and Multimedia Appendix 6). The median daily step

counts were between 4500 and 7200 for participants with diabetes. In contrast, the median daily step counts were between 6500 and 8000 for the referents (Figure 1B). We further performed association analyses to quantify the associations. On average, the participants with diabetes took 1611 fewer daily steps (95% CI 863-2360; *P*<.001) compared with referents, adjusting for age, sex, race, and daily watch-wearing time (Table 2). The participants with prediabetes took 392 fewer daily steps (95% CI 13-770; *P*=.04) compared with the referents. Adjusting for BMI in addition to age, sex, race, and daily watch-wearing time, the association between diabetes categories and average daily steps was greatly attenuated. In model 2, the participants with diabetes walked 773 fewer steps (95% CI 67-1479; *P*=.03) compared with referents (Table 2). The difference in the number of steps became nonsignificant between the participants with prediabetes and the referents after including BMI as an additional covariate (Table 2). Further adjustment for alcohol consumption and smoking as additional covariates slightly attenuated the associations between the diabetes categories and average steps (Table 2). In model 3, the participants with diabetes walked 799 fewer steps (95% CI 94-1503; *P*=.03) compared with referents (Table 2). To investigate whether the follow-up duration may confound the association between step counts and diabetes status, we included the number of follow-up days as an additional covariate in model 1 for a sensitivity analysis. We observed a minimum change in the regression estimate for daily step counts as the outcome variable (Multimedia Appendix 7).

Table 2. Association between diabetes categories and daily routine patterns measured by the smartwatch.

Outcome and diabetes categories	Model 1[a]		Model 2[b]		Model 3[c]	
	Mean differences (95% CI)	*P* value	Mean differences (95% CI)	*P* value	Mean differences (95% CI)	*P* value
Daily steps[d]						
Referent	Reference	N/A[e]	Reference	N/A	Reference	N/A
Prediabetes	−392 (−770 to −13)	.04	−11 (−380 to 359)	.96	−2 (−371 to 367)	.99
Diabetes	−1611 (−2360 to −863)	<.001	−773 (−1479 to −67)	.03	−799 (−1503 to −94)	.03
Variation of first watch time[f]						
Referent	Reference	N/A	Reference	N/A	Reference	N/A
Prediabetes	3 (0 to 7)	.048	3 (−1 to 6)	.10	3 (−1 to 6)	.12
Diabetes	12 (6 to 18)	<.001	11 (4 to 17)	.001	10 (4 to 17)	.002
Variation of last watch time[f]						
Referent	Reference	N/A	Reference	N/A	Reference	N/A
Prediabetes	1 (−1 to 3)	.16	1 (−1 to 3)	.29	1 (−1 to 3)	.37
Diabetes	6 (2 to 9)	.005	5 (1 to 9)	.02	5 (1 to 9)	.02
Variation of non–watch time[f]						
Referent	Reference	N/A	Reference	N/A	Reference	N/A
Prediabetes	3 (−1 to 6)	.19	1 (−2 to 5)	.45	1 (−3 to 5)	.62
Diabetes	13 (6 to 20)	<.001	10 (3 to 17)	.006	10 (2 to 17)	.009

[a]Model 1 covariates included sex, age, and race or ethnicity at the Framingham Heart Study health examination.

[b]Model 2 covariates included sex, age, race or ethnicity, and BMI at the Framingham Heart Study health examination.

[c]Model 3 covariates included sex, age, race or ethnicity, BMI, smoking, and alcohol drinking at the Framingham Heart Study health examination.

[d]In the analysis of daily steps as the outcome variable, we added daily smartwatch wearing time as an additional covariate in the 3 models.

[e]N/A: not applicable.

[f]The unit for variation is minute.

Association Analyses of Variations in Watch Times With Diabetes

The participants with diabetes had larger variations in their day-to-day median values of the first watch time compared with the referents (Figure 1C and Multimedia Appendix 8). Using the 90-day window as an example, the median values of first watch times were between 6:45 AM and 8:30 AM for the participants with diabetes. In contrast, the median values of first watch times were between 7:15 AM and 7:45 AM for the referents (Figure 1C). Similar results were observed using the sampling procedures (Multimedia Appendix 8). In model 1, adjusting for age, sex, and race, on average, participants with diabetes had 12 more minutes (95% CI 6-18; *P*<.001) in the variation of the first watch time compared with the referents (Table 2). The variation in first watch time was also significantly

different between the participants with prediabetes and the referents (*P*=.048; Table 2).

The participants with diabetes had a much larger variation in their median values of the last watch time compared with the referents (Figure 1D and Multimedia Appendix 9). The medians of last watch time were between 9:20 PM and 22:40 PM for the participants with diabetes; however, it was between 9:45 PM and 10 PM for the referents (Figure 1D). In model 1, on average, participants with diabetes had 6 more minutes (95% CI 2-9; *P*=.005) in the variation of last watch time compared with the referents (Table 2), adjusting for age, sex, and race. Similarly, the participants with diabetes had 13 more minutes of variation in non–watch time (95% CI 6-20; *P*<.001) compared with the referents (Table 2). The participants with prediabetes did not have significant differences in the variation of last watch time or non–watch time compared with the referents.

Adjusting for BMI in addition to age, sex, and race or ethnicity, the associations between diabetes category variables and variation in watch time variables slightly attenuated in the magnitude of associations. In model 2, participants with diabetes had 11 more minutes (95% CI 4-17; *P*=.001) in the variation of the first watch time, 5 more minutes (95% CI 1-9; *P*=.02) in the variation of the last watch time, and 10 more minutes (95% CI 3-17; *P*=.006) in the variation of the non–watch time compared with the referents (Table 2). In model 3, adjusting for alcohol consumption and smoking as additional covariates, all the estimates in both the prediabetes group and the diabetes group remained similar to model 2 (Table 2). In a sensitivity analysis, we included the number of follow-up days and daily smartwatch wearing time in addition to the covariates included in model 1. We observed a slight change in beta estimates for the first watch time, last watch time, and non–watch time (Multimedia Appendix 7).

Discussion

Principal Findings

To understand how daily routines function in persons with diabetes, we evaluated the associations of daily routine variables derived from a smartwatch with diabetes status in the eFHS, a community-based cohort of middle-aged to older adults. In this study, we derived several variables to reflect daily routine patterns based on smartwatch data over a long follow-up period in a home environment. We observed that the participants with diabetes, on average, walked significantly fewer steps per day compared with the referents without diabetes, adjusting for a few sets of covariates. In addition, on average, the participants with diabetes had significantly larger intraindividual variations in their daily routine patterns reflected by the first watch time, last watch time, and non–watch time compared with the referents, adjusting for the same sets of covariates.

The observation that the participants with diabetes and prediabetes walked significantly fewer daily steps compared with the referents supported the previous findings that participants with higher daily steps had a lower risk of incident diabetes [32]. In addition, the observations that the participants with diabetes had larger variations in their daily routine pattern variables than the referents are consistent with an earlier study showing that irregular daily routines are highly prevalent among adults with diabetes [11,33,34]. Previous studies have also reported that sleep abnormalities are linked to impairments in glucose homeostasis, metabolic syndrome, and diabetes [35,36]. Shift work or irregular sleep–wake cycles may increase the risk of developing diabetes [10,37,38]. Most of these previous studies collected data from laboratory tests with a small number of participants during a short study period (eg, approximately 100 participants over a few weeks) or questionnaires [10,37]. Our study used a novel approach in that we collected daily routine patterns (eg, watch times and daily steps) from smartwatches worn by 796 participants with up to 3 years of smartwatch use.

As a nested study, the eFHS was initiated at the in-person FHS health examination and completed 3 years later. To the best of our knowledge, this is the longest mHealth study with a relatively large number of middle-aged to older adult participants. However, this study was cross-sectional with respect to diabetes status as the disease status was evaluated at the time of enrollment of the eFHS. Nevertheless, the study participants were middle-aged to older adults, and their daily routine patterns were collected for >30 days and up to 3 years. Therefore, we speculated that the observations were likely to reflect their habitual daily routine patterns in adulthood. To that end, irregular daily routines (eg, daily sleep and wake-up patterns) and lower physical activity (eg, daily steps) may play important roles in the development of diabetes and are also critical in diabetes self-management.

We acknowledge that this study had several limitations. The analyses were cross-sectional with the eFHS and were ascertained after the diabetes status was evaluated at an FHS health examination; therefore, we were unable to evaluate the causal relationships between the habitual daily routine patterns and the development of diabetes. In addition, the magnitude of associations of diabetes and watch time variables was modest (<15 minutes), despite the fact that the median watch times of participants with diabetes in a 90-day follow-up had a noticeably higher day-to-day variation in the first watch time and last watch time as compared with referents. The wake-up time and bedtime were not directly measured with a standard accompanying digital survey for sleep times, although the eFHS participants were provided clear instructions that they should wear the study smartwatch daily after waking up and remove it at bedtime for charging. In addition, applying exclusions to remove low-quality data reduced the sample size from 1043 to 796. The characteristics of the excluded participants were similar to those of the included participants, indicating that the removal of participants was not likely to bias the analyses (Multimedia Appendix 4). The eFHS participants were likely to have a higher socioeconomic status, which was reflected in the lower rates of prediabetes and diabetes compared with the rest of FHS participants at the health examination; therefore, the findings in this study may not be generalizable to other populations at a higher risk for diabetes. Furthermore, the eFHS participants were middle-aged to older adults of mostly European origin from New England; thus, the generalizability of our findings to participants of other age ranges or race or ethnicities in different geographical areas remains to be studied. Moreover, the small

number of participants with diabetes gave rise to wide CIs for the effect sizes. Therefore, further studies are warranted to replicate our findings.

Conclusions

In conclusion, the eFHS is a digital cohort embedded in a traditional community-based longitudinal cohort study. Therefore, the study participants had comprehensive and accurate measures for most characteristics of their cardiovascular health. The use of the smartwatch to collect habitual physical activity and sleep behaviors in eFHS complements the traditional measurements to evaluate the role of daily routine variables in cardiovascular health. Our findings have important public health implications, as lifestyles are becoming increasingly sedentary around the globe, and the regularity of sleep behaviors is considerably disturbed by the modern environment [9,34]. On the basis of the findings of this study, health care professionals should encourage and motivate people with diabetes to increase their physical activities (eg, step counts) and maintain regular sleep behaviors, which are important for diabetes self-management. Indeed, this study has demonstrated that mHealth is a feasible and powerful approach for investigating the associations between daily routine activities and health outcomes in a traditional prospective cohort. Nevertheless, the results of this study were preliminary and hypothesis generating. Future larger mHealth studies are needed to replicate these findings. Dropout in epidemiological studies, including this study, is also an important issue in all mHealth studies. Thus, it is important to develop effective strategies to enhance adherence to improve the usefulness of mHealth in large cohort studies. In addition, advanced statistical methods are needed to account for the complex data structure and missing data of longitudinal mHealth data. With the increasing use of smartphones and the continuous improvement of mobile devices, mHealth studies will greatly enhance our understanding of the role of daily routines and lifestyle factors in the development of human diseases.

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Conflicts of Interest

DDM has received research support from Apple Computer, Bristol–Myers Squibb, Boehringer–Ingelheim, Pfizer, Flexcon, Samsung, Philips Healthcare, and Biotronik, and he has received consultancy fees from Bristol–Myers Squibb, Pfizer, Flexcon, Boston Biomedical Associates, and Rose Consulting. DDM also declares financial support for serving on the Steering Committee for the GUARD-AF study (NCT04126486) and advisory committee for the Fitbit Heart study (NCT04176926). VK is a principal, and CN is an employee of CareEvolution, Inc, a health care technology company. Apple was not involved in the study design, analysis, interpretation, or reporting of study results. Starting 2020, EJB was an uncompensated member for MyHeartLab Steering Committee, a principal investigator–initiated study from Samsung to University of California, San Francisco principal investigator Jeffrey Olgin, MD. NLS received funding from Novo Nordisk for an investigator-initiated research grant unrelated to the current paper. JMM received funding as a guest lecturer for Merck unrelated to this work. The remaining authors declare no conflicts of interest.

Multimedia Appendix 1
Flow chart of exclusion process.
[DOCX File , 39 KB - diabetes_v7i1e29107_app1.docx]

Multimedia Appendix 2
Distribution of first watch time.
[DOCX File , 27 KB - diabetes_v7i1e29107_app2.docx]

Multimedia Appendix 3
Distribution of last watch time.
[DOCX File , 27 KB - diabetes_v7i1e29107_app3.docx]

Multimedia Appendix 4
Characteristics of 3522 participants at Framingham Heart Study health examination.
[DOCX File , 14 KB - diabetes_v7i1e29107_app4.docx]

Multimedia Appendix 5
Sample sizes for 4 follow-up time windows.
[DOCX File , 13 KB - diabetes_v7i1e29107_app5.docx]

Multimedia Appendix 6
The median values of daily step counts from participants in 3 diabetes categories within 90 days with sampling of the same sample size.
[DOCX File , 2196 KB - diabetes_v7i1e29107_app6.docx]

Multimedia Appendix 7
Association between diabetes categories and daily routine patterns measured by the smartwatch.
[DOCX File , 16 KB - diabetes_v7i1e29107_app7.docx]

Multimedia Appendix 8
The median values of first watch time from participants in 3 diabetes categories within 90 days with sampling of the same sample size.
[DOCX File , 2770 KB - diabetes_v7i1e29107_app8.docx]

Multimedia Appendix 9
The median values of last watch time from participants in 3 diabetes categories within 90 days with sampling of the same sample size.
[DOCX File , 2327 KB - diabetes_v7i1e29107_app9.docx]

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Abbreviations

eFHS: electronic Framingham Heart Study
FHS: Framingham Heart Study
mHealth: mobile health
NOS: new offspring spouses

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Original Paper

Evaluation of a Web Platform to Record Lifestyle Habits in Subjects at Risk of Developing Type 2 Diabetes in a Middle-Income Population: Prospective Interventional Study

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Abstract

Background: Lifestyle is the focus of type 2 diabetes (T2D) prevention strategies. Prevention strategies using mobile health (mHealth)–based therapy have shown positive results for T2D prevention in high-income settings, but little is known about their effectiveness in low- and middle-income populations where the burden of T2D is substantial. “Vida Sana” is a web platform designed to record lifestyle habits and medication use within a lifestyle change program.

Objective: We sought to identify the barriers, feasibility, usability, and effectiveness of Vida Sana to record lifestyle habits in subjects at risk of developing T2D in a middle-income setting.

Methods: This was a 3-month prospective interventional study in Mexican individuals. A total of 77 subjects at risk of T2D (with prediabetes and BMI between 24 and 40 kg/m^2) were selected. Feasibility was assessed by study retention. Usability was evaluated with the System Usability Scale (SUS). Effectiveness measures included changes in weight, body composition, BMI, glycated hemoglobin A_{1c} (HbA_{1c}), and fasting blood glucose from baseline to 3 months. Linear regression models were used to account for covariates.

Results: The feasibility of Vida Sana was 42%, with 33 subjects using the platform, and the usability was 48.7 (SD 14.24). Reported barriers to platform usage were; difficulty in accessing the platform from difficulty of use (12 subjects, 36%), lack of time to record their habits (11 subjects, 34%), lack of interest to record their habits (6 subjects, 18%), and lack of resources (4 subjects, 11%). The platform was effective for lowering glucose in fasting (–3.1 mg/dL vs –0.11 [SD 8.08] mg/dL; *P*=.038) and at 2 hours (–16.9 mg/dL vs 2.5 [SD 26.1] mg/dL; *P*=.045), body fat percentage (–1.3 [–2.2 to –0.7] vs –1.02 [–1.9 to –0.3]; *P*=.02), and waist circumference (–3.2 [SD 5.1] cm vs –1.7 [SD 5.0] cm; *P*=.02) independent of their age, sex, treatment, and education level.

Conclusions: The use of the web platform was effective for improving glycemic and anthropometric parameters in a population at risk of developing diabetes. Improving accessibility and ease of navigation could improve the acceptance of digital health solutions in a middle-income population.

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KEYWORDS

mHealth; prediabetes; type 2 diabetes; preventive medicine; diabetes; lifestyle; body mass index

Introduction

Type 2 diabetes (T2D) is a global health threat, and it is rapidly increasing worldwide, particularly in low- and middle-income countries [1]. T2D prevention has been declared a target priority by the World Health Organization [2] and the United Nations [3]. Target populations for prevention comprise people at high risk, such as those in the prediabetes state. Prediabetes is characterized by increased glucose concentrations without reaching T2D levels [4].

The most effective therapy to decrease T2D risk is lifestyle modification [5] and, in some cases, addition of pharmaceutical therapy [6]. Weight loss and improvements in body composition have been established as therapeutic targets in prediabetes management [6]. However, low adherence rates to lifestyle changes are major concerns in lifestyle modification trials [5,7-11]. Self-monitoring of lifestyle habits (ie, recording dietary intake, eating habits, physical activity, emotional state, sleeping hygiene, alcohol consumption, and smoking habits) is an effective tool to increase patients' adherence to and awareness about their habits [6]. However, in some cases, the lack of a repository to track the records results in implementation difficulties.

Telemedicine has the potential to overcome barriers to treatment, such as self-monitoring, long distances to clinics, and long waiting times. Telemedicine is likely to continue growing and become more prevalent in medical care, especially due to the pressures placed on the health care system by the COVID-19 pandemic [12]. Most web-based interventions are more affordable than face-to-face therapy, allowing for broad dissemination of treatment, flexibility, and greater access. Although the use of health apps in dietary practice is common, the current digital applications for dietary counseling have not been extensively investigated [13]. The reports available describe high-income settings, and the effectiveness in other populations with different rates of metabolic disorders and social determinants of health is unknown. Hence, evidence regarding the barriers, feasibility, and effectiveness of these technologies is needed, particularly where the burden of T2D is substantial and access to highly trained health care professionals is limited. The aim of this study is to identify the barriers, feasibility, usability, and effectiveness of a web platform to record lifestyle habits in subjects at risk of developing T2D in a middle-income setting.

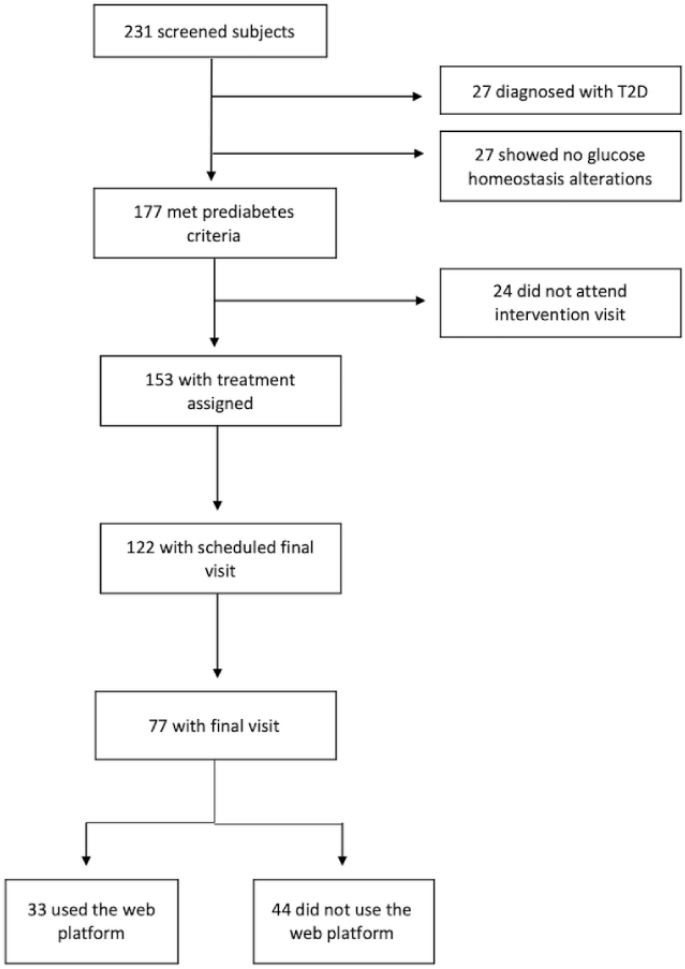
Methods

Study Participants

Participants were recruited at the Research Unit for Metabolic Diseases (UIEM) of the public hospital Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (INCMNSZ) in Mexico City from September 2018 to March 2020, as outlined in Figure 1. Participants were invited through telephone calls as well as physical and electronic advertisements posted on the campuses and Facebook pages of UIEM and INCMNSZ, respectively. The prospective participants were subjects seeking treatment at the diabetes, obesity, internal medicine, or dyslipidemia outpatient clinics at the INCMNSZ, one of the most important institutions treating metabolic disorders in the country covering the largest population in the south of the Valley of Mexico. The criteria for selecting the study subjects were as follows: meeting at least 1 of the prediabetes criteria according to the American Diabetes Association, namely fasting glucose between 100 and 124 mg/dL, glycated hemoglobin A_{1c} (HbA_{1c}) between 5.7 and 6.4, and 2-hour blood sugar level of 140 to 199 mg/dL after an oral load of 75 grams of glucose [4]. We included males and females aged between 18 and 65 years, and they were overweight or obese (BMI between 25 and 40 kg/m^2).

Exclusion criteria included chronic diseases, pregnancy, chronic use of medications that alter plasma glucose levels, and subjects under or unable to maintain nutritional or physical activity therapies. The research protocol was approved by the ethics committee of the INCMNSZ. Written informed consent was obtained from each participant. Research was conducted according to the principles expressed in the Helsinki Declaration of Human Studies.

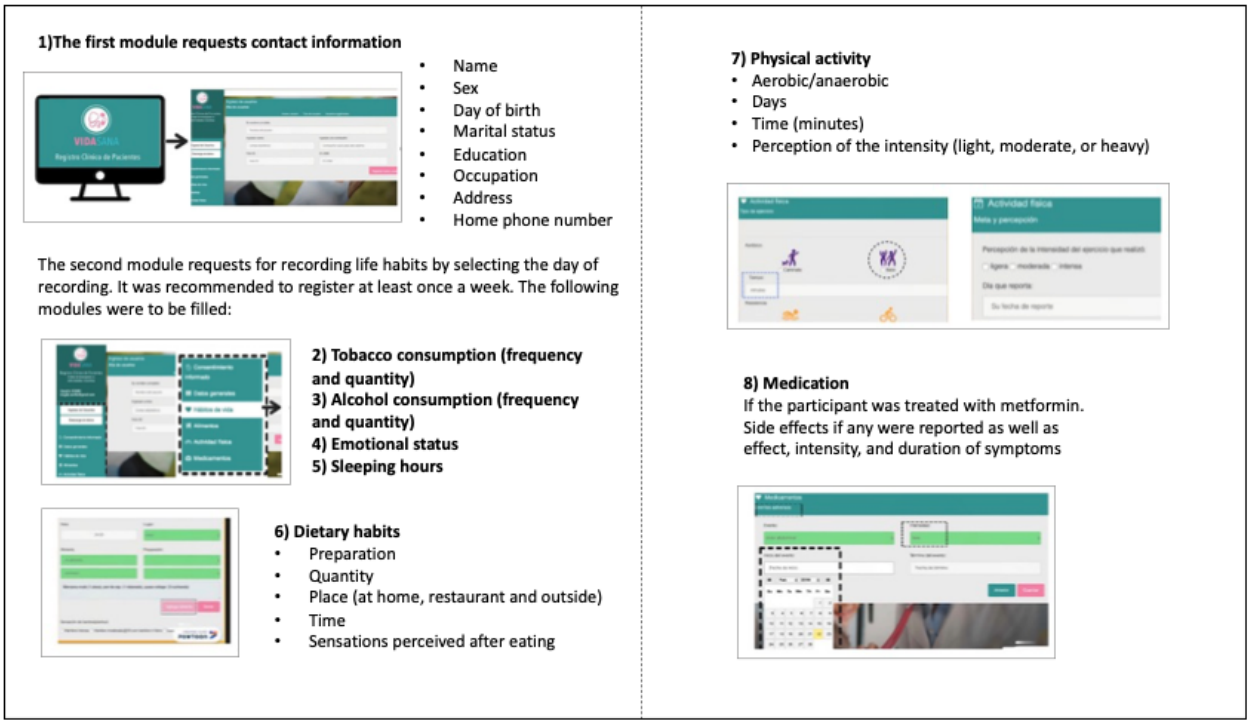
Figure 1. Number of individuals involved in the recruitment and screening process for selecting study participants. T2D: type 2 diabetes.



Description of the Vida Sana Platform

Vida Sana is a web platform designed for this study by researchers of the Network for Research Support of the Universidad Nacional Autonoma de Mexico in 2017 to record lifestyle habits. User profiles were created for all participants using their email addresses. They accessed the platform either on a mobile phone or using a computer with internet. The dietitian explained the aims and scopes of the platform and trained the participants by filling an example record along with them during the first visit. In addition, participants were provided a video with instructions for using the web platform. The platform was composed of eight modules: (1) The first section in the first module asks for contact information, and the second section requests for recording lifestyle habits by selecting the day of recording. The other modules are as follows: (2) “tobacco consumption” indicating yes or no, and the number of cigarettes consumed if the answer is yes; (3) “alcohol consumption,” indicating the type of drink (options: beer, wine, liquor, and distilled) and the number of drinks; (4) predominant “emotional state” during the day (sad, anxious, angry, bored, guilty, happy, tired, and a blank space to type any other mood); (5) “hours of sleep,” (options: less than 4 hours, 4 hours, 5 hours, 6 hours, 7 hours, 8 hours, 9 hours, 10 hours, or more than 12 hours; and if they felt rested when awake). (6) “dietary habits” for recording the food consumed in 24 hours, splitting it into meals (breakfast, lunch, dinner, and snacks), and the time and place where the meals were consumed (house, restaurant, and work). Furthermore, the subjects are also required to enter the amount consumed in units (grams, pieces, cups, spoons, and milliliters) and the type of preparation (fried, weathered, breaded, roasted, boiled, raw, and stewed). Vida Sana also offers the option to select perceived sensations after eating (intense hunger, moderate hunger, neither hungry nor full, satisfied, and hard to digest). (7) “physical activity” for entering the type of exercise performed (options: aerobic exercises, such as walking, dancing, and aerobics; resistance exercises, such as swimming, cycling, garters, and weights; and flexibility exercises). Participants also had to enter the perception of the intensity with which they performed the exercise, namely light, moderate, or intense. (8) “medication” for entering the dose, frequency, and duration of intake, and secondary symptoms such as nausea, vomiting, abdominal pain, dizziness, diarrhea, constipation, and dry mouth, with the option of tracking the beginning of the symptoms (Figure 2).

Figure 2. Vida Sana description. It is composed of 8 modules, 1 for personal information, and 7 for recording habits: tobacco consumption, alcohol consumption, emotional status, sleeping hours, dietary habits, physical activity, and medications.



Study Procedures

This was a 3-month follow-up intervention trial, with 2 arms of intervention including lifestyle changes and lifestyle changes + metformin. The study covered six visits: screening, 4 intermediate visits, and 1 final visit. In the first visit, subjects underwent a 3-hour oral glucose tolerance test [14] and body composition assessment involving dual-energy X-ray absorptiometry to confirm compliance with the inclusion criteria. In addition, anthropometric measurements were recorded; waist and hip circumferences (to the nearest 0.5 cm) were measured at the midpoint between the lower ribs and the iliac crest, and at the level of the trochanter major, respectively. Participants who met the inclusion criteria were invited to return for the intervention visit in the following week.

The intervention included lifestyle modification counseling with the goal of reaching a weight loss of >3%. Nutritional and physical activity modifications were prescribed by a dietitian. The nutritional care process [15] was used to establish patients' evaluations, diagnosis, and interventions. The strategies aimed to reduce caloric intake, with the following macronutrient distribution: 45% carbohydrates, 25% protein, and 30% lipids in the total caloric intake. The number of calories were determined by reducing 500 kcal from the total energy expenditure. The minimum and maximum calories established in the study were 1300 and 1900 kcal, respectively. Some individuals were randomly prescribed 750-mg extended-release metformin every 12 hours to evaluate the "medication" module of the web platform. During the intervention visit, patients were asked for their email accounts to give them access to the Vida Sana web platform.

Participants were asked to return every 2 weeks for follow-up visits to undergo lifestyle modification counseling for reinforcing their knowledge toward fulfillment of their treatment goals. These visits took place at the UIEM, according to the subjects' availability of time. Body composition measurements were conducted using a bioimpedance instrument (SECA mBCA514).

The final visit took place 12 weeks after the intervention visit. Laboratory tests and body composition measurements were conducted, and questionnaires for diet and physical activity were used.

Questionnaires and Calculations

Daily energy, and macronutrient and micronutrient intakes were assessed through a 24-hour food recall. Data were analyzed using ESHA's Food Processor® Nutrition Analysis software. For baseline and final visits, body composition was assessed through dual- energy X-ray absorptiometry (General Electric); patients were asked to fast for a minimum of 4 hours. For assessing insulin resistance, we used the homeostasis model assessment for insulin resistance given by the following formula: glucose × fasting insulin/405 and the oral glucose insulin sensitivity index (OGIS) [16,17].

Outcome Measurements

The feasibility of Vida Sana was assessed by self-reports through a single question asked to each of the participants: "Did you use the web platform during the study?" Barriers were evaluated by asking the following question to those who did not use the platform: "Which barriers did you find for not using Vida Sana?" Vida Sana's usability was assessed with the System Usability Scale (SUS) [18] among individuals who reported usage of the platform at least twice during the study.

Effectiveness measurements included changes in fasting glucose, glucose at 120 minutes, body fat percentage, waist circumference, visceral adipose tissue, and free-fat mass index. The intervention was not expected to pose any serious risk of adverse events (AEs) for participants. Participants were instructed to call the research team over telephone in case of an adverse event (AE) so that they could provide details for determining whether the event was related or unrelated to the intervention.

Biochemical and Sample Analyses

Measurements derived from the oral glucose tolerance test included glucose levels, insulin, and lipid profiles, determined using colorimetric enzymatic methods (Unicel DxC 600 Synchron Clinical System, Beckman Coulter). Insulin was measured with a chemiluminescence essay (Access 2, Beckman Coulter). As for HbA_{1c}, a 4-mL peripheral blood sample was drawn via venipuncture using the standardized technique and measured using a Variant II Turbo system (BIORAD); the method used was high pressure liquid chromatography.

Statistical Analysis

Participants who did not attend their follow-up visits in the first 2 months and those with more than 20% of missing data were not considered during the analysis. The baseline characteristics of the study population were analyzed with descriptive statistics. Quantitative variables were reported as means and SDs for parametric variables, and medians and IQRs for nonparametric variables. Normality was assessed using the Kolmogorov-Smirnov test. Qualitative variables were presented as frequencies and percentages. For continuous outcome measures, the delta from baseline was calculated by subtracting the value of the baseline visit from that of the final visit. To estimate statistical differences between those who used Vida Sana and those who did not use it, a *t* test or Mann-Whitney *U* test was conducted according to the variable distribution. Differences before and after treatment were computed with a paired *t* test or Wilcoxon test according to the distribution. Fold changes were computed to account for baseline values. Lineal regression models were used to adjust for covariates using fold changes as the outcomes and age, sex, treatment, and education attainment as the confounders. All analyses were performed using the R software package (version 3.6.1; The R Project for Statistical Computing).

Results

Population Characteristics

The population baseline characteristics are given in Table 1. A total of 231 subjects were screened to participate in the study; however, the recruitment was interrupted by the COVID-19 pandemic, and only 77 individuals completed the 3-month intervention. The population was mainly composed of women (54/77, 70%). The mean age of the final sample was 48.45 (SD 11.32) years, and the most frequently altered diagnostic criterion was HbA_{1c} in 33 subjects (42%) with a mean of 5.90% (SD 0.26%). The lifestyle modification arm comprised 45 subjects (58%), whereas the metformin + lifestyle modification arm comprised 33 subjects (43%). Eating habits of the participants reflect unhealthy habits such as deficiency in fiber intake with a mean consumption of 16.75 (SD 16.51) grams, indicating a lower fiber consumption compared with that given in the World Health Organization guidelines [19]. Likewise, excess consumption of simple sugars was observed, with a median of 49.89 grams, exceeding the recommended daily intake of 25 grams [19].

Table 1. Baseline population characteristics (N=77)[a].

Characteristic	Value
Age (years), mean (SD)	48.4 (11.3)
Male, n (%)	24 (30)
Education attainment, n (%)	
Elementary school diploma	4 (5.1)
Junior high school diploma	7 (9)
High school diploma	17 (22)
Technician degree	3 (3.8)
Bachelor's degree	37 (48)
Graduate school degree	9 (11.6)
Treatment, n (%)	
Lifestyle modification	45 (57.6)
Lifestyle modification + metformin	33 (42.3)
Fasting glucose (mg/dL), mean (SD)	97 (9.6)
Glucose after 120 minutes (mg/dL), mean (SD)	127 (26.2)
HbA_{1c}[b] (%), mean (SD)	5.9 (0.2)
Fasting insulin (U/mL), mean (SD)	7.9 (4.2)
Cholesterol (mg/dL), mean (SD)	188.7 (37.6)
Triglycerides (mg/dL), mean (SD)	151 (92)
HOMA[c], mean (SD)	1.9 (1.1)
OGIS[d], mean (SD)	404.4 (77.0)
Weight (kg), mean (SD)	78.8 (13.4)
BMI (kg/m^2), mean (SD)	30.4 (4.4)
Waist circumference (cm), mean (SD)	98.5 (11.4)
WHR[e], mean (SD)	0.9 (0.07)
Body fat (%), mean (SD)	40.2 (7.0)
Free-fat mass index, mean (SD)	17.0 (2.0)
VAT[f] (g), mean (SD)	1219.5 (488.5)
Daily caloric intake (kcal), mean (SD)	1863.1 (1193.9)
Daily protein consumption (%), mean (SD)	17.6 (6.5)
Daily fat consumption (%), mean (SD)	31.1 (9.0)
Carbohydrate consumption (%), mean (SD)	51.4 (12.6)
Daily average sugar consumption (g), mean (SD)	49.8 (52.5)
Daily average fiber consumption (g), mean (SD)	16.7 (16.5)
Sleep (hours), mean (SD)	6.4 (1.1)

[a]Variables are presented as means and SDs or medians and IQRs according to the variable distribution.

[b]HbA_{1c}: glycated hemoglobin A_{1c}.

[c]HOMA: homeostasis model assessment.

[d]OGIS: oral glucose insulin sensitivity index.

[e]WHR: waist-hip ratio.

[f]VAT: visceral adipose tissue.

After the 3-month intervention, 4 of the 77 subjects (5.12%) progressed to T2D, whereas prediabetes regression was observed in 9 subjects (12%); 64 subjects (82%) remained in the prediabetes state. Overall, 44 subjects (56%) reached the total body weight loss goal of >3%. The average weight loss per person was 2.92 (SD 2.77) kg.

Feasibility and Usability

Out of the 77 subjects, 33 (42%) reported using Vida Sana. Among the subjects who did not use the platform, the main barriers reported were classified into four main categories: difficulty in accessing the web platform owing to difficulties in using the platform (16, 36%), lack of time to record their habits (15, 34%), lack of interest to record their habits (8, 18%), and lack of resources (computer or internet) (5, 11.36%). The usability of Vida Sana was estimated to be 48% (SD 14.24%) (low usability) according to the SUS. Through the questionnaire, the subjects reported the following weaknesses and strengths: The better functioning of the web platform on a computer than on a mobile phone made the recording process complicated. Similarly, the number of sections to be completed was found to be considerably high. Lastly, having to type the answers instead of selecting options made the recording process cumbersome. The positive aspects were that the web platform did not need detailed usage training or previous experience using electronic applications.

Table 2 presents the participant details based on their usage of Vida Sana at baseline. Statistically significant differences were found in fasting glucose concentrations (P=.04) and education attainment (P=.006).

Table 2. Baseline characteristics of the population based on platform usage (N=77)[a].

Characteristics	Used web platform (n=33)	Did not use web platform (n=44)	*P* value[b]
Age (years), mean (SD)	48 (12.0)	48.4 (10.8)	.89
Male, n (%)	12 (36.3)	12 (27.2)	.39
Education attainment, n (%)			.006
Elementary school diploma	0 (0)	4 (9)	
Junior high school diploma	0 (0)	7 (15.9)	
High school diploma	4 (12.1)	13 (29.5)	
Technical degree	2 (6)	1 (2.2)	
Bachelors' degree	22 (66.6)	15 (34)	
Graduate school degree	5 (15.1)	4 (4)	
Treatment, n (%)			.18
Lifestyle modification	6 (48.4)	28 (63.6)	
Lifestyle modification +metformin	17 (51.5)	16 (36.3)	
Fasting glucose (mg/dL), mean (SD)	94.6 (9.0)	99 (9.6)	.05
Glucose at 2 hours (mg/dL), mean (SD)	125.2 (28.1)	130 (24.9)	.44
HbA_{1c}[c] (%), mean (SD)	5.8 (0.3)	5.9 (0.2)	.52
HOMA[d], mean (SD)	1.7 (0.9)	2.0 (1.3)	.22
OGIS[e], mean (SD)	406 (86.1)	403 (70.1)	.87
Weight (kg), mean (SD)	81.4 (16.5)	78.5 (13.7)	.40
BMI (kg/m^2), mean (SD)	30.8 (16.5)	30.6 (4.2)	.87
Waist circumference (cm), mean (SD)	98.6 (12.3)	99.2 (11.8)	.84
WHR[f], mean (SD)	0.91 (0.7)	0.92 (0.0)	.68
Body fat (%), mean (SD)	32.5 (7.1)	40.7 (6.9)	.44
Free-fat mass index, mean (SD)	17.2 (2.2)	16.8 (1.8)	.41
VAT[g] (g), mean (SD)	1269 (609)	1183.6 (381)	.48
Daily caloric intake (kcal), mean (SD)	1228 (1313)	2031 (1129)	.89
Daily caloric protein intake (%), mean (SD)	18.2 (4.1)	16.3 (7.5)	.21
Daily lipid intake (%), mean (SD)	31.2 (10.3)	31.4 (12)	.97
Carbohydrate consumption (%), mean (SD)	51.7 (12.9)	50.9 (11.9)	.99
Sugar consumption (g), mean (SD)	65.1 (42.3)	55.6 (40.8)	.32
Fiber consumption (g), mean (SD)	16.7 (14.7)	17.5 (17.6)	.75
Sleep (hours), mean (SD)	6.3 (0.9)	6.5 (1.1)	.39

[a]Variables are presented as means and SDs or medians and IQRs according to their distribution.

[b]*P* values were calculated from Student *t* or Mann-Whitney *U* tests according to the distribution.

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

[d]HOMA: homeostasis model assessment.

[e]OGIS: oral glucose insulin sensitivity index.

[f]WHR: waist-hip ratio.

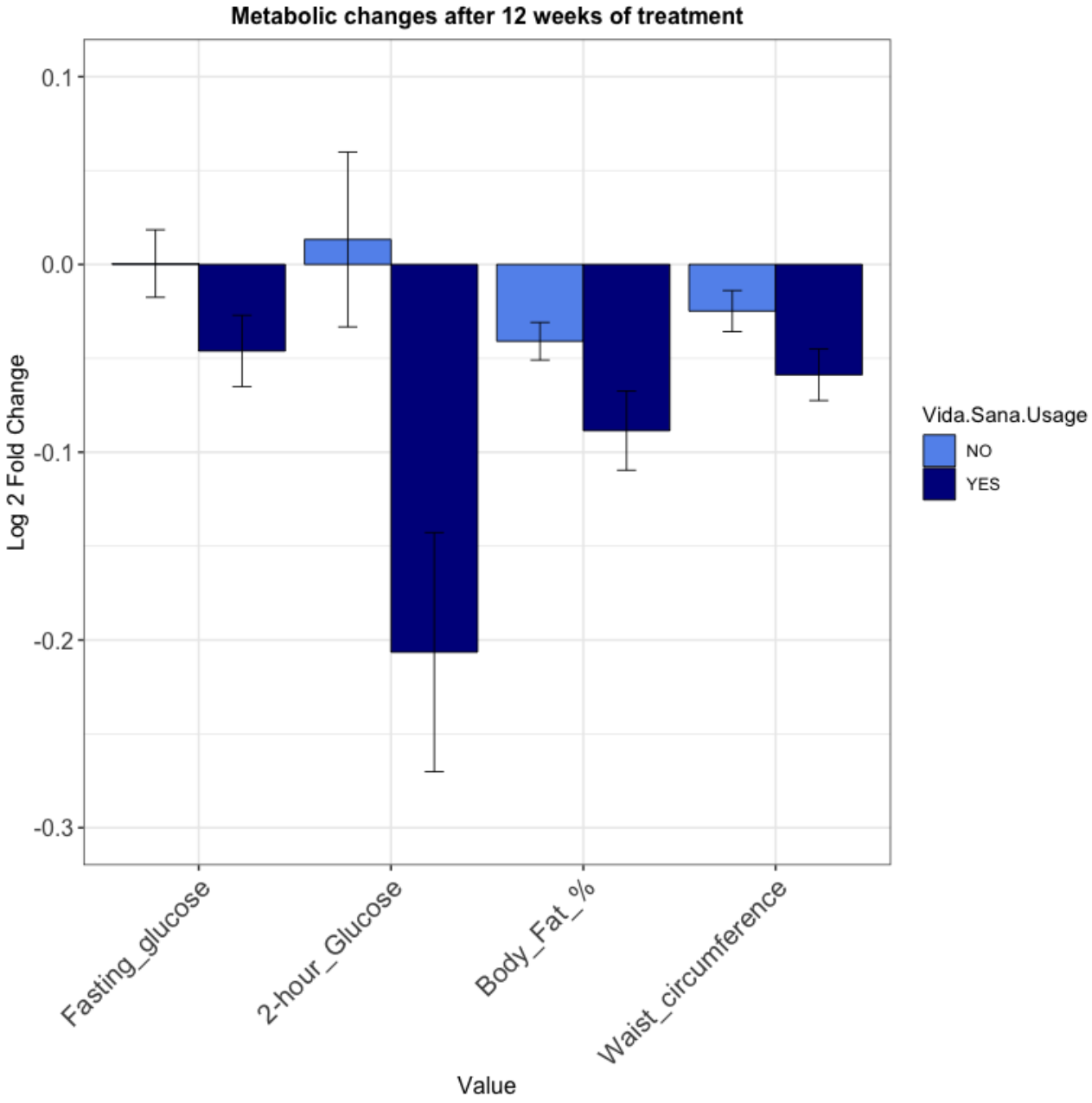
[g]VAT: visceral adipose tissue.

Effectiveness and Safety

Anthropometric, biochemical, and eating habit changes after the intervention are shown in Figure 3. Implementation of Vida Sana after 3 months of intervention showed a significant decrease in fasting glucose, 2-hour glucose, body fat percentage, and waist circumference after adjusting for age, sex, treatment,

baseline values, and education attainment, as observed in Table 3.

Figure 3. Changes in metabolic parameters after 12 weeks of treatment according to platform usage. Log 2 fold changes are presented. *P* values were computed with a linear regression model using fold changes as outcomes, and age, sex, treatment, and education attainment as covariates. Vida Sana implementation after 3 months of intervention showed a significant decrease in fasting glucose (*P*=.03), 2-hour glucose (*P*=.04), body fat percentage (*P*=.024), and waist circumference (*P*=.023).



Others showed interesting clinically relevant changes without statistical significance; there was a reduction in the daily carbohydrate and sugar intake among subjects who used Vida Sana. Conversely, there was an increase in daily protein intake and lean body mass in those who did not use the platform. However, these were not statistically significant (Table 3). There were no AEs reported in this study.

Table 3. Changes in metabolic parameters after 12 weeks of intervention by platform usage (N=77).

Change in metabolic parameter	Used the web platform (n=33)	Did not use the web platform (n=44)	*P* value[a]	Adjusted *P* value[b]
Δ[c] Weight (kg), mean (SD)	–3.4 (3.1)	–2.5 (2.3)	.13	.19
Δ BMI (kg/m^2), mean (SD)	1.2 (1.1)	–0.9 (0.9)	.24	.28
Δ Body fat (%)	–1.3 (–2.2 to –0.7)	–1.0 (–1.9 to –0.3)	.12	.02
Δ Free-fat mass index, mean (SD)	–0.1 (0.5)	–0.09 (0.4)	.51	.47
Δ VAT[d] (g), mean (SD)	–177 (232.3)	–35.5 (187.9)	.008	.12
Δ Waist circumference (cm), mean (SD)	–3.9 (5.1)	–1.7 (5.0)	.06	.02
Δ HbA_{1c}[e] (%), mean (SD)	–0.07 (0.2)	0.01 (0.3)	.26	.35
Δ Glucose at 0 minutes or baseline (mg/dL), mean (SD)	–3.1 (7.0)	–0.1 (8.0)	.08	.03
Δ Glucose at 120 minutes (mg/dL), mean (SD)	–16.9 (29.5)	2.5 (26.1)	.03	.045
Δ Daily caloric intake (kcal), mean (SD)	–116.4 (1136)	–427.3 (1001)	.71	.20
Δ Daily protein intake (%), mean (SD)	1.4 (7.2)	1.0 (7.8)	.68	.59
Δ Daily lipid intake (%), mean (SD)	1.1 (12.3)	–1 (9.2)	.82	.66
Δ Carbohydrate consumption (%), mean (SD)	–3.6 (15)	0.10 (14.8)	.49	.49
Δ Sugar (g), mean (SD)	–20.0 (48.7)	–7.8 (43.0)	.25	.69
Δ Fiber (g), mean (SD)	–0.08 (15.8)	–3.2 (15.7)	.96	.22
Δ Sleeping hours, mean (SD)	0 (0 to 1.0)	0 (0 to 1.0)	.52	.31

[a]*P* values were calculated from paired *t* or Mann-Whitney *U* tests according to the variable distribution.

[b]Adjusted *P* values were computed with a linear regression model using fold changes as outcomes, and age, sex, treatment, and education attainment as covariates.

[c]Δ: change.

[d]VAT: visceral adipose tissue.

[e] HbA_{1c}: glycated hemoglobin A_{1c}.

Discussion

Our study showed that Vida Sana was effective in lowering glucose in fasting, 2-hour glucose, body fat percentage, and waist circumference independent of age, sex, treatment, and education attainment. We found a feasibility of 42.8% (33 subjects) and a usability level of 48.71 (SD 14.24) for Vida Sana. To our knowledge, this is the first study conducted in Mexico and one of the first studies in Latin America to determine the barriers associated with and effectiveness of telemedicine as part of a nutritional intervention.

Our study provides important evidence on the barriers that arise when implementing mobile health (mHealth) technologies in a middle-income country. Although diabetes is the most commonly targeted medical condition for implementing mHealth technologies, implementation remains inadequate [20]. We found that the main barrier was the difficulty in accessing the web platform, as the subjects found it difficult to use. Previous studies [21-23] have indicated similar barriers such as the lack of infrastructure, lack of equipment, and technology gap while addressing security and privacy issues, illiteracy, technical problems, costs, and financial sustainability [24]. Conversely, the reported key factors associated with the success of telemedicine programs are integrating these programs with existing systems, minimizing the burden for health care providers, and applying user-friendly technology [25]. Considering the barrier of technology gap, our study proved that education level was an important determinant for platform usage. It is well known that lower rates of education attainment in low- and middle-income countries, which are critically correlated with the familiarity in using technologies. To overcome this barrier, we believe it is critical to invest in training to increase familiarity with the platform, particularly in subjects with low education attainment. This would also help overcome the second barrier, namely lack of interest to use the tool. Training people in using the tool coupled with an orientation on the importance of self-monitoring and self-efficacy are strategies that would improve the feasibility and acceptance of such platforms. The lack of resources such as time turned out to be a major barrier; therefore, it is important to consider scheduling the most appropriate times for data recording with the patients. Additionally, features that could help increase interest in recording habits include sending reminders, designing friendly interfaces, acknowledging the users' achievements, and visually tracking their records.

In this study, we determined a feasibility rate of 42% (33 subjects), which is lower than that observed in studies with similar inclusion criteria and study designs but different populations, in which the feasibility rates reached 71.1% [26]

and 86% [27]. The platform developed by Everett [27] had some important different features such as personalized automatic notifications through a machine learning algorithm according to the patients' habits that could help to improve the app's usability. In contrast, the platform described by Brock [26] used a website with the aim of providing behavioral support to improve physical activity, eating habits, and factors such as weight loss, stress, and sleep. Our platform differed slightly in this regard. We sent reminders during the week by email and via mobile phone to the participants that could help improve the feasibility and usability of the platform.

Despite its low usability, Vida Sana was effective in reducing metabolic parameters such as fasting glucose, 2-hour glucose, body fat percentage, and waist circumference, independently of age, sex, baseline values, treatment, and education attainment. This result is consistent with the findings from a previous systematic review indicating that 50% of the eHealth and mHealth interventions were effective in increasing physical activity, and 70% of the identified interventions were effective in improving diet quality [28]. However, despite the highly positive results shown by a systematic review of randomized controlled trials, reaching a clear conclusion about the effectiveness of mHealth interventions against noncommunicable diseases is not yet possible because of the limited number of studies, heterogeneity of the evaluated mHealth interventions, and wide variety of reported outcome measures [28].

The strengths of the study lie in the appropriate clinical characterization of the subjects with prediabetes; we evaluated the barriers, feasibility, usability, and effectiveness associated with an intervention in a single study. We developed a standardized, qualified nutritional intervention that helps reduce the risk of bias in terms of the quality and variability of the intervention, described as an important aspect of treatment effectiveness. Our sample is diverse with varying education levels and age groups although it predominantly comprised women. The follow-up time during the 3 months allowed us to evaluate adherence in the short term. These findings may be somewhat limited by the sample size. Therefore, further studies with more focus on improving usability, longer follow-ups, and diverse disease outcomes are suggested.

These results reinforce the effectiveness of telemedicine in nutritional and lifestyle interventions. It shows that even with low usability and feasibility, telemedicine is effective in improving glycemic and anthropometric parameters in a population at risk of diabetes. Improving accessibility, ensuring easy navigation, and providing an orientation regarding the potential benefits of using technology should be the objectives of future research to improve the acceptance of mobile apps in a middle-income setting.

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Authors' Contributions

MRSG conceived the idea, analyzed and interpreted the data, and wrote the manuscript. BBR and LSLC researched the data and wrote the manuscript. AMR reviewed and edited the manuscript. DVGV and TLVR collected the data.

Conflicts of Interest

None declared.

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Abbreviations

AE: adverse event
HbA_{1c}: glycated hemoglobin A_{1c}
INCMNSZ: Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán
mHealth: mobile health
OGIS: oral glucose insulin sensitivity index
SUS: System Usability Scale
T2D: type 2 diabetes

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Viewpoint

Small Practices, Big (QI) Dreams: Customizing Quality Improvement (QI) Efforts for Under-Resourced Primary Care Practices to Improve Diabetes Disparities

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Abstract

Electronic health record quality improvement (QI) initiatives hold great promise in improving adoption of clinical practice guidelines, including those related to diabetes. QI initiatives implemented in under-resourced primary care settings that primarily serve racial/ethnic minority populations have potential to improve quality of care and ultimately improve diabetes disparities. The “Screen at 23” campaign was launched in 2011 to increase screening for prediabetes and diabetes at lower BMI thresholds (ie, 23 kg/m2) for Asian Americans, in line with the new guidelines put forth by the American Diabetes Association. Here, we describe the implementation of a customized electronic health record QI initiative in under-resourced practices that primarily serve low-income South Asian populations in New York City, designed to increase diabetes screening using updated BMI guidelines and in alignment with the “Screen at 23” campaign. The customization involved the implementation of an innovative, semi-manual alternate solution to automated clinical decision support system (CDSS) alerts in order to address the restrictions on customizing CDSS alerts in electronic health record platforms used in small practice settings. We also discuss challenges and strategies with this customized QI effort. Our experience suggests that multisector partnership engagement, user-centered approaches, and informal strategies for relationship building are even more critical in under-resourced, small practice settings. Relatively simple technological solutions can be greatly beneficial in enhancing small practice capacity to engage in larger-scale QI initiatives. Tailored, context-driven approaches for implementation of equity-focused QI initiatives such as the one we describe can increase adoption of clinical practice guidelines, improve diabetes-related outcomes, and improve health disparities among underserved populations.

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KEYWORDS

electronic health record; quality improvement; health equity; clinical practice guidelines; diabetes

Introduction

Clinical practice guidelines inform clinicians about evidence-based medicine with the goal to improve population health. However, adoption of clinical practice guidelines has been poor due to various factors, including lack of awareness of changing guidelines, complexity and volume of guidelines, clinician attitudes, and misalignment of guidelines with clinical workflow [1-3]. Thus, although guidelines provide the content that informs clinical decision-making, they do not provide a roadmap on how to implement these decisions in real-world settings [4]. Moreover, guidelines can unintentionally widen health disparities when barriers to implementation are not explicitly considered [5]. There has been growing interest in translating clinical practice guideline–based quality

improvement (QI) initiatives into practice by addressing barriers to adoption [4], in addition to calls for disparities-focused QI initiatives that address barriers to adoption specifically for underserved populations [6].

There has been an increase in clinical practice guideline–based QI using electronic health records (EHRs) [7] such as clinical decision support systems (CDSS) that include a variety of provider-based point-of-care tools including alerts, condition-specific order sets, diagnostic support, and practice-wide reminders [8]. CDSS and other EHR-based health information technology are an effective way of changing clinical practice behavior [9] and subsequently improving health outcomes. These tools are particularly critical for chronic disease management, including cardiovascular diseases and diabetes [10,11]. The Community Preventive Services Task force has recommended the use of CDSS to prevent and manage cardiovascular diseases [12], and the American Diabetes Association further underscored the potential role of CDSS in reducing diabetes disparities [13].

A recent systematic review of guideline-based CDSS QI initiatives found that there are 4 broad dimensions of challenges to their implementation, which include system use, structure, information quality, and system quality [14]. These implementation barriers are exacerbated for under-resourced practices, including federally qualified health centers and small physician- or family-owned community-based practices [6]. Small practices serve a large proportion of low-income immigrants and minorities, especially in urban settings [15]. In New York City (NYC), small practices comprise 40% of primary care providers (PCPs) and serve NYC's poorest and most racial/ethnically diverse neighborhoods [16]. CDSS QI initiatives often require an infrastructure that is not readily available to small practices and require purchasing of additional software and applications as well as training on these systems to use them accurately [16,17]. Small practices' lack of access to or suboptimal participation in QI initiatives, therefore, can potentially widen the gap in provision of quality care to health-disparity populations [18-21].

Like many other clinical practice guidelines, the adoption of guidelines put forth by the American Diabetes Association [22] for diagnosing and treating patients with diabetes has been low. Approximately 30 million Americans have diabetes, of which 24% are undiagnosed [23], and there are significant disparities by race/ethnicity [23]. In particular, South Asians have higher diabetes prevalence compared with some other Asian American subgroups as well as other racial/ethnic groups [24,25]. Despite the high and increasing burden of diabetes, an online survey showed that only 53% of clinicians were using diabetes guidelines routinely, with non-guideline users more likely to be practicing in smaller clinics (patient volume <250 a month) [26].

In the 2015 American Diabetes Association guidelines, recommendations were made for lowering the BMI threshold for screening overweight or obese Asian Americans for prediabetes and diabetes from 25 kg/m^2 to 23 kg/m^2 [22]. Compared with all other racial/ethnic groups, the prevalence of undiagnosed diabetes is highest for Asian Americans (50%) [27], in large part due to lower screening rates [28]. In response to the American Diabetes Association guidelines and low adoption of racial/ethnic-specific clinical practice guidelines on diabetes, the "Screen at 23" campaign was launched in 2011 to increase awareness and diagnosis of prediabetes and diabetes at this new threshold [29].

To our knowledge, there have been no published studies describing the implementation process of the Screen at 23 campaign, which is critical for providing insight and guidance to health systems seeking to address diabetes disparities serving Asian patient populations. In this paper, we describe the implementation of an EHR QI initiative in under-resourced practices that primarily serve low-income, limited English-proficient South Asian populations in NYC, designed to increase diabetes screening using updated guidelines and in alignment with the Screen at 23 campaign. Smaller EHR platforms serving independent practices often do not have the capability to customize existing CDSS alerts. In response, we developed and implemented a semimanual alternate solution to automated CDSS alerts that incorporate Asian BMI guidelines. We also discuss strategies and challenges with this customized EHR QI effort and implications for improving diabetes and other health disparities in diverse patient populations, with a particular emphasis on deploying informal, community-engaged approaches.

Implementation of the Customized EHR QI Initiative

Overview of the DREAM (Diabetes Research, Education, and Action for Minorities) Initiative

The DREAM (Diabetes Research, Education, and Action for Minorities) Initiative is a 5-year randomized controlled trial to support weight loss and glycemic control efforts among South Asian patients receiving care in a network of PCPs in NYC. Details on project study design are described elsewhere [30]. The DREAM Initiative leverages multisectoral partnerships in its implementation, including the Primary Care Information Project (PCIP) at the NYC Department of Health and Mental Hygiene and EHR vendors representing the 2 systems utilized across study sites (MDLand and eClinicalWorks [eCW]). PCIP implements citywide EHR-based QI initiatives by deploying trained practice facilitators to small practices [31]. Their efforts have demonstrated that implementing QI strategies in these settings can effectively improve clinical outcomes, including increased screening (eg, cervical cancer) and disease management (eg, retinal exams, hemoglobin A_{1c} testing) [32-36].

Design and implementation of this initiative were guided by the Chronic Care Model, which identifies the essential elements of a health care system that encourage high-quality chronic disease care and has been widely used in the implementation of diabetes management interventions [37]. Relevant elements of the model for this initiative include delivery system design and clinical information systems, which are addressed by enhancing practice capacity to implement registries of individuals with uncontrolled diabetes. Further guided by PCIP's best practices [32,33,36] and literature on common challenges

faced by under-resourced practices in implementing QI efforts (with emphasis on employing user-centered strategies) [17,36], implementation was conducted in 3 phases. Each phase of the QI initiative, associated activities, and challenges and strategies used to address them are summarized in (Table 1) and briefly described in the following sections.

Table 1. Summary of electronic health record (EHR) quality improvement (QI) activities.

QI initiative phases and strategies	Description of activities	Challenges identified and strategies used to address challenges
Development and customization of registry reports, alerts, and training materials		
Develop a customized registry report	• Identification of patients at risk of diabetes using revised BMI threshold for Asian Americans • Attention to user-friendliness (eg, shortened report run time) with feedback provided from practice facilitators	• To monitor fidelity to the QI initiative, it was critical to ensure that registry report generation could be tracked by practices. In developing this feature, a key challenge was identified, namely the differences in report customization process between EHR platforms. In one system (MDLand), reports are customized to allow for tracking of report generation and downloads. In eClinicalWorks (eCW), adding this information to the customized report was not feasible; instead, we provided training on how to download reports to the desktop, which would then require a manual count of the number of downloads.
Develop semimanual customized alert	• Development of a user-friendly workflow to implement the customized alert	• Each EHR system required different locations for documenting. After discussion with EHR vendors and PCIP, the team determined that the easiest and fastest way of documentation would be in the chief complaints section for eCW users and internal notes section for MDLand users.
Develop training manual	Inclusion of the following topics: • Review of updated BMI threshold for Asian Americans • Systematic documentation of vitals (including BMI) • Running customized reports • Review of semimanual alternate solution to alerts • Inclusion of vendor-specific screenshots of the EHR platform where necessary	• The overall goal of the training manual was to provide concise, practical information. With practice facilitator feedback, the training manual underwent multiple rounds of revisions to ensure that only the minimum amount of essential information was communicated. • Because of the difference in functionality between the different EHR systems, 2 separate training manuals were developed for each EHR system, including 2 separate suggestions for workflows related to customized alerts in patient charts.
Deploy customized report	• Creation of a temporary username for the practice facilitator • EHR vendor deployment of the report for each clinic • Practice facilitator/ academic research coordinator testing of the customized report on-site, involving a comparison of the customized report against a random set of individual patient records and noncustomized registry reports	• Some practices did not have the technical knowledge to create additional users, and others were hesitant to provide an additional account. In these cases, the practice facilitator/academic research coordinator made an in-person visit to create the user account in the presence of a clinic staff and deleted the account promptly after testing. • Testing by the practice facilitator/academic research coordinator required coordination with the clinic during a time that the clinic was not actively using their EHR system during non-business hours. The practice facilitator held a flexible schedule and developed a rapport with clinic staff by offering technical assistance and communicating frequently. • If the practice facilitator found errors in the report, the EHR vendors were available to remotely log-in to assess the issue in real time and revise the customized report accordingly.
Workflow training		
Conduct training	• Trainings with clinician and clinician staff who are primary users of the EHR • Training duration: 1-2 hours, ending with hands-on practice running customized report and implementing the semimanual alert • Provision of pdf and hard copies of training manual to trainees	• Common to many small practices that experience staff shortage and frequent staff turnover, each staff took on multiple roles. For this reason, training all EHR users was critical. However, coordinating a time for all users at the clinic to be present was logistically difficult. We were able to schedule times during existing team meetings or by engaging a senior-level person at the clinic who was able to effectively guarantee attendance.
Ongoing technical assistance		

QI initiative phases and strategies	Description of activities	Challenges identified and strategies used to address challenges
Conduct follow-up, in-person technical assistance sessions on a bi-monthly basis	• Session duration: approximately 1 hour • Review of training manual (if necessary) and customizing of the screening workflow to minimize barriers for implementation • Provision of technical assistance on any other EHR issue clinic may be experiencing	• Due to high staff turnover, the follow-up session often entailed a new round of training for newly onboarded staff members. • The generic workflow suggested during the training session was not manageable to some clinics due to time or workload constraints; this workflow was revised. Rather than following up with the entire list of at-risk patients, the clinic would instead follow-up with 10-15 patients who already had a scheduled appointment in the upcoming month.

Ethics Approval

The study was approved by the Institutional Review Board of NYU Grossman School of Medicine.

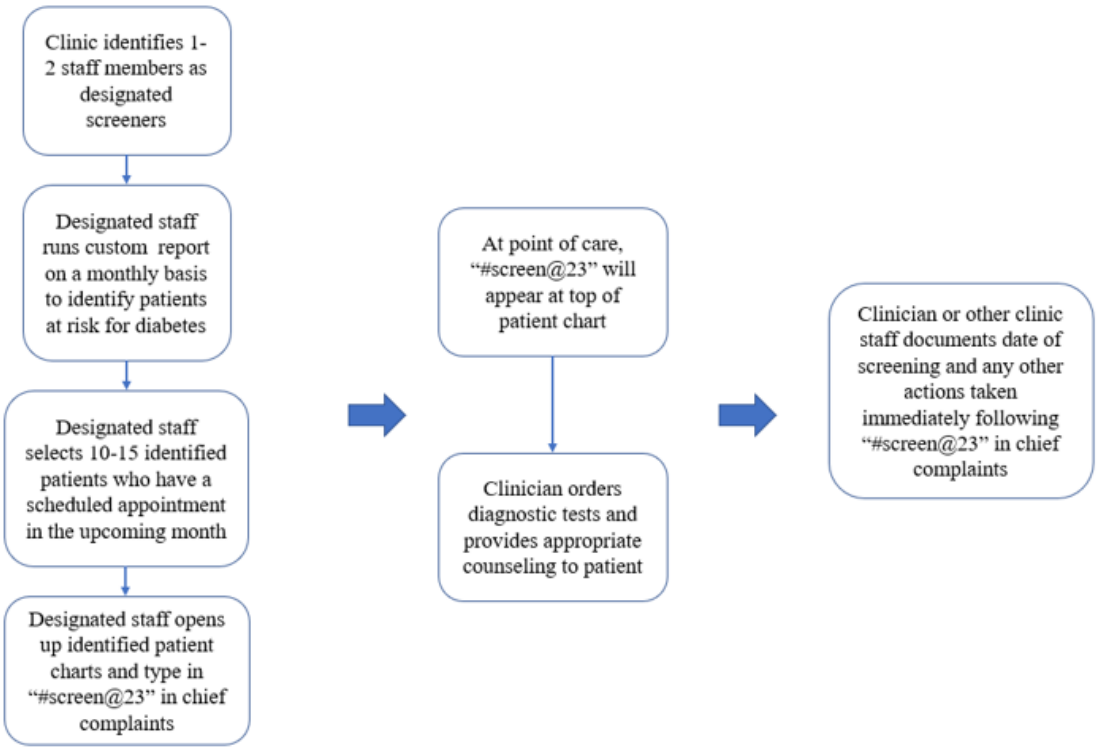
Phase 1: Development and Customization of Registry Reports, Semiautomated Alerts, and Training Materials

We developed a customized diabetes registry report in collaboration with EHR vendors and PCIP for the purposes of identifying patients at risk for diabetes using the updated BMI criteria for Asian Americans. Reports were customized to ensure user friendliness (eg, selecting essential information from the EHR to minimize the number of columns in the report and minimizing report runtime). Because CDSS alerts are based on clinical practice guidelines for the general population, they could not be customized for specific racial/ethnic groups in the 2 EHR systems at our practices. Instead, we developed a semimanual alternate solution to automated CDSS alerts for patients identified as at-risk. After identifying patients via a customized registry report, eCW users were asked to document the need for screening using the hashtag "#screen@23" in the chief complaints section and MDLand users in the internal notes section. At point of care, the first text that will appear at the top of the progress note is "#screen@23." We subsequently developed a training manual with topics including updated BMI thresholds for Asian Americans, systematic documentation of vitals, running customized reports, and using the semimanual alert.

Phase 2: Workflow Training

Building upon past successful strategies [11,17,32,38], the practice facilitator and an academic research coordinator conducted an initial 1- to 2-hour training with clinic staff and clinicians. We presented the clinics with a generic suggested workflow (Figure 1) that could be customized to each clinic.

Figure 1. Suggested workflow for identification of at-risk patients and documentation in eClinicalWork's electronic health record platform.



Phase 3: Ongoing Technical Assistance

Following the initial training, the practice facilitator conducted bimonthly follow-up technical assistance (TA) sessions that included reviewing the manual and re-evaluating the workflow to minimize barriers to screening and documenting. Preliminary feedback indicates that clinics are satisfied with several aspects of the initiative, including the user-friendliness of the reports, the simple workflow for screening and follow-up, and increased awareness on diabetes-related clinical practice guidelines. Some clinics have taken on further customization of workflow; for example, one clinic is now including progress updates for screening at the lower BMI threshold and follow-up of identified patients as a standing agenda item at their monthly team huddles.

The study intervention is conducted in 3 waves across 3 years and 20 primary care practices. To date, we have conducted training with Wave 1 providers (n=7); the practice facilitator collected evaluation data via Salesforce immediately at the end of the in-person training and again during the follow-up TA call approximately 2 months afterwards. All 7 of the Wave 1 providers indicated that the training was very or somewhat useful, they are very or somewhat likely to screen for diabetes using the American Diabetes Association guidelines for a lower BMI for Asians, and they are very or somewhat likely to run the registry reports. At follow-up, 5 of the 7 providers had run the registry report at least once since the training (range: 1-2 times); the 2 providers who did not run the report indicated that they did not remember how to run the reports and were provided with a refresher training.

Implications for EHR QI Initiatives to Increase Adoption of Clinical Practice Guidelines

The implementation process described here has important implications both for national and local efforts to support the Screen at 23 campaign and more broadly for QI efforts designed to address disparities in diabetes and other health outcomes for minority populations. Although some of the implementation strategies reinforce previous guidance (eg, user-centered designs), other more informal strategies centered around engagement and trust building are more innovative and relevant especially when working with smaller, under-resourced practices who serve minority patients. These implications are summarized in the following sections.

Multisector Partnership Engagement Is Even More Critical to Success of QI Efforts for Under-Resourced Settings

A critical component of our implementation process was early engagement with partners from a wide range of sectors, including municipal agency–supported practice facilitation services and direct engagement with EHR vendors. PCIP's practice facilitators have established relationships with small practices, have extensive knowledge about the EHR platforms, and can tailor QI initiatives based on individual practice needs. Programmers at EHR vendors often lack clinical contextual knowledge [32]; by having PCIP's input during the customized report development, EHR vendors were able to incorporate critical contextual knowledge that would have otherwise been missed. Further, only by bringing both PCIP and EHR vendors to the table together were we able to co-develop an alternate solution to automated CDSS alerts (ie, semimanual, customized solution) that incorporates diabetes screening guidelines specific to Asian Americans. Broader conversations with EHR vendors should be initiated so that seemingly simple customizations (eg, different BMI screening criteria for Asian Americans) can be made to the automated CDSS alerts, which would preclude the need for alternate solutions.

As this and other diabetes-related QI initiatives have demonstrated, leveraging multisectoral partnerships can be a promising implementation strategy [39]. Because not all municipalities have access to a specialized entity like PCIP, it is important to find sustainable ways to support similar efforts, which could include financing strategies to increase the practice facilitator workforce [21]. Without explicit resources toward these efforts in engaging small practices, the disparity in adoption of clinical practice guidelines will widen, with ensuing ramifications on quality of care and health outcomes among immigrant, minority populations [18].

User Satisfaction and Adoption of QI Initiatives Rely on Implementation of User-Centered Approaches at Every Stage of the Process

As the recent systematic review of CDSS QI initiative highlighted, challenges to implementation primarily center on lack of usability [14]. For this reason, user-centered principles guided our implementation at every stage: The customized report was developed such that only the minimal clinically relevant information was included and took less than 2 minutes to run; the training manual was developed to be user-friendly and practical (eg, step-by-step screenshots); we encouraged a flexible work flow for identification and follow-up of at-risk patients that was manageable for clinic staff members' workload; and lastly, we developed a semimanual alert for screening that was available at point-of-care but did not significantly disrupt clinician workflow (ie, no additional screen changes or clicks required). This ability to implement user-centered principles depended on meaningful engagement and feedback from key stakeholders, which has been similarly emphasized in other studies [14].

Informal and Formal Strategies to Develop and Sustain Relationships With Primary Users of the QI Initiative Are Essential for Increasing Trust, Legitimacy, and Ultimately, Adoption

In addition to implementation barriers related to user-friendliness, user attitudes (eg, clinician skepticism about utility of CDSS) can significantly impede adoption [14]. Our previous work with small practices demonstrated the utility of applying community-based participatory research approaches to communication and relationship building to surmount these challenges [17]. Indeed, small practices often do not have the resources for a dedicated informatics staff member or an internal informatics department, which can amplify issues of distrust (especially around sharing patient data with external QI implementers). Accordingly, we sought to develop trust by

conducting frequent on-site visits from the practice facilitators and the academic research team, being transparent about the procedures (eg, creating and deleting user accounts in the presence of a clinic staff member), and offering TA at each contact. TA was offered on a wide range of EHR issues and not just those related to our Screen at 23 efforts such as assistance with system updates and submitting tickets for technical support. It was equally important that we engaged not just the clinician in the process but also all staff at the clinic since small practice staff often wear multiple hats to offset the common challenge of staff shortage. Lastly, sustained contact in the form of formal follow-up TA sessions helped with continued communication and increased accountability for adoption of the initiative.

Conclusion

A common thread underpinning the implementation strategies discussed in this paper is the importance of tailoring to the context of each clinic and using informal strategies to build trust, especially critical in small practice settings due to their relative lack of access to resources. Our body of work engaging small practices [17,21,40] underscores that relatively simple health information technology adjustments can confer great advantage to these under-resourced settings that often provide services to disadvantaged populations. As national trends demonstrate rising diabetes disparities among minority communities [23,41], it is imperative that clinical settings prioritize strategies to improve diabetes-related outcomes among patients. Our experience may provide a road map for tailored, context-driven, and community-engaged approaches for implementation of equity-focused QI initiatives to increase adoption of clinical practice guidelines, improve clinical outcomes related to diabetes, and broadly improve health disparities among underserved populations.

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Conflicts of Interest

None declared.

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Abbreviations

CDSS: clinical decision support systems
DREAM: Diabetes, Research, Education, and Action for Minorities
eCW: eClinicalWorks
EHR: electronic health record
NYC: New York City
PCIP: Primary Care Information Project
PCP: primary care provider
QI: quality improvement
TA: technical assistance

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Original Paper

Open-source Web Portal for Managing Self-reported Data and Real-world Data Donation in Diabetes Research: Platform Feasibility Study

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Abstract

Background: People with diabetes and their support networks have developed open-source automated insulin delivery systems to help manage their diabetes therapy, as well as to improve their quality of life and glycemic outcomes. Under the hashtag *#WeAreNotWaiting*, a wealth of knowledge and real-world data have been generated by users of these systems but have been left largely untapped by research; opportunities for such multimodal studies remain open.

Objective: We aimed to evaluate the feasibility of several aspects of open-source automated insulin delivery systems including challenges related to data management and security across multiple disparate web-based platforms and challenges related to implementing follow-up studies.

Methods: We developed a mixed methods study to collect questionnaire responses and anonymized diabetes data donated by participants—which included adults and children with diabetes and their partners or caregivers recruited through multiple diabetes online communities. We managed both front-end participant interactions and back-end data management with our web portal (called *the Gateway*). Participant questionnaire data from electronic data capture (REDCap) and personal device data aggregation (Open Humans) platforms were pseudonymously and securely linked and stored within a custom-built database that used both open-source and commercial software. Participants were later given the option to include their health care providers in the study to validate their questionnaire responses; the database architecture was designed specifically with this kind of extensibility in mind.

Results: Of 1052 visitors to the study landing page, 930 participated and completed at least one questionnaire. After the implementation of health care professional validation of self-reported clinical outcomes to the study, an additional 164 individuals visited the landing page, with 142 completing at least one questionnaire. Of the optional study elements, 7 participant–health care professional dyads participated in the survey, and 97 participants who completed the survey donated their anonymized medical device data.

Conclusions: The platform was accessible to participants while maintaining compliance with data regulations. The Gateway formalized a system of automated data matching between multiple data sets, which was a major benefit to researchers. Scalability of the platform was demonstrated with the later addition of self-reported data validation. This study demonstrated the feasibility

of custom software solutions in addressing complex study designs. The Gateway portal code has been made available open-source and can be leveraged by other research groups.

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KEYWORDS

diabetes; type 1 diabetes; automated insulin delivery; diabetes technology; open-source; patient-reported outcomes; real-world data; research methods; mixed methods; insulin; digital health; web portal

Introduction

Under the hashtag *#WeAreNotWaiting*, people with diabetes and their families have come together to develop and support the use of open-source automated insulin delivery systems (also called do-it-yourself artificial pancreas systems). With insulin pumps and data from continuous glucose monitoring, automated insulin delivery systems are able to automate insulin dosing in response to glucose levels through algorithmic prediction [1-4]. With an estimated >10,000 individuals using open-source automated insulin delivery worldwide, there is a wealth of data produced from these systems in real-world settings [5].

Web-based data repositories, such as Nightscout, allow users to collect, upload, review, analyze, and share data from open-source automated insulin delivery systems with their caregivers and health care teams [6]. Until recently, data uploaded to these sites were rarely used for research, which left an important source of real-world evidence largely untapped. Open-data platforms, such as Open Humans [7], allow users to anonymously donate their data from repository sites for use in research [7-9]. Data from Open Humans have previously been used in research and increasingly to evaluate open-source automated insulin delivery [8].

An international consortium of patient innovators, clinicians, social scientists, computer scientists, and patient advocacy organizations initiated a project called OPEN (Outcomes of Patients' Evidence with Novel, Do-it-Yourself Artificial Pancreas Technology [10,11])) and investigated the *#WeAreNotWaiting* movement and open-source automated insulin delivery use, which led to a web-based survey [12].

It is common practice to use tools such as REDCap for electronic data capture and management in the implementation of web-based surveys. However, it is not possible to achieve required flexibility and user friendliness using such tools alone. The overall aim of this study was to assess the feasibility of developing a platform that would enable participants to share anonymized retrospective diabetes data in addition to completing surveys.

Methods

Study Design

The study design and linkage of multiple elements—including follow-up and satellite projects—is complex. The study concept contained an analysis of real-world diabetes data, and a survey that included questionnaires that collected basic demographic data, self-reported clinical outcomes, and responses to open-ended questions, as well as assessments of quality of life (Pediatric Quality of Life Inventory, World Health Organization-Five Well-Being Index), depression and anxiety (Depression Anxiety Stress Scale), sleep quality (Pittsburgh Sleep Quality Index), problem areas in diabetes (Problem Areas in Diabetes scale), fear of hypoglycemia (Hypoglycemia Fear Survey-II), impact of diabetes (Diabetes Attitudes, Wishes, and Needs), diabetes treatment satisfaction (Diabetes Treatment Satisfaction Questionnaire), diabetes well-being, partner diabetes distress, hesitation around automated insulin delivery systems (DIWHYnot), and the effects of the COVID-19 pandemic on diabetes management and quality of life.

The study included participants who self-identified as an adult or adolescent with diabetes, and caregiver or partner of a person with diabetes. Furthermore, both users and nonusers of open-source automated insulin delivery were included. At a later stage in the study, adult participants were also provided the option to independently validate their self-reported health data and clinical outcomes by their health care professional (endocrinologist, pediatric endocrinologist, diabetes educator or specialist nurse). Thus, the study was made up of 3 major elements: a survey containing questionnaires alone, device data donation on Open Humans, and a linked follow-up study on health care professional–validated health data and clinical outcomes.

Platform Requirements

The nature of this research—a real-world study with human participants—required that data management be compliant with European Union General Data Protection Regulations [13] and that risks related to data sharing for the individual be minimized (pseudonymization, deidentification, informed consent, and right to withdraw). Enabling participants to join follow-up studies without storing their personal information also necessitated a custom solution for pseudonymous data management. Safely and securely managing data from multiple data streams also presented a unique challenge.

Making study participation simple required the development of a web portal for users. Such a web portal needed to also act as a formalized system of automated data matching between multiple data sets. The first objective in creating the platform—the Gateway—was linking questionnaire responses in REDCap to optionally donated device data in Open Humans. The second was for this platform to link data from participants to their partners or health care professionals. The final objective was that the entire process be anonymized and General Data Protection Regulation–compliant.

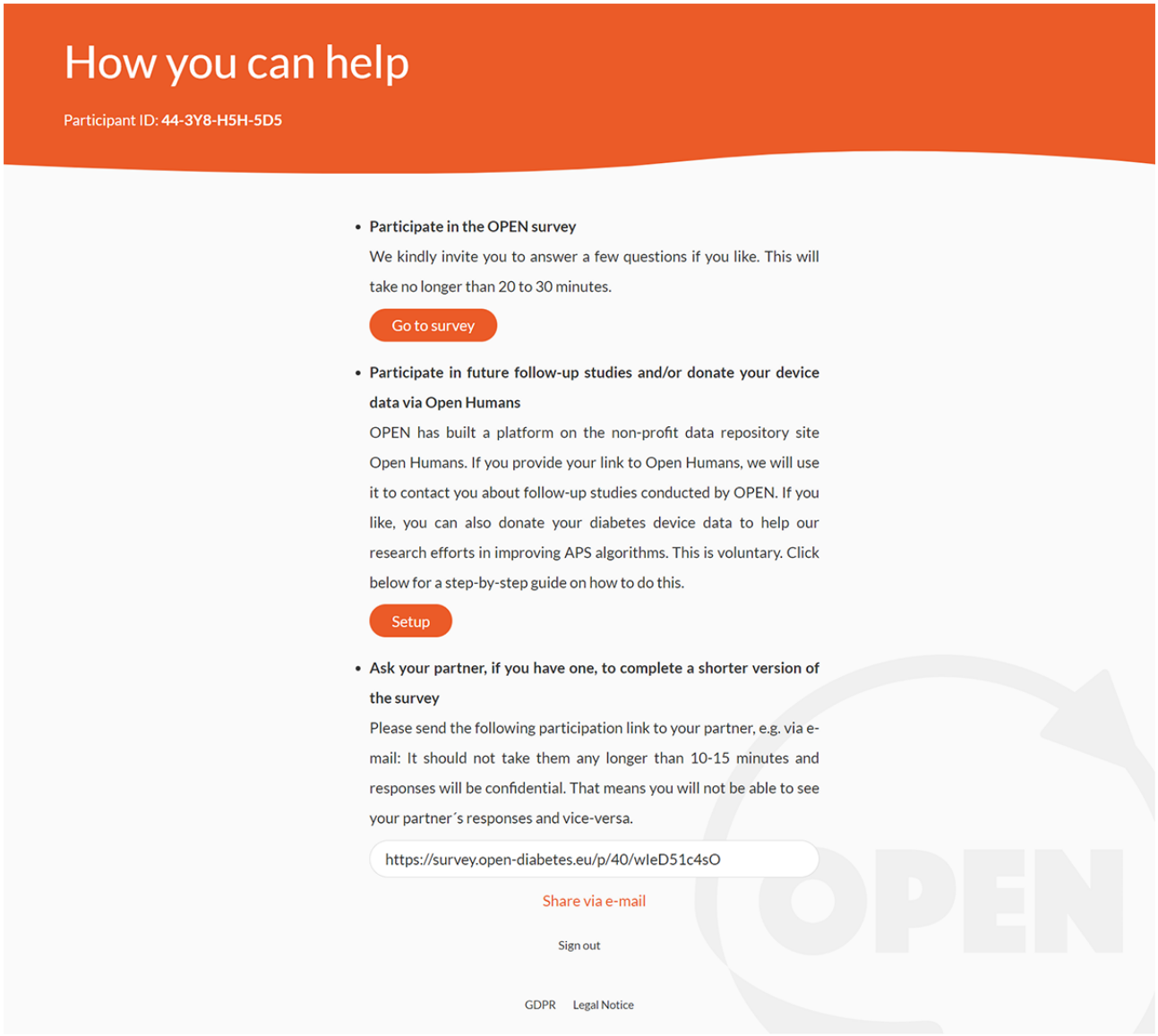
Front-end Architecture

To users, the Gateway was a landing page (Figure 1) with a simple graphical user interface through which participants selected the profile with the appropriate characteristics (person with diabetes or caregiver of a person with diabetes; user or nonuser of automated insulin delivery) and were provided a unique *Participant ID*. Participants were informed of their rights regarding their survey data and optionally donated diabetes data and could then sign an electronic form if they wished to consent.

Participants responded to a sequence of questionnaires, and upon completion, they were asked if they wished to donate anonymized diabetes data and were provided with a survey link to send to other parties (eg, partners, parents, and health care providers) (Figure 2).

Figure 1. Landing page for the Outcomes of Patients' Evidence with Novel, Do-it-Yourself Artificial Pancreas Technology (OPEN) project.

Figure 2. The Gateway webpage where participants can participate in the survey, donate their medical device data to Open Humans, or ask their partner to participate in the survey.



Responses to questionnaires were logged using REDCap (Vanderbilt University [14,15]). For privacy reasons, we did not use any device data cloud storage identifiers directly, as personal accounts may not be secure or anonymous. Rather, we managed medical device data donation through Open Humans with a specific project for OPEN [7]. OPEN positively evaluated the ability to communicate anonymously with study participants to notify them about follow-up studies, which is why Open Humans was chosen in addition to its ability to facilitate anonymized data donation. A *record ID* was generated for each participants' survey response in REDCap, and an anonymous *Project Member ID* was generated when they joined the OPEN project on Open Humans. The Participant ID was used to link the record ID and Project Member ID within the Gateway.

Back-end Architecture

The platform was developed using an open-source framework (Ktor, version 1.4.0; JetBrains [16]) in the Kotlin programming language. SQL data were translated (Exposed, version 0.26.1; JetBrains [17]) to Kotlin data types and stored using connection pooling (ie, opening as many database connections as necessary for reliable operation) (HikariCP, version 3.4.5; Brett Wooldridge [18]). Exposed and HikariCP support various databases by using the Java Database Connectivity interface [19], which added additional flexibility to the Gateway; for production, MariaDB [20] was chosen.

The database contained a table with the record ID and the Project Member ID for every survey participant. Application programming interfaces (APIs) were used to interact with these services to access survey and device data; data from these services were not stored in the database itself. In REDCap, each survey had an additional Gateway Instrument variable used to store each Participant ID as a backup measure, as well as additional survey information (eg, participant group, adult or caregiver, user or nonuser), which was used to establish branching logic sequences within specific surveys.

When a participant started the survey for the first time, REDCap's *import record* API was initiated to create a new record containing that participant's information (such as Participant ID and participant group). In that API call, the *Autogenerate record ID* flag was enabled, so that a new record

was created instead of an existing record being edited, and the new record ID was returned in the API response. The record ID was then stored in the database; multiple record IDs could be stored for a single Participant ID, allowing for implementation of multiple surveys and follow-up studies. To send the user to the survey, another API call was made to REDCap to export the survey queue link for that given record ID and redirect the user.

Participant ID

The Participant ID was formatted as *1-222-222-222*, where the first number was a consecutive counter (eg, first generated ID: 1, second ID: 2, 100th ID: 100), followed by a 9-digit secret number. The counter was generated by the SQL *auto-increment* feature, and the secret number was randomly generated using a random number generator.

A 9-digit secret number was included to minimize the risk that an unauthorized person could inadvertently or intentionally compromise survey data. For security reasons, the Gateway did not provide any information (questionnaire responses or device data) except for auxiliary status messages (eg, whether the survey has been completed or not), so that no confidential or personal data were exposed in the event that Participant IDs were accidentally made public.

Participants were advised to securely record their Participant ID, because this number allowed participants to start, stop, and resume the survey at any time, and link to the OPEN project on Open Humans.

Authorization

An authorization protocol (OAuth [21]) created for third-party apps to access APIs without requiring app passwords from users—thus creating secure authorization flows—allowed access to and between the Gateway, REDCap, and Open Humans.

The authorization flow was implemented using Ktor's built-in OAuth tool (OAuth, JetBrains [22]). When participants completed the survey, they were invited to donate their diabetes data to the OPEN project on Open Humans. To initiate this process, OAuth first referred participants to a URL on Open Humans where they can register or sign in to Open Humans and join the OPEN project, thereby granting the Gateway access to their data. After this step, the user was redirected back to the Gateway, with a *bearer token* in the URL. The Gateway recognized the token and traded it in at Open Humans for an access token and a refresh token. The access token was used to access the user's data—the refresh token provided a new access token (and refresh token) once the current access token expired. These tokens were stored in the Gateway's database.

Data Set Linkage

Linkage between REDCap records and Open Humans data sets was accomplished by storing the survey record ID and the Project Member ID in the same row as the Participant ID (Table 1) or with a reference using a foreign key. In SQL, every table has a column with a primary key whose values must be unique, which therefore allow a specific row to be referenced without conflict. This is usually just a counter (the first part of the Participant ID), which allows an entry to be referenced from another table. The foreign key is a special constraint that ensures the entry with a given ID exists and that can automatically delete and update an entry if its reference is altered.

Table 1. Data structure of a table of the Gateway database. (Data in the table are an example and not from study participants.)

Consecutive counter, *id*	9-digit secret	Participant group (0–6)[a], *enrollment_type*	REDCap Record ID, *survey_record_id*	Open Humans Project Member ID, *project_member_id*	Access token, *access_token*	Refresh token, *refresh_token*	Unix timestamp (milliseconds), *expires_at*
1	5DBJ4D9R7	2	2	NULL[b]	NULL	NULL	NULL
2	G253LY4VC	1	1	79565297	YmtpPH-HCug8FgVkQBvm-szyP4nmXu6c	ZPhUY2pK85vvYu-vhTr8qbEAtaCGAks	1606799777655
3	290FA1D9B	0	3	NULL	NULL	NULL	NULL

[a]0 indicates an adult using open-source automated insulin delivery,1 a nonuser adult, 2 a parent of a child user, 3 a parent of a child nonuser, 4 a teenage user, 5 a partner of an adult user, and 6 a partner of an adult nonuser.

[b]NULL indicates that there are no entry data.

Hosting

The Gateway is hosted on a virtual storage server, running CentOS [23] and Docker [24]. The Docker image for the Gateway was created based on the official OpenJDK [25] image published on Docker Hub by including the compiled Gateway executable file and the MariaDB Java Database Connectivity [19] connector, whereas the official MariaDB image was used unmodified. A volume to store the database files was created, and both containers were connected using a bridge network. The Gateway container exposed the default ports 80 and 443 for HTTP to be accessed publicly by the participants. TLS (Transport Layer Security) certificates were retrieved from Let's Encrypt—a nonprofit certificate authority—using Certbot, which proved domain ownership using the ACME (Automatic Certificate Management Environment) protocol, and were mounted into the container [26,27].

Participant Recruitment

A group of 18 people with, or caregivers and partners of people with, diabetes were recruited to pilot test the platform prior to

survey launch. Their responses and data were not included in the final data set.

For the final data set, we sought adults (aged ≥18 years) with diabetes (type 1, 2, or other), caregivers of children and adolescents (aged 3-17 years) with diabetes, and partners or health care professionals of people with diabetes. Participants were recruited via multiple online communities for diabetes, including Facebook groups (such as multinational Looped groups, AndroidAPS users, CGM in the cloud, Nightscout Deutschland), and through the OPEN project website, social media accounts, and Diabetes Daily.

Participant Roles

Upon survey completion, participants were able to send survey links to their partners or caregivers, inviting them to participate in the study. Survey responses from partners or caregivers were linked via the Participant ID to the original participant; partners were linked to adults with diabetes, and caregivers were linked to adolescents with diabetes.

Health care professionals were added at a later stage (while the study was still ongoing). Health care professionals could be invited by people with diabetes to validate their self-reported data by providing information on comorbidities, most recent hemoglobin A_{1c} level, and episodes of severe hypoglycemia and diabetic ketoacidosis based on clinical records. Participants were asked to provide consent for the release of these data by their health care professionals by signing a physical consent form that was given to health care professionals directly and stored in participant health records.

Ethical Approval and Data Privacy

Survey and data donation components of the study were approved by the Life Sciences Human Research Ethics Committee at University College Dublin (LS-20-37).

These study elements are in compliance with data regulation standards of the European Union General Data Protection Regulation. Open Humans is in compliance with regional data privacy laws, particularly those of the United States and European Union. Prior to participation in the study, participants electronically signed an agreement stating that their authorization of data sharing may waive their countries' data privacy laws.

Results

By the survey's close at the end of November 2020, a total of 1052 unique individuals had accessed the Gateway (Figure 3; Table 2), of whom 930 completed at least one questionnaire (users: 696/930, 74.8%; nonusers: 234/930, 25.2%).

Figure 3. Flow diagram of study participation, prior to the addition of health care professional validation. OPEN: Outcomes of Patients' Evidence with Novel, Do-it-Yourself Artificial Pancreas Technology.

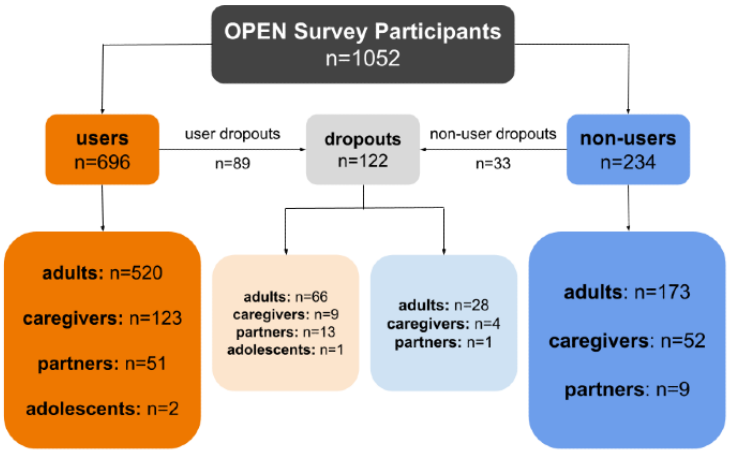


Table 2. Participants who completed at least one questionnaire prior to addition of the health care professional validation element.

Participant type	Users (n=696), n (%)	Nonusers (n=234), n (%)	All (n=930), n (%)
Adults	520 (55.9)	173 (18.6)	693 (74.5)
Adolescents	2 (0.2)	0 (0.0)	2 (0.2)
Caregivers	123 (13.2)	52 (5.6)	175 (18.8)
Partners	51 (5.5)	9 (1.0)	60 (6.5)

After the Gateway was extended to enable health care professional validation of self-reported clinical outcomes, an additional 164 individuals visited the Gateway page, of whom 20 did not proceed to the survey and 2 dropped out during the first questionnaire; therefore, 142 participants (users: 105/142, 73.9%; nonusers: 37/142, 26.1%) completed at least one questionnaire (Figure 4; Table 3). A total of 7 participants allowed their health care professional to validate their clinical data—5 completed the survey before and 2 completed the survey after health care professional validation was added.

Figure 4. Flow diagram of study participation, with the addition of health care professional validation. OPEN: Outcomes of Patients' Evidence with Novel, Do-it-Yourself Artificial Pancreas Technology.

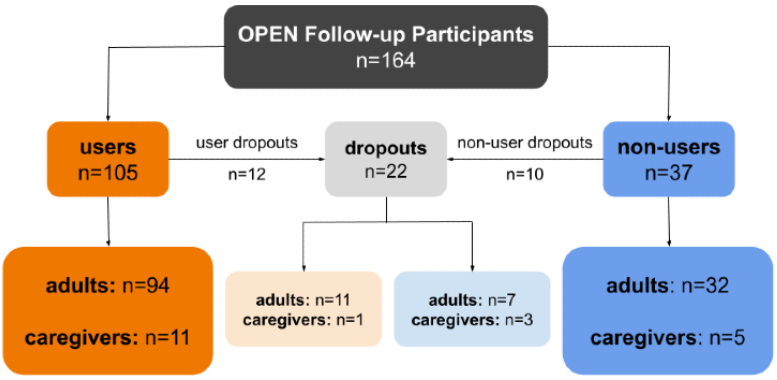


Table 3. Participants who completed at least one questionnaire after the addition of the health care professional validation element.

Participant type	Users (n=105), n (%)	Nonusers (n=37), n (%)	Total (n=142), n (%)
Adults	94 (66.2)	32 (22.5)	126 (88.7)
Caregivers	11 (7.7)	5 (3.5)	16 (11.3)

During the survey period, 137 individuals joined Open Humans. Of those 137 individuals, 97 participated in the survey, uploaded device data, and authorized the OPEN project to access their data on Open Humans; these 97 participants are represented within the larger group of 930 participants who completed at least one survey questionnaire. Open-source automated insulin delivery systems are highly individualized, allowing for a variety of pumps and continuous glucose monitoring systems to be used. Thus, data contained records from multiple different devices, including continuous glucose monitoring data from Dexcom (models G4, G5, or G6), Eversense, Medtronic (Guardian or Enlite models) and Freestyle Libre (model 2), as well as information about insulin delivery provided by pumps—Accu-Chek (Insight or Combo models), older Medtronic pumps, SOOIL Dana Diabecare (R or RS models), and Omnipod (Eros model). Continuous glucose monitoring data included timestamp entries of blood glucose levels, whereas pump data included information about insulin delivery such as extended boluses and temporary basal rates. Nonusers of open-source automated insulin delivery uploaded continuous glucose monitoring and pump data but did not have algorithmic automated insulin delivery data to donate. Individualized profiles from automated insulin delivery systems captured variable and algorithm output data, including changes to blood glucose targets, dosing decisions, carbohydrate entries, and general manual inputs.

Discussion

Principal Results

The Gateway fulfilled 3 main requirements to facilitate anonymous participation in multiple questionnaires and paired diabetes data donation: linking survey records in REDCap to Open Humans Project Member IDs as an optional extension, linking records from partners and health care professionals in addition to open-source automated insulin delivery users and nonusers, and making the entire process anonymized and General Data Protection Regulation–compliant.

Linking, the low cost of services, and familiarity were all related to the central objective of developing a platform for sharing anonymized diabetes data and completing surveys. Linking services improved ease of use for participants; open-source software is free and easier to expand upon (open repositories, direct communication with developers); and familiarity with the services (within research domains) provided a larger body of knowledge to pull from in experimental design, best practices for implementation, and data security. This last element is important—data privacy and security are critical when working with medical data for the protection of participants.

The initial approach was to let participants create an Open Humans account and join the OPEN project (thus generating a Project Member ID), then manually enter their Project Member ID into REDCap and create an identifier on their own with which their partner and health care professional could also join the survey. However, the Project Member ID from Open Humans could not be entered after the REDCap survey was completed, which made setting up data donation on Open Humans before starting the survey necessary. Furthermore, because registering for Open Humans, uploading data, and joining the OPEN project was a multistep process, participants could become fatigued and leave the study before reaching the questionnaires. There was additional concern that participants might accidentally reveal identifying information by creating linking identifiers, hence this approach was abandoned.

Another approach that we considered was requiring that all participants sign up for a personal account on Open Humans, to ensure that every participant had a Project Member ID available when beginning the survey. To minimize the burden of participation, we did not impose this requirement (ie, mandatory registration on a third-party platform), which could have limited the number of potential survey participants.

However, the use of Open Humans as a device data donation platform provided improved security and anonymity. We decided against using Nightscout accounts—or identifiers of any other device data cloud storage—for privacy reasons.

Personal accounts may not be secure or anonymous; whereas, registration through Open Humans provided each participant with a unique anonymous ID and allowed for a standardized process of providing data to the OPEN project.

Existing tools and platforms were used; REDCap and Open Humans are both trusted, well-established, and have proven reliability, which has been demonstrated in previous studies [28-31]. Developing the Gateway was thus a feasible task as it only had to establish a linkage between data sets, whereas implementing questionnaires and data donation were predefined processes in their respective web-based services. Such a design kept overhead costs low relative to development and made use of familiar digital systems.

Completion of an electronic consent form was a prerequisite for participating in the study. While such a consent form was suitable for the bulk of the study—direct participant signatures were not required, only anonymous agreement to the study terms—the release of health care professionals from confidentiality (if participants participated in that component of the study) required a direct signature from the participant. An e-signature stored in the Gateway would have directly tied identifying information to participants' survey responses and medical device data, compromising anonymity.

The decision was made to use physically signed consent forms that were given directly to health care professionals and ultimately stored with participants' health records. These consent records were not available to OPEN—this enabled health care professionals to provide participant information without violating data protection regulations.

With the level of centralization afforded by the Gateway, it was feasible to add health care professional validation at a later stage of the study. It was only necessary to add another record ID from REDCap to the database and link it to the correct Participant ID; REDCap did not directly provide mechanisms for establishing such links; therefore, this would not have been possible without the Gateway.

Data were immediately accessible to the OPEN team at the end of data collection, with conditional access through an internal application process. Questionnaire responses were logged in REDCap and could be downloaded directly; similarly, Open Humans data could be downloaded directly from the OPEN project's profile on Open Humans. The Gateway database—containing all participant IDs, survey record IDs, and Project Member IDs—was shared with OPEN members through a shared cloud drive. The Gateway was designed for adaptation to future studies and remains operational; the late addition of health care professional–validation demonstrated the functionality of linking new elements, allowing for continuous extensibility of the portal.

Limitations

Despite the overall success of the study, there were some drawbacks to the final structure. To donate their diabetes data, participants first had to create Open Humans accounts, upload their data (which may involve first joining and utilizing an *uploader project*), and then join the OPEN Project on Open Humans (ie, authorize the OPEN project to access their device data). All steps had to be completed for the OPEN team to be able to access the anonymous donated diabetes data. The discrepancy between individuals who joined Open Humans and participants who completed the survey and authorized data donation could be attributed to all study elements being optional. Similar to the survey—where individuals across groups left before even completing the baseline demographic information (Figures 3 and 4)—individuals attempting to authorize the OPEN project to access their data may have exited the process before completion. Because all study elements were optional, individuals could choose to complete the survey but not authorize data access, authorize data access but not complete any questionnaires, complete both study elements, or exit before completing anything. The long list of questionnaires and multistep process of data authorization may have been too extensive for some individuals; this may have limited the potential amount of diabetes data captured.

While we thought that ensuring data privacy and anonymity could help to reduce the perceived burden of participation—based on the assumption that people would be more likely to provide detailed information if their identity remains private—there is evidence against this idea [32]. Additionally, the extensiveness of the study may have overpowered any potential reductions in perceived burden of participation due to anonymity; survey fatigue may have negated any retention achieved due to privacy. The presence of dropouts from each participant group is evidence that counters the argument that privacy precipitates participation.

In line with this, the potential risk of participants uploading simulated or falsified data was also considered. On one hand, anonymity theoretically makes tracing these participants more difficult. On the other hand, the number of steps required to produce authentic falsified data would be prohibitively complex. Most falsified automated insulin delivery data can be identified by researchers, as there are a number of elements (such as formatting, quantity and structure, algorithm decisions and variables) within data sets, which would create major barriers to generating authentic falsified data. To date, there are no reported issues of this occurring within research leveraging Open Humans. In general, it has been shown elsewhere [33-35] that real-world data are an important and robust source of information in addition to those from clinical trials. Furthermore, we screened both survey and device data for false entries and removed obvious outliers and erroneous entries where necessary.

While physical signatures were a feasible approach for obtaining consent from participants for their health care professionals to release medical data, the low number of participating health care professionals relative to survey participants may have been a consequence of adding a singular physical element to a study that is largely web-based. Participants may have been less willing to print out and personally send, rather than electronically sign, a form. Health care professional involvement was also the last element to be added to the study; this may have impacted participation. There are many potential factors resulting from the ongoing COVID-19 pandemic (maintaining safety precautions, continued changes to daily life, and carrying out vaccinations) that may have contributed to lower

participation rates in the health care professional validation part of the study.

While not necessarily a limitation in this study, future studies may be impacted by tools and frameworks used by this study. Because of the developer's familiarity with Ktor—which did allow for quick prototyping—any future developers working with this codebase that decide to replicate this approach may have to use a completely different toolchain that better fits their needs.

Conclusion

The Gateway, as a portal made OPEN studies [10-12] both accessible for participants and manageable for researchers while maintaining General Data Protection Regulation compliance. Implementation of the disparate study elements was not necessarily complicated; creating the linkages between them required a creative solution, and scalability was also demonstrated with the later addition of health care professional validation of self-reported clinical outcomes. A practical mechanism for matching data sets and establishing links between disparate systems made this study and its extensions possible. In the future, custom software solutions such as the Gateway may become the norm in research with increasingly large data sets across disparate digital services.

Acknowledgments

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Data Availability

After the completion of the OPEN project, requests to access study data can be made to SO. The Gateway codebase [36] is available for use by researchers aiming to implement similar multimodal study designs.

Conflicts of Interest

KB received fees for medical consulting and public speaking from Roche Diabetes Care, Dexcom, Medtronic Diabetes, Diabeloop, Sanofi Diabetes, Novo Nordisk, and BCG Digital Ventures that are not related to this study. DL reports grants from the Robert Wood Johnson Foundation, the Juvenile Diabetes Research Foundation, New Zealand Health Research Council that are not related to this study.

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Abbreviations

API: application programming interface
OPEN: Outcomes of Patients' Evidence with Novel, Do-it-Yourself Artificial Pancreas Technology

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Original Paper

Constructing an Adapted Cascade of Diabetes Care Using Inpatient Admissions Data: Cross-sectional Study

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Abstract

Background: The diabetes mellitus cascade of care has been constructed to evaluate diabetes care at a population level by determining the percentage of individuals diagnosed and linked to care as well as their reported glycemic control.

Objective: We sought to adapt the cascade of care to an inpatient-only setting using the electronic health record (EHR) data of 81,633 patients with type 2 diabetes.

Methods: In this adaptation, *linkage to care* was defined as prescription of diabetes medications within 3 months of discharge, and *control* was defined as hemoglobin A_{1c} (HbA_{1c}) below individual target levels, as these are the most reliably captured items in the inpatient setting. We applied the cascade model to assess differences in demographics and percent loss at each stage of the cascade; we then conducted two-sample chi-square equality of proportions tests for each demographic. Based on findings in the previous literature, we hypothesized that women, Black patients, younger patients (<45 years old), uninsured patients, and patients living in an economically deprived area called the Promise Zone would be disproportionately unlinked and uncontrolled. We also predicted that patients who received inpatient glycemic care would be more likely to reach glycemic control.

Results: We found that out of 81,633 patients, 28,716 (35.2%) were linked to care via medication prescription. Women and younger patients were slightly less likely to be linked to care than their male and older counterparts, while Black patients (n=19,141, 23.4% of diagnosed population vs n=6741, 23.5% of the linked population) were as proportionately part of the linked population as White patients (n=58,291, 71.4% of diagnosed population vs n=20,402, 71.0% of the linked population). Those living in underserved communities (ie, the Promise Zone) and uninsured patients were slightly overrepresented (n=6789, 8.3% of diagnosed population vs n=2773, 9.7% of the linked population) in the linked population as compared to patients living in wealthier zip codes and those who were insured. Similar patterns were observed among those more likely to reach glycemic control via HbA_{1c}. However, conclusions are limited by the relatively large amount of missing glycemic data.

Conclusions: We conclude that inpatient EHR data do not adequately capture the care cascade as defined in the outpatient setting. In particular, missing data in this setting may preclude assessment of glycemic control. Future work should integrate inpatient and outpatient data sources to complete the picture of diabetes care.

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KEYWORDS

diabetes mellitus; cascade of care; EHR data; health care monitoring; inpatient care

Introduction

A total of 34 million patients in the United States are currently diagnosed with diabetes mellitus, which equates to roughly 10% of the population. Diabetes was the seventh leading cause of death in 2017. Type 2 diabetes is further complicated by comorbidities, such as high blood pressure, cholesterol, and cardiovascular disease (CVD) [1], and accounts for roughly US $327 billion per year in the US health care system [2].

Overall, new cases of diabetes have been decreasing over the last decade, even among younger patients, while disparities by both race and education level were noted in the US Centers for Disease Control and Prevention's 2017 diabetes report. The report indicated that Hispanic, Black, and Native American and Alaska Native patients had a higher prevalence of diabetes compared to White patients. Additionally, diabetes was almost twice as prevalent among adults without a high school diploma in contrast to adults who at least graduated and pursued further degrees [3]. It has been shown that Black patients receiving Medicare are also less likely than those not covered by Medicare to report well-controlled blood sugar [4], and women diagnosed with diabetes face increased risk of cardiac and kidney comorbidities compared to men [5].

The cascade of diabetes care exists to examine the treatment path from diagnosis to linkage to care for diabetes patients through follow-up visits with their primary care provider, prescription of diabetes medications, and visits with diabetes or nutritional specialists. Diabetes *control* refers to adherence to quality-of-care metrics, including hemoglobin A_{1c} (HbA_{1c}) measurements below individualized target levels, controlled systolic and diastolic blood pressure, assessment of lipids and urine microalbumin, and nonsmoking status.

Using National Health and Nutrition Examination Survey data from 2005 to 2016, previous research found that 70% of patients were linked to care, while just 20% of patients reached the composite treatment targets [6]. They reported that diabetes care, in terms of linkage to care and control, had not improved significantly from 2005-2006 to 2015-2016, nor were there improvements in disparities in linkage to care and disease control between sexes, races, and age groups. Younger patients and female patients were consistently less likely to be linked to care after their diagnosis. In addition, younger, female, non-White, and Hispanic patients were less likely to reach glycemic control, blood pressure, and cholesterol targets than their older, male, White, and non-Hispanic counterparts [7]. These disparities have been explored in previous studies compiled by the American Journal of Public Health [8] and have been tied to different behavioral factors, such as stress and substance abuse; psychological factors, such as depression; and clinical factors, such as quality of care and timely diagnosis and treatment.

According to the American Diabetes Association (ADA), roughly one-third of health care costs associated with diabetes are related to hospital inpatient care [9]. Basal-bolus insulin regimens for inpatient glycemic control have been shown to reduce hospital complications, particularly for postsurgical patients [10,11], with potentially improved glycemic control in subsequent follow-up periods as well [12]. While diabetes is seldom the primary focus of an inpatient admission, a hospitalization is nonetheless an opportunity for diabetes diagnosis and linkage to care, and this has not been thoroughly studied. Therefore, we sought to address this gap in the literature by examining a proposed inpatient cascade of diabetes care for patients with type 2 diabetes. This paper provides a construction and analysis of this framework by examining patients who were initially diagnosed in the inpatient setting and their linkage to care during their stay. Additionally, we assessed for disparities in care according to the demographic and socioeconomic characteristics of patients.

Methods

Study Population

Our study population was comprised of 93,433 patients with diabetes who were seen in the inpatient setting of a 15-hospital health care system in St. Louis, Missouri, from 2010 to 2019. We focused our study on individuals with or without complications of diabetes, and we excluded those diagnosed with diabetes during pregnancy (International Classification of Diseases, Tenth Revision [ICD-10] O24.xx, n=3875). Additionally, we excluded patients with type 1 diabetes (ICD-10 E10.xx, n=7925) from our study, given our objective to focus on those diagnosed with type 2 diabetes. We also focused on only those for which the diagnosis of type 2 diabetes appeared in the problem list for that admission. Our final study population included 81,633 patients.

Constructing the Inpatient Cascade of Care

We consulted published guidelines from the ADA [9,10,13] with input from an endocrinologist (CH) to adapt the outpatient cascade of care [6] for the inpatient setting. Data were procured from the electronic health records (EHRs) of a large St. Louis, Missouri–area medical center. For the inpatient cascade, patients were considered diagnosed, linked to care, or controlled based on the following:

- Patients were considered diagnosed if they had a diagnosis of type 2 diabetes mellitus, with or without complications (ICD-10 E11.xx), and were admitted to the hospital system with their first recorded diabetes diagnosis in the problem list within a day of diagnosis.
- Patients were considered linked to care if they were prescribed insulin, noninsulin injectables, or oral anti-diabetes drugs (Multimedia Appendix 1) within 3 months of discharge.
- Patients were considered controlled if their recorded HbA_{1c} 6 months after discharge was between 7% and 8.5%. This definition was individualized per existing guidelines and the previously published outpatient cascade of care [6].
  - Patients less than 65 years of age were considered controlled ($HbA_{1c} \leq 7\%$) if they had diabetes without complications or CVD, and were considered controlled ($HbA_{1c} \leq 8\%$) if they had complications or CVD.
  - Patients 65 years of age or older were considered controlled ($HbA_{1c} \leq 7.5\%$) if they had diabetes without

complications or CVD, and were considered controlled (HbA_{1c}≤8.5%) if they had complications or CVD.

Variables of Interest

Our population was mainly White, consistent with the population in the St. Louis metropolitan area. Thus, we categorized race into categories of White, Black, and other. We defined age groups according to the following cutoffs: 18 to 44 years, 45 to 64 years, and 65 years of age and older [6]. Patients with self-pay insurance or no recorded insurance were considered uninsured, and patients with insurance that did not include Medicare or Medicaid were considered privately insured.

We classified the zip code of residence for each patient according to whether or not they lived in the Promise Zone. The Promise Zone is an area in North St. Louis City and County designated in 2015 that is defined by a poverty rate or extremely low–income rate equal to or greater than 33% of the federal poverty level, where a federal local partnership has been established to improve education, economic activity, health, and wellness in the community [14].

To assess which HbA_{1c} control cutoff to use, we considered patients' diabetes diagnoses, as well as any CVD diagnoses as previously described, and the patients' ages. Our definition of CVD included myocardial infarction, heart failure, and angina (Multimedia Appendix 1). Finally, as a proxy to evaluate if and how diabetes was recognized in the inpatient setting (ie, inpatient glycemic care indicator), we assessed whether HbA_{1c} was measured, whether insulin lispro was administered within 24 hours of their admission, or whether a consultation with a diabetes or endocrinology specialist was called at any point during their admission.

Analysis

We constructed descriptive statistics of the distributions of race, sex, and age at diagnosis, as well as insurance status, residence in the Promise Zone, and inpatient glycemic care indicators: HbA_{1c}, insulin, and diabetes consultation in our data set. We then compared proportions within each category along the cascade of care to assess disparities using two-sample chi-square tests.

We explored geographic disparities in the data and compared the cascade of diabetes care for patients who lived in Promise Zone zip codes to those residing in the remaining zip codes in the patient catchment area.

Hypotheses

We hypothesized that patients living in Promise Zone zip codes and those with self-pay insurance or on Medicaid would be less likely to be linked to care and to reach HbA_{1c} control. Additionally, we hypothesized that patients who had an inpatient glycemic care indicator would be more likely to be linked but less likely to be controlled, as those patients may be more severe cases to begin with to require inpatient insulin treatment. From findings in the previous literature, we hypothesized that women, Black patients, and younger patients would be disproportionately unlinked and uncontrolled [7].

Ethical Considerations

This study was approved by the Washington University St. Louis Institutional Review Board (IRB) as an "exempt" project. The IRB ID for this project was 202007104.

Results

Overview

In our data set, 81,633 patients met the inclusion criteria. Our study population was 48.9% (n=39,880) female, 51.1% (n=41,748) male, and predominately White (n=58,291, 71.4%) and older (≥65 years of age: n=46,860, 57.4%; Table 1). A total of 35.5% (n=28,997) of patients were privately insured and 38.9% (n=31,742) received Medicare. A total of 17.5% (n=14,309) of patients resided in a Promise Zone zip code (Table 1), compared to 8% of the general St. Louis metropolitan population (data not shown).

Table 1. Demographic and clinical characteristics of our study population.

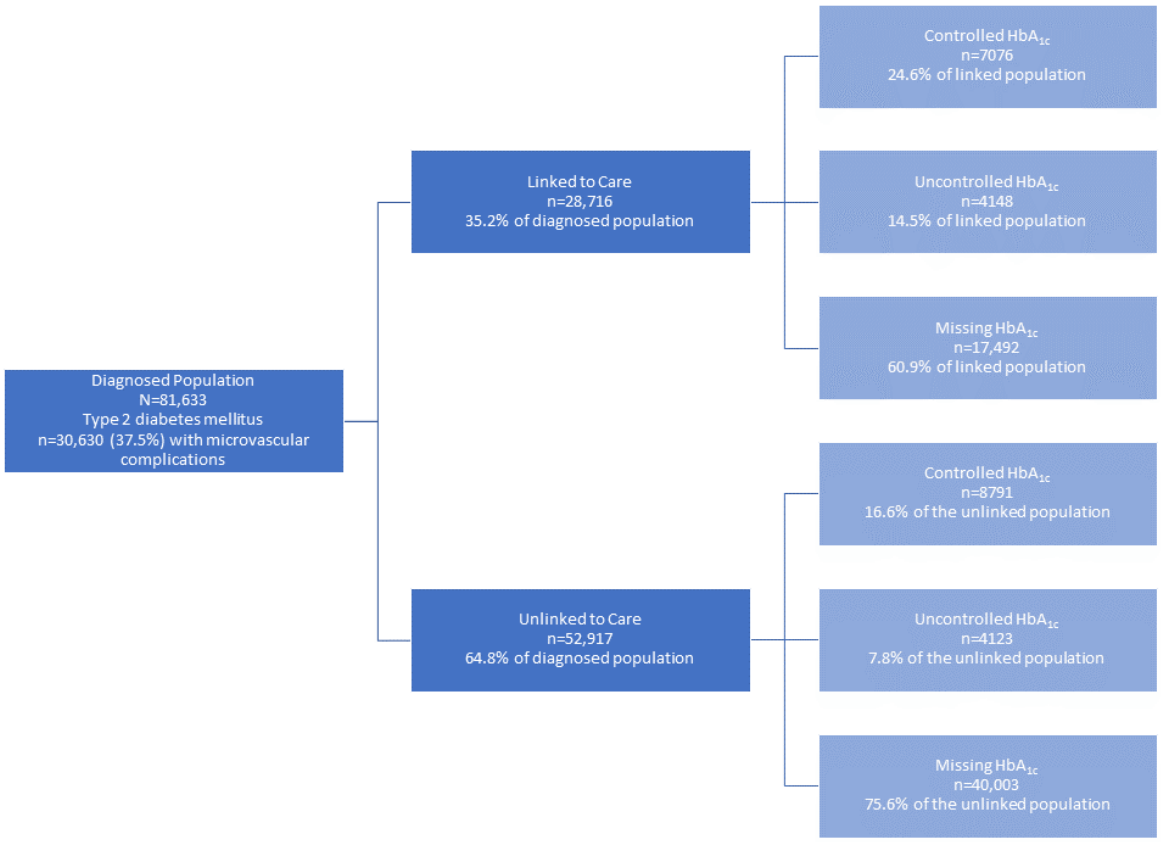
Variable	Participants (N=81,633), n (%)
Sex	
Female	39,880 (48.9)
Male	41,748 (51.1)
Missing	5 (<1.0)
Race	
White	58,291 (71.4)
Black	19,141 (23.4)
Other	2625 (3.2)
Missing	1576 (1.8)
Age at diagnosis (years)	
18-44	5887 (7.2)
45-64	28,886 (35.4)
≥65	46,860 (57.4)
Missing	4 (<1.0)
Residence in Promise Zone	14,309 (17.5)
Insurance status	
Private	28,997 (35.5)
Medicare	31,742 (38.9)
Medicaid	14,096 (17.3)
Uninsured or self-pay	6798 (8.3)
Missing	4 (<1.0)
Inpatient glycemic care markers	
HbA_{1c}[a] measured within 24 hours	22,337 (27.4)
Insulin lispro administered within 24 hours	59,220 (72.5)
Diabetes or endocrinology specialist consultation during stay	4988 (6.1)
At least one glycemic care marker	63,222 (77.4)

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

The Inpatient Cascade of Care

Out of 81,633 patients in our data set, 35.2% (n=28,716) met the linkage-to-care criteria for medication prescription within 3 months of discharge. Figure 1 shows the proportion of patients achieving each of the stages in the cascade of care, stratified by linked and unlinked to care, and then by in control, not in control, and missing a measure of HbA_{1c}. A total of 70.4% of patients (n=57,495) had no HbA_{1c} values recorded in the inpatient setting 6 months after their initial admission. While this is a large proportion of missing values, we recognize that after an initial inpatient encounter, diabetes patients generally transition into outpatient settings for their continued care. Therefore, these values may not be recorded in inpatient EHR records.

Figure 1. This flowchart illustrates the cascade of type 2 diabetes care with cohort sizes at each stage of the cascade, including information about missing glycemic data. Note, the control row of the flowchart indicates the percentage of the linked or unlinked cohorts, not the percentage of the original diagnosed cohort. HbA_{1c}: hemoglobin A_{1c}.



In our data, females and younger patients were less likely to be linked to care compared to males and middle-aged patients. Women made up 48.9% (n=39,880) of the diagnosed population, but 48.9% (n=13,814) of the linked population (<1% change, *P*=.03). Younger patients made up 7.2% (n=5887) of the entire diagnosed population, but were just 6.8% (n=1963) of the linked population (<1% change, *P*=.03). We did not find that patient race varied between the diagnosed, linked, and unlinked populations. Patients living in the Promise Zone (n=14,309, 17.5% of diagnosed population vs n=5366, 18.7% of linked population; *P*<.001) and uninsured patients (n=6798, 8.3% vs n=2773, 9.7%; *P*<.001) were more likely to be linked to care, while those with private insurance were less likely to be linked to care (n=28,997, 35.5% vs n=9611, 33.5%; *P*<.001).

Differences in HbA_{1c} control among individuals linked to care must be interpreted with caution in the setting of missing data. Among those linked to care, patients 65 years of age and older and men were less likely to be uncontrolled compared to younger patients and women. Black patients were overrepresented in the uncontrolled group, but they were also less likely to be missing a recorded HbA_{1c} value at 6 months as measured in the inpatient setting. While patients in the Promise Zone were more likely to be linked to care, approximately one-third (n=1612, 30.0% of linked patients residing in the Promise Zone) of those patients reached HbA_{1c} control. Finally, individuals with self-pay insurance and those on Medicaid were less likely to be controlled but were also less likely to be missing HbA_{1c} data over the course of the 6-month follow-up window.

Table 2. Cascade of care by population covariates.

Variable	Diagnosed (N=81,633), n (%)	Linked to care (n=28,716), n (%)	Unlinked to care (n=52,917), n (%)	Linked to care, n (%)[a]		
				Controlled HbA_{1c}[b] (n=7076)	Uncontrolled HbA_{1c} (n=4148)	Missing HbA_{1c} (n=17,492)
Sex						
Female	39,880 (48.9)	13,814 (48.1)*	26,066 (49.3)	3592 (50.8)*	2102 (50.7)*	8120 (46.4)*
Male	41,748 (51.1)	14,902 (51.9)*	26,846 (50.7)	3484 (49.2)*	2046 (49.3)*	9372 (53.6)*
Missing	5 (<1.0)	0 (0)	5 (<1.0)	0 (0)	0 (0)	0 (0)
Race						
White	58,291 (71.4)	20,402 (71.0)	37,889 (71.6)	4789 (67.7)*	2584 (62.3)*	13,029 (74.5)*
Black	19,141 (23.4)	6741 (23.5)	12,400 (23.4)	2012 (28.4)*	1418 (34.2)*	3311 (18.9)*
Other	2625 (3.2)	1001 (3.5)*	1624 (3.1)	246 (3.0)	109 (2.6)	679 (3.9)*
Missing	1576 (1.8)	572 (1.9)	1004 (1.9)	74 (<1.0)	32 (<1.0)	473 (2.7)*
Age at diagnosis (years)						
18-44	5887 (7.2)	1963 (6.8)*	2924 (7.4)*	349 (4.9)*	516 (12.4)*	1098 (6.3)*
45-64	28,886 (35.4)	10,397 (36.2)*	18,489 (34.9)	2376 (33.6)*	2130 (51.4)*	5891 (33.7)*
≥65	46,860 (57.4)	16,356 (57.0)	30,504 (57.6)	4351 (61.5)*	1502 (36.2)*	10,503 (60.0)*
Residence in Promise Zone	14,309 (17.5)	5366 (18.7)*	8943 (16.9)*	1612 (22.9)*	847 (28.5)*	2661 (15.2)*
Insurance status						
Private	28,997 (35.5)	9611 (33.5)*	19,386 (36.6)*	1937 (27.4)*	1140 (38.4)*	6145 (35.1)*
Medicare	31,742 (38.9)	11,487 (40.0)*	20,255 (38.2)*	3132 (44.3)*	731 (24.6)*	7152 (40.9)
Medicaid	14,096 (17.3)	4845 (16.9)	9251 (17.5)	1261 (17.8)	583 (19.6)*	2813 (16.1)*
Self-pay	6798 (8.3)	2773 (9.7)*	4025 (7.6)*	746 (10.5)*	515 (17.3)*	1382 (7.9)*
Inpatient glycemic care markers						
HbA_{1c} measured within 24 hours	22,337 (27.4)	8255 (28.7)*	14,082 (26.6)*	1979 (28.0)*	1390 (33.5)*	4886 (27.9)
Insulin lispro administered within 24 hours	59,220 (72.5)	23,003 (80.1)*	36,217 (68.4)*	5589 (79.0)*	3649 (88.0)*	13,765 (78.7)*
Diabetes or endocrinology specialist during stay	4988 (6.1)	2335 (8.1)*	2654 (5.0)*	737 (10.4)*	687 (16.5)*	910 (5.2)*
At least one inpatient glycemic care marker	63,222 (77.4)	24,159 (84.1)*	39,064 (73.8)*	5937 (83.9)	3800 (91.6)*	14,421 (82.4)*

[a]Proportions in the glycemic control columns denote the proportion of linked patients, not of the entire diagnosed population.

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

*P<.05 between proportions from one stage of the cascade to the next.

Patients with inpatient glycemic care markers were more likely to be linked to care. For example, 72.5% (n=59,220) of the diagnosed population were administered insulin lispro within 24 hours, and those patients made up 80.1% (n=23,003) of the linked cohort versus 68.4% (n=36,217) of the unlinked cohort (P<.001). Additionally, 77.4% (n=63,222) of patients in the diagnosed population had at least one inpatient glycemic care indicator, and these patients were also overrepresented in the linked population (linked: n=24,159, 84.1% vs unlinked: n=39,064, 73.8%; P<.001). However, individuals with at least one glycemic care indicator were overrepresented in the uncontrolled population (uncontrolled: n=3800, 91.6% vs controlled: n=5937, 83.9%; P<.001).

Discussion

Principal Findings

The analysis in this study is a first step in using inpatient EHR data to explore the diabetes cascade of care in an inpatient setting. Among a population of individuals with type 2 diabetes diagnoses newly noted during hospital admission, we were able to determine how many were linked to care using a definition

of diabetes medication prescription within 3 months of discharge. We were able to determine indicators of inpatient glycemic management (ie, HbA_{1c} checked, insulin started, or diabetes service consulted) and identified that individuals with one or more of these indicators were significantly more likely to be linked to care. Our findings highlight the importance of recognizing diabetes during a hospital stay in establishing appropriate follow-up.

We observed that a significant proportion of individuals treated with insulin lispro during a hospital stay did not meet criteria for linkage to care, identifying a potential opportunity for intervention. In addition, very few patients were seen by a diabetes or endocrinology specialist in the hospital; however, this is not unexpected given that diabetes consultations, when available at a particular hospital, are typically reserved for only the most severely uncontrolled patients. We also examined HbA_{1c} values at 6 months postdischarge; however, conclusions about control were limited by significant *missingness* in the data, and these associations should be explored with more complete data in the future.

Our analysis highlights three important points: (1) a possible "leaky pipeline," or patients that drop out of the cascade of care after discharge from the hospital; (2) the importance of recognizing and acting on diabetes in the inpatient setting to mitigate this leaky pipeline; and (3) the difficulty of using inpatient data alone for the definition of a diabetes cascade of care.

Linkage to Care, Leaky Pipeline, and Inpatient Glycemic Care Markers

First, we noted that only 35% of the population was linked to care by our definition of receiving medication for diabetes within 3 months of discharge. This likely overestimates loss to follow-up; however, because 19% of patients in the unlinked group were noted to have a controlled HbA_{1c} at 6 months postdischarge, these patients were likely linked to outpatient care. Nonetheless, even if those who were linked to care and those who were unlinked but controlled were considered together, they would comprise 54% of the population. This proportion is much lower than the 77% who met one of the inpatient glycemic care indicators in the inpatient setting.

We observed that patients with at least one of the inpatient glycemic care markers were much more likely to be linked to care than those without, underscoring the importance of recognizing and acting on diabetes during a hospital stay. Additionally, and not surprisingly, at 6 months postdischarge, a larger proportion of individuals who were linked to care had controlled HbA_{1c} as compared to those not linked to care, and a smaller proportion of those who were linked to care had missing HbA_{1c} data as compared to those not linked to care. We hypothesized that while patients with inpatient glycemic care markers were more likely to be linked to care, they would also be less likely to reach their HbA_{1c} target at 6 months, possibly representing diabetes that is more difficult to control.

Counter to our hypothesis, patients with no insurance were more likely to be linked to care, and patients with private insurance were less likely to be linked. Meanwhile, patients living in the Promise Zone were more likely to be linked to care as compared to those not residing in the Promise Zone. These findings were unexpected but could reflect the type of follow-up data available within our hospital system. Privately insured individuals and those living in zip codes with higher economic opportunity may be more likely to follow up with a physician outside of our system, whereas uninsured patients and those living in the Promise Zone may be more likely to be readmitted to our system as an inpatient during the follow-up period.

Glycemic Control Assessment and Data Missingness

Data *missingness* refers to the prevalence of data not captured in the inpatient EHR. Black patients, younger patients, patients with no insurance, or those receiving Medicaid were overrepresented in the uncontrolled population as compared with the overall diagnosed population; however, these groups were also less likely to be missing HbA_{1c} data than their comparators, so it is difficult to draw firm conclusions with this information. The lower proportion of missing HbA_{1c} data among these populations may be related to these populations being seen in the inpatient setting more often; thus, their data were better captured.

Difficulty Defining Diabetes Cascade of Care With Inpatient Data Alone

Overall, our analysis demonstrates that defining a cascade of diabetes care using inpatient data alone is limited by the fragmentation in the health care ecosystem. Given that diabetes is managed almost exclusively in the outpatient setting, the utility of an inpatient diabetes cascade of care would be primarily to (1) determine appropriate management of hyperglycemia in the inpatient setting for individuals with diabetes and (2) identify newly diagnosed diabetes and action by the inpatient team to prescribe appropriate therapy and connect the patient to an outpatient provider upon discharge. Our analysis highlights a challenge commonly encountered in the United States, in that inpatient data may not be linked to outpatient data, even within a network of affiliated outpatient practices in a hospital system [15,16]. Interoperability of EHR systems is critical to optimize this type of analysis in the future.

The "Ideal" Inpatient Cascade of Diabetes Care

An optimal investigation of a diabetes cascade of care would focus on diabetes first noted in the inpatient setting and identifying individuals first noted in a hospital stay to have glucose values outside of the normal range. The next steps would be to determine what proportion of these individuals subsequently had an HbA_{1c} evaluation, and then to quantify how many of those diagnosed with diabetes via an HbA_{1c} value equal to or more than 6.5% were initiated on diabetes medication and referred to a primary care provider for follow-up. Such an investigation would also include detailed glucose data during the hospital stay to determine what proportion of individuals with blood sugars greater than 180 mg/dL in the inpatient setting were started on insulin during the hospital stay and how many had a diabetes consultation in the hospital. The cascade would then follow individuals in the outpatient setting to determine how many ultimately achieved glycemic control, blood pressure,

cholesterol, and smoking targets, which are associated with CVD risk among patients with diabetes. The benefit of using fully integrated inpatient and outpatient EHR data for this type of analysis lies in the potential for longitudinal follow-up and the opportunity to identify individuals most severely affected by complicated diabetes who are hospitalized.

System-Level Challenges in Transition of Care From Inpatient to Outpatient Settings

The lack of interoperability between inpatient and outpatient EHR systems creates significant opportunities for loss to follow-up in clinical care. Hospital discharge summaries may not reach the primary care physician, and they may not specifically address diabetes if this was not the reason for admission [17,18]. Moreover, enhanced diabetes education in the inpatient setting with specific transition instructions provided to the patient and primary care physician improved HbA_{1c} over a 1-year follow-up [19]. However, inpatient diabetes self-management education is not a reimbursed service, and outpatient access to certified diabetes education is limited [20]. Diabetes-specific structured communication between inpatient and outpatient providers is essential to improve diabetes follow-up along the cascade of care.

Limitations

Significant limitations exist in the study, as outlined in the previous section, in part due to fragmentation. This is evidenced in the high number of missing HbA_{1c} measures due to the limitations of inpatient EHR data that we had access to for the analysis. Additionally, we pulled the first inpatient admission of diabetes mellitus based on the problem list for each patient, which means they could have been diagnosed earlier in the outpatient or primary care setting and received linkage to care for their diabetes in another setting not captured in our analysis.

Conclusions

An inpatient encounter may be an opportunity for incidental diabetes diagnosis, treatment, and linkage to care. However, a cascade of diabetes care using inpatient data alone is insufficient and difficult to align with the outpatient cascade of diabetes care [6] because of differences in care delivery and guidelines between the two settings. Additionally, we noted that while there were statistically significant differences between demographic variables of sex, race, age, insurance, and socioeconomic status indicated by residence in the Promise Zone and patients' linkage to care and glycemic control, those relationships may not be clinically significant. We recommend further study using integrated EHR data from inpatient and outpatient settings to define a cascade of care across the continuum of care to better define the utility of the inpatient setting in capturing and linking individuals with diabetes to appropriate outpatient care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Variable definitions using administrative codes.
[DOCX File , 15 KB - diabetes_v7i1e27486_app1.docx]

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Abbreviations

ADA: American Diabetes Association
CDTR: Center for Diabetes Translation Research
CVD: cardiovascular disease
EHR: electronic health record
HbA_{1c}: hemoglobin A_{1c}
ICD-10: International Classification of Diseases, Tenth Revision
IRB: Institutional Review Board
NICHD: National Institute of Child Health and Human Development

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Original Paper

The Rapid Implementation of an Innovative Virtual Diabetes Boot Camp Program: Case Study

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Abstract

Background: COVID-19 disrupted health care, causing a decline in the health of patients with chronic diseases and a need to reimagine diabetes care. With the advances in telehealth programs, there is a need to effectively implement programs that meet the needs of patients quickly.

Objective: The aim of this paper was to create a virtual boot camp program for patients with diabetes, in 3 months, from project conception to the enrollment of our first patients. Our goal is to provide practical strategies for rapidly launching an effective virtual program to improve diabetes care.

Methods: A multidisciplinary team of physicians, dieticians, and educators, with support from the telehealth team, created a virtual program for patients with diabetes. The program combined online diabetes data tracking with weekly telehealth visits over a 12-week period.

Results: Over 100 patients have been enrolled in the virtual diabetes boot camp. Preliminary data show an improvement of diabetes in 75% (n=75) of the patients who completed the program. Four principles were identified and developed to reflect the quick design and launch.

Conclusions: The rapid launch of a virtual diabetes program is feasible. A coordinated, team-based, systematic approach will facilitate implementation and sustained adoption across a large multispecialty ambulatory health care organization.

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KEYWORDS

telemedicine; diabetes; virtual health; mhealth implementation; virtual diabetes; digital health; mobile health; virtual health; virtual interventions

Introduction

The COVID-19 crisis necessitated an abrupt adjustment to the delivery of outpatient care in order to protect vulnerable populations from avoidable exposure to the virus while providing continuity of care to patients with chronic health issues. One result of the crisis was that telemedicine use exploded worldwide, especially in patients with diabetes [1-6]. In response to COVID-19, UPMC (University of Pittsburgh Medical Center) Central Pennsylvania made an immediate pivot to deliver most ambulatory care via telehealth, resulting in a 1000% surge in telehealth use across all medical and surgical specialties in the early months of the pandemic. In September 2020, we launched a virtual diabetes boot camp program to complement our existing services.

UPMC Central Pennsylvania is a large, integrated, not-for-profit health care system with over 2900 physicians across 7 acute care hospitals and 200 ambulatory care sites, serving over 10 counties in central Pennsylvania. UPMC Central Pennsylvania established their telehealth program in 2013, when a telestroke initiative was launched. The telehealth department has since grown and is led by the chief medical information officer and supported by a director, analysts, clinical implementation consultants, and trainers. It is also supported by a dedicated patient phone and email hotline for telehealth and portal issues. UPMC Central Pennsylvania uses the Epic (Epic Systems

Corporation) electronic health record (EHR), the accompanying MyChart patient portal, and the EHR-integrated telehealth platform Vidyo (Vidyo Inc). The platform offers audio and video calls, messaging, file sharing, and automatic vital sign reporting. The diabetes boot camp also uses the website Tidepool (Tidepool Project) [7]. Tidepool is a 501(c)(3) nonprofit organization that provides a web-based platform to coview diabetes-related data entered by the patient.

The all-virtual, holistic diabetes program was conceived and developed in less than 3 months and includes diabetes education, nutrition counseling, coping mechanisms, planned exercise, and medication adjustment via a team of physicians, registered dieticians, and diabetes educators. Patients meet virtually with a team member once a week, alternating between a diabetes educator and a dietician, and regularly interact with the Tidepool application. Follow-up HbA1c (glycated hemoglobin) values are obtained after the completion of the 3-month program.

We started the program at selected pilot clinical sites, refining the program with input from all members of the team before adopting the program at the organizational level. Success was assessed by monitoring HbA1c improvement, weight and blood pressure control, and the number of patients completing the program. By using integrated workflows in the EHR and simplifying the process for both patients and providers, we were able to keep the changes minimal for most of those involved. Educating clinic staff to guide patients through enrollment and the use of the software was critical to the success of the program. Few studies have looked to described generalizable strategies to quickly design, launch, and implement a scalable virtual diabetes program across a large multispecialty ambulatory clinic group.

Methods

UPMC Central Pennsylvania is comprised of multiple primary care offices consisting of 300 primary care physicians across 50 clinics and 3 endocrinology clinics across a 10-county region. We have a dedicated telehealth department that guides strategy, implements, and supports all virtual programs across the organization. In July 2020, due to the growing need from patients with diabetes to be seen virtually, a diverse group of clinical, operational, and telehealth leaders were engaged to support the launch of a new way of taking care of patients with diabetes who required frequent appointments. The virtual program was developed to alleviate the need for frequent in-person visits during the pandemic using previous and new lessons learned through the pandemic and serve a large geography of patients traveling as far as 1 hour to see their endocrinologist. A quick timeline was decided for the program, and bimonthly meetings were held to optimize the project due to the pandemic emergency and to improve the virtual access of patients with diabetes to doctors.

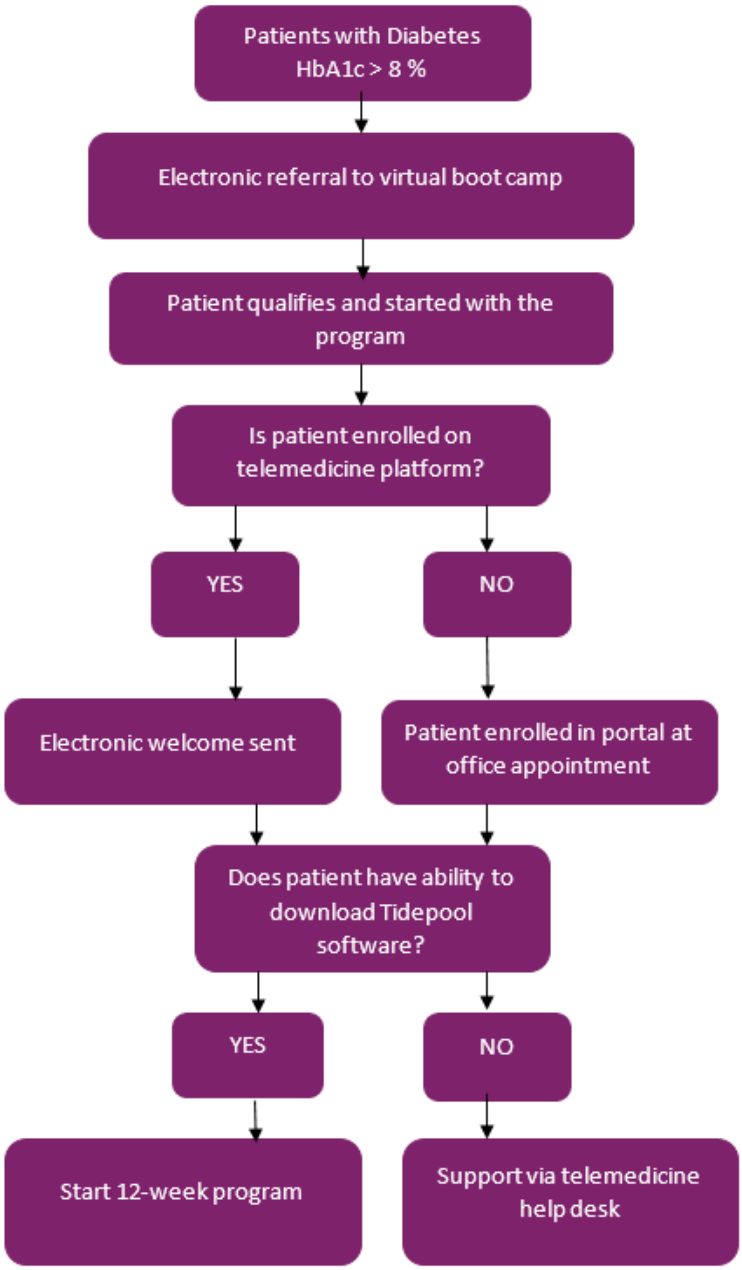
We were able to embed the new virtual workflows into the Epic ambulatory EHR, facilitating ease of adoption and operational efficiency. A documentation template was created to guide diabetes educators through medication change-related decisions. We also created a unique electronic referral in the EHR for the virtual boot camp to identify it as a new clinical service and for tracking purposes. Both the dieticians and the nutritionist team could receive this referral from physicians. The Tidepool software was installed on provider, educator, and dietician computers. Tidepool provides a diabetes web-based data platform to view data from multiple patient devices and display it together on one timeline. Physicians and staff were trained on using the Tidepool software to download glucose monitoring home data. Our endocrinologists introduced primary care physicians to the program via virtual educational seminars.

Using the endocrinology office as a pilot, a patient registry of patients with diabetes who had laboratory values of HbA1c>8% was generated from the EHR. The endocrinologists discussed the virtual boot camp program with these patients and initiated the referral process for interested patients. Administrative support personnel scheduled the virtual sessions and guided patients through the enrollment process. Patient education, including online instructions for downloading and uploading glucose data (using the Tidepool software), was delivered via the patient portal. If the patients had difficulty following the online instructions, the patient help desk or clinic staff engaged them via phone to guide them through the process.

Each week, the patients met virtually for a 30-minute session, alternating weekly between a diabetes educator and a dietician, to review glucose monitoring data from their mobile app, diet, exercise plans, and lifestyle changes. The virtual meetings were also held to address other education and medication or therapy changes. Progress was followed closely, using real time blood glucose data. Weekly feedback showing improvements helped to keep the patients engaged and adherent to the program. We found that gamification of the process (by tracking the numbers closely and meeting target results) kept the patients motivated throughout the program. At the end of the 12-week program, HbA1c values were rechecked, and each patient had a follow-up telehealth visit with an endocrinologist. Our program's success was assessed via changes in HbA1c levels, and by patient engagement as measured by the completion of the program. A survey assessed patient satisfaction with the virtual program. Following the launch at the pilot clinic site, the program was opened to patients with diabetes at primary care clinics. Education was provided by a lead endocrinologist champion to primary care clinics about the new virtual boot camp program, the patient criteria, its aim, and the referral process. This study was submitted for Institutional Review Board approval and was found to be exempt since it did not contain any patient-specific data.

Figure 1 describes the workflow for virtual boot camp program with a remote enrollment process using video technology.

Figure 1. Workflow for virtual boot camp program with a remote enrollment process using video technology. HbA1c: glycated hemoglobin.



Results

After the program's launch and successful implementation at the pilot clinic site, it was extended to all 50 primary care clinics in the UPMC Central Pennsylvania network. Within 3 months of the September 2020 launch, we referred and quickly enrolled over 100 patients. Our strategies in 5 broad domains reflect an effort to expedite the launch while creating a sustainable program that can grow beyond the pandemic. Various approaches can be deployed to overcome barriers to implement a virtual program. Using the experience gained through our decades of implementing telehealth programs, we propose recommendations that can be deployed at the system-level for health care organizations to overcome barriers in a rapid time frame (Table 1).

Table 1. Implementation strategy and recommendations.

Implementation strategy	Challenges	Recommendations
Project coalition	• Need a wide array of representation of stakeholders • Agreement on the concept of redesign care • Creating a vision to improve care in new models during a pandemic • Creating a vision to improve care in new models during a pandemic	• Include representation from clinical, operational, and telemedicine area • Share vision of need for redesign care • Align and remind project goals and scope • Create early goals and metrics for the program
Selecting patient population	• Technology challenges for patients • Is it a right fit for the program? • Identify clinical metrics that can be improved with the virtual program • Keeping a sustained patient engagement virtually	• Need to clearly identify patient population • Mock previsit training for patients enrolled in the boot camp • Embed virtual boot camp in the electronic health record and workflows • Identify compatible platforms and apps • Leverage the electronic health record to use metrics to identify and track patients • Minimal data entry for patients • Provide real time feedback and measure progress with patients
Selecting pilot site	• Pilot a clinic that can be model for the organization • The practice must be ready to be an early adopter and work with challenges • Rapid change can cause disruption in clinic workflow	• Identify early a pilot clinic enthusiast of the new program • Plan frequent communications and updates as the program evolves • Designate program champions that can help adoption
Workflow	• Multiple different workflows and platforms can hinder adoption • Must be efficient to ease transition • Virtual documentation templates can be different	• Engage the telemedicine or electronic health record team to keep workflows succinct within the same electronic health record • Design patient support and education material • Plan remote virtual training for providers and staff • Collaborate across disciplines to enhance system changes

Of the 37 patients who completed the program, the mean age was 53 years, with the age range of 22-78 years, 62% (n=23) were female, and 38% (n=14) were male. Moreover, 81% (n=30) were White and 19% (n=7) were African American; 81% (n=30) of the patients had commercial health insurance, and 19% (n=7) were on government health insurance such as Medicaid (Table 2). Of the 30 patients who completed the full program, HbA1c levels decreased from an average of 10.2% to an average of 8.8% (P<.001), with a range percentage decrease of 0.7-3%. A survey after completion of the program showed that a majority (n=26, 88%) were very satisfied or satisfied with the virtual boot camp, while 76% (n=23) reported that they felt the virtual boot camp saved them time. A wide majority, 94% (n=28), would recommend the program to their family or friends.

Table 2. Demographics of patients who completed the full 12-week virtual program.

Characteristics	Values
Age (years), mean (SD; range)	53.4 (13.9; 22-78)
Gender, n (%)	
Male	14 (38)
Female	23 (62)
Race, n (%)	
White or Caucasian	30 (81)
Black or African American	7 (19)

Discussion

Study Impact

We demonstrated a quick 3-month implementation of virtual diabetes boot camp with the enrollment of over 100 patients. Our program intervention made an improvement of diabetes in a majority of patients (75%) who completed the program. Our proposed practical steps on guiding strategies can be used for quick implementation solutions for digital health programs. Telehealth has been used in diabetes care since 2000. The IDEATel (Informatics for Diabetes Education and Telemedicine) project, a randomized trial conducted over 5 years in New York, compared usual care with telemedicine among older Medicare beneficiaries [8]. Statistically significant reductions in HbA1c levels, LDL (low-density lipoprotein) cholesterol, and systolic and diastolic blood pressure were seen in the telemedicine group. A meta-analysis of other telediabetes care trials also revealed significant and clinically relevant HbA1C reduction rates (≤-0.5%) [9].

Previous telehealth and diabetes care trials have studied the effectiveness of virtual nurse coaching and mobile health to improve physical activity [10], the impact of self-management skills and psychological aspects in diabetes [11], the effectiveness of virtual care in different genders [12], and web-based dietary interventions [13]. Advances in diabetes telemedicine tools have contributed to a broad availability of solutions; however, barriers to use in terms of acceptance, technical issues, and lack of knowledge remain [14]. A similar study on using telemedicine in treating patients with diabetes, conducted over a 4-month period, showed HbA1c decreased significantly from 9.98% to 8.23% [15]. For patients with diabetes, virtual clinics are shown to reduce treatment burden and to improve therapeutic adherence; it also has societal and psychological benefits that further guide the implementation of such programs [16]. In an mHealth (mobile health) study protocol [17], technologies such as electronic coaching, remote monitoring, and virtual visits showed that patients will improve their activation in diabetes care management, defined as improved self-management.

Our successful holistic interventions for patients with diabetes included a mobile app, diabetes education, nutrition guidelines, lifestyle intervention, therapy adjustment with integrated decision support system, and a dedicated telemedicine help desk phone for support and guidance. Though we faced a few challenges, specifically a quick timeline, we were able to use practical approaches to overcome them (Table 1). Having our primary care doctors and endocrinologist encouraging and enrolling patients likely contributed to the increased adherence and program completion by patients. The relatively short length of the program (12 weeks) and quick results also likely contributed to adherence.

Barriers and Enablers

Consistent barriers remain such as manual data entry by patients with diabetes, with automation and immediate feedback identified as enablers [18]. The virtual diabetes program offers patients and physicians more time and analytical ability but also offers an alternative to face-to-face visits that may be insufficient [19]. Using integrated workflows in the EHR, we simplified and automated the process for both patients and providers to ease the rapid transition to the new model. Frequent virtual check-ins enabled the patients to remain engaged and provided vital feedback to improve their diabetes. Using a multidisciplinary team, we focused on optimizing the program at the pilot clinic site and utilized the lessons learned for rollout across primary care clinics. Focusing on integrated EHR workflows led to the successful launch of a program in 3 months. The education of clinic staff to guide patients through the enrollment and use of software is critical to the success of the program.

Conclusion

The virtual diabetes boot camp was launched to improve the overall health of our patients with diabetes and to reduce the need for in-person visits during the pandemic. We successfully launched the program within 3 months, with promising early clinical results and patient satisfaction. The program facilitated frequent engagement between the providers and the patients, decreased the burden for the providers, and increased communication between members of the provider team.

We recommend aligning organizational goals to strategies (Table 1) for the rapid implementation and rollout of a virtual diabetes program. Health systems are finding it challenging to develop effective strategies to address diabetes with the growing shortage of clinicians and health care professionals. Digital strategies such as our virtual boot camp program can help alleviate this burden [20]. The strategy guidelines have been instrumental for our clinic's rapid transition to telehealth. Our strategies can be adopted by other organizations wishing to launch their own virtual diabetes programs. Most health care organizations have the necessary staff and providers to launch such a program, but only require practical guidelines on technical and operational workflows to deploy it. Though our program's focus was on patients with diabetes, our strategies could be adapted to manage other chronic diseases virtually. The first step is to form a stakeholder group of leaders who are willing to experiment and launch new ways of delivering care virtually. The key to implementing these strategies is to use the momentum COVID-19 has given to telehealth, sharing the vision of the program with the organization and coordinating the project across different teams.

We launched the program quickly in the endocrinology clinics, but it took sustained educational and communication efforts by primary care clinics to improve adoption across the organization. Sustained effort is needed to successfully roll out a new virtual program and to engage physicians and patients in a multispecialty, large clinic organization. Frequently highlighting the program benefits and continuously monitoring progress is vital to adoption. We were able to use our dedicated patient telehealth help desk to support patients struggling with the telehealth platform. In our experience, a previsit education intervention led to an easier and more successful virtual visit by patients, as confirmed by others [21]. We realize that smaller clinics may not have such a resource and propose training the clinic support staff so they are prepared to help patients. In conclusion, an expedited implementation of virtual programs

within large multispecialty US health care systems is possible. In the future, we plan to increase enrollment by enhancing criteria for patients who can be referred to the program; this will lower the threshold for patients who need interventions, such as patients at risk of diabetes or those who are prediabetic. We also plan to include group visits to improve the efficiency of the program. Future studies can look at whether patient interest and engagement will be sustained once temporary pandemic measures are relaxed. We envision we will continue to grow this program as it was set up for a long-term goal beyond the pandemic. The strategies and infrastructure set up will be used to facilitate similar virtual digital health programs across specialties.

Conflicts of Interest

None declared.

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Abbreviations

HbA1c: glycated hemoglobin
EHR: electronic health record
IDEATel: Informatics for Diabetes Education and Telemedicine
LDL: low-density lipoprotein
mHealth: mobile health
UPMC: University of Pittsburgh Medical Center

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Original Paper

Implementation of Teleophthalmology to Improve Diabetic Retinopathy Surveillance: Qualitative Interview Study of Clinical Staff Informed by Implementation Science Frameworks

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Abstract

Background: The store-and-forward camera-based evaluation of the eye, or teleophthalmology, is an effective way to identify diabetic retinopathy, the leading cause of blindness in the United States, but uptake has been slow. Understanding the barriers to and facilitators of implementing teleophthalmology programs from those actively adopting, running, and sustaining such programs is important for widespread adoption.

Objective: This study aims to understand the factors that are important in introducing teleophthalmology to improve access to diagnostic eye care for patients with diabetes in primary care clinics by using implementation science.

Methods: This qualitative study in 3 urban, low-income, largely racial and ethnic minority–serving safety-net primary care clinics in Rochester, New York, interviewed nurses and physicians on implementing a teleophthalmology program by using questions informed by the Practical, Robust Implementation and Sustainability Model and the Consolidated Framework for Implementation Research.

Results: Primary care nurses operationalizing the program in their clinics saw increased work burden and a lack of self-efficacy as barriers. Continuous training on the teleophthalmology process for nurses, physicians, and administrative staff through in-service and peer training by champions and superusers were identified by interviewees as needs. Facilitators included the perceived convenience for the patient and a perceived educational advantage to the program, as it gave an opportunity for providers to discuss the importance of eye care with patients. Concerns in making and tracking referrals to ophthalmology because of challenges related to care coordination were highlighted. The financial aspects of the program (eg, patient coverage and care provider reimbursement) were unclear to many staff members, influencing adoption and sustainability.

Conclusions: Streamlining processes and workflows, training and assigning adequate staff, effectively coordinating care between primary care and eye care to improve follow-ups, and ensuring financial viability can all help streamline the adoption of teleophthalmology.

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KEYWORDS

Consolidated Framework for Implementation Research; teleophthalmology; diabetic retinopathy; implementation; qualitative study; Practical, Robust Implementation and Sustainability Model

Introduction

Background

Diabetic retinopathy is the leading cause of blindness in working-age US adults, resulting in high personal, social, and economic costs [1,2]. Although having an annual dilated eye examination can timely identify vision-threatening disease and avoid blindness with timely treatment in ≥95% of patients with diabetes, annual dilated retinal examination rates are still <50%, especially for those with low income and who are uninsured or underinsured [3,4]. Teleophthalmology for diabetic retinopathy surveillance (DRS) is the store-and-forward process of remotely evaluating patients with diabetes for retinopathy. It involves placing digital nonmydriatic retinal cameras in nonophthalmic health care settings and linking them to eye care providers via telecommunication technology such as the internet [5-16]. Notably, ubiquitous screening programs in the United Kingdom have helped replace diabetic retinopathy with inherited eye diseases as their leading cause of blindness (>90% of patients with diabetes have an annual eye examination or retinal screen) [17].

Although the effectiveness of teleophthalmology to substantially increase annual retinal screening rates for vision-threatening diabetic retinopathy at primary care clinics caring for low-income populations is well-established, sustained implementation is challenging [18]. Those programs funded through grants or philanthropic support may not be sustainable once initial funding ends. Moreover, not all clinics are willing to initiate or adopt telemedicine-based DRS. Currently, the implementation of teleophthalmology for DRS uses a trial-and-error process. Generalized knowledge is needed to implement and sustain teleophthalmology programs to avoid each new group “re-inventing the wheel” [18].

Teleophthalmology Implementation

Implementation science is the systematic study of strategies to adopt and integrate evidence-based [19] approaches into real-world practice. Frameworks and models from implementation science can be tailored to effectively study how and why teleophthalmology programs are accepted and sustained in some clinics but not in others [20]. To date, the published literature has focused on reporting standard outcomes of teleophthalmology for DRS programs that have increased annual rates of examining eyes for vision-threatening retinopathy [21] rather than on implementation. Specific outcome measures have included changes in the number of patients screened, the number who followed up to eye care, demographics, modeled costs, and patient satisfaction [5,6,8-18,21-25]. A recent study focused on implementing teleophthalmology explored how rural primary clinics in Wisconsin viewed the implementation of teleophthalmology using qualitative analysis and an implementation science framework [26]. Another study focused on the implementation of teleophthalmology across federally qualified health centers in Kentucky using implementation science metrics [27]. In this study, we report on the implementation of a teleophthalmology program for diabetic retinopathy and visual acuity surveillance in urban, low-income, largely racial and ethnic minority–serving primary care clinics in Rochester, New York, using implementation science frameworks.

Methods

Ethics Approval

The Research Subjects Review Board of the University of Rochester approved this study (approval number RSRB00065090). Given the activities and nature of the study, the Research Subjects Review Board deemed that verbal consent was sufficient for participating in the study, and all interviewees provided informed verbal consent and agreed to have their interview audio-recorded. A description of the teleophthalmology program has been previously published [28].

Participants, Setting, and Description of the Intervention

Providers and staff from 3 safety-net primary care clinics that cared for low-income, uninsured, and underinsured largely racial and ethnic minority populations (both Hispanic and African American) and had implemented teleophthalmology to increase retinal evaluations for their patients with diabetes were invited to participate in a semistructured interview regarding their experience with program implementation. The research team then followed up with each interested participant to schedule a face-to-face interview based on participant availability. All primary care clinics were teaching sites for trainees in medicine and were staffed by attending physicians.

The 3 clinics cared for between 550 and 1250 patients with diabetes and had annual eye examination rates for this population of 20% to 40%, which doubled after the implementation of teleophthalmology. A Zeiss Visucam NM PRO (Zeiss) nonmydriatic fundus camera was used in 67% (2/3) of the clinics, and the Topcon NW400 (Topcon) nonmydriatic fundus camera was used in the third clinic. The teleophthalmology program used software that was developed internally by the ophthalmology department to capture data on the patients who were evaluated via teleophthalmology. This system required the manual entry of patient information, such as name, date of birth, and demographics. This system remained outside the electronic medical record system routinely used by the clinics. Staff were trained on the cameras and teleophthalmology program software by ophthalmology staff and signed off on being proficient at using the cameras and assessing vision for the program. The training was held at the beginning of the program and was repeated every 3-4 months as necessary when new staff joined the clinics.

During the imaging training and in subsequent refresher sessions, staff were trained on recognizing the difference between readable and unreadable images. An image quality comparison guide was provided during training to indicate which factors had the potential to compromise image clarity resulting in an unreadable image. The most commonly seen factors were shadows; dust, dirt, or other camera lens opacities; haze; artifacts; and small pupils. Unreadable images as graded by a retina specialist (RSR) accounted for 11% (69/627) of the patients assessed with the camera at the time the staff were interviewed. Photographers were given feedback on image

quality as specified on each report to ensure staff captured readable images. Image quality was graded by RSR as *poor*, *adequate*, *good*, *fair*, and *excellent*, and the factors that influenced the image grade were included in the report provided to the clinics. Providing image grading allowed photographers the opportunity to re-evaluate their techniques and make continuous improvement on capturing readable images.

The results and recommended follow-up directions to see an ophthalmologist by RSR, who reviewed the images and patient data, were sent to the primary care office, who then contacted the patients. Notification that a report was ready to be downloaded was sent by email to the primary care clinic contact, and the report was accessed via a web-based portal by the clinic staff. The clinic staff added these reports to the patient's electronic medical record. The primary care office also communicated the results of screenings to the patients and notified patients regarding when they needed to follow up for further eye care. These results were shared with the patient via phone by the primary care clinic within a week of the camera-based eye evaluation. The program in 67% (2/3) of the clinics was grant-funded, and patients were not billed for the digital camera images taken of their eyes. Patients receiving teleophthalmology in the third clinic may have been billed for having images of their eyes taken, but billing was inconsistent as it was not routinely monitored [22].

Data Collection

The participants who were involved in championing, implementing, and day-to-day operations of the teleophthalmology program at each clinic were emailed the interview questions in advance of the face-to-face interviews. They were also given the option to complete the questions via email. Of the 11 participants, 1 (9%; a primary clinic physician) chose this option, and the remaining 10 (91%) were interviewed. The interviews were conducted by research staff from August to October 2017 in 3 primary care settings. Each interview lasted approximately 15 to 20 minutes and was audiotaped. The participants provided verbal consent for audio-recording and could decline to answer any question. The recordings were then transcribed word-for-word by a professional transcriptionist.

The interview questions were selected from the adapted Practical, Robust Implementation and Sustainability Model (PRISM) [29] and Consolidated Framework for Implementation Research (CFIR) [30]. These questions included items related to the intervention characteristics (eg, adaptability, trialability, and complexity), characteristics of the individuals (eg, knowledge and beliefs about the intervention), the organization or inner setting (eg, infrastructure, resources, workflows, and supports), the external environment or outer setting (eg, patient beliefs, financial barriers, and reimbursement mechanism), the process of implementation (eg, engaging, executing, and reflecting and evaluating), and sustainability (eg, structural characteristics, implementation climate, readiness for implementation, resources, and modifications needed for sustainability; see Multimedia Appendix 1 for the interview guide). The interview guide served to direct the conversation, but the interviewees were able to discuss other issues that were not included in the guide.

Data Analysis

Thematic codes about program implementation were generated from the interview data using the PRISM and CFIR frameworks. Authors (RR, RYN, and SY) coded the transcripts based on an initial coding framework informed by the CFIR and PRISM. The coding framework expanded inductively through the coding process to address new themes not originally included. All authors discussed all coded segments in regular meetings and reached a consensus on the structure of emerging themes. This step entailed a rigorous back-and-forth comparison of data against the elements of the PRISM and CFIR frameworks and other emerging themes. Although both frameworks were considered to inform the analysis, we used the CFIR to organize the results and frame various determinants of the implementation. The PRISM mostly informed themes related to the organizational resources and infrastructures as well as considerations on sustainability. Although implementation frameworks informed the thematic analysis, we paid special attention to themes pertaining to other considerations not covered by these 2 frameworks. For example, we incorporated themes related to training staff, leadership support, and the role of champions as important ingredients of implementation success.

Results

Overview

Over 1 year of implementing the teleophthalmology program, each clinic doubled its annual retinal examination rate for patients with diabetes.

The project began as a community service quality improvement pilot project at 67% (2/3) of the clinics before the fee-for-service billing for the intervention was considered. Fee-for-service billing was implemented at the third primary care clinic upon starting the teleophthalmology program as this clinic was in the same health system as the partner ophthalmology department, and billing for the technical and professional component using the 99250 Current Procedural Terminology code was conducted for the ophthalmic photographs taken as part of the teleophthalmology program [22]. Of the 14 clinic staff members who were contacted, 11 (79%) agreed to participate in the semistructured interviews across all 3 sites. This group included 3 primary care physicians (medical doctors; 3/11, 27%), 1 pharmacist (1/11, 9%), 1 nurse practitioner (NP; 1/11, 9%), 1 administrator (1/11, 9%), and 5 registered nurses (RNs; 5/11, 45%) who ran the day-to-day operations and were responsible for the daily workflow of the teleophthalmology process. Of the other 3 clinic staff members invited to participate, 1 (33%) RN reported not having direct experience with the teleophthalmology program, and the other 2 (67%), both RNs, did not respond.

Through the qualitative analysis of the staff interviews, we identified five main categories of themes related to the implementation of teleophthalmology: individuals involved in the implementation, characteristics of the intervention (technology and tasks), process of implementation, and characteristics of the inner and outer setting or environment of the primary care clinic. Not surprisingly, respondents involved

in day-to-day operations (RNs) noted specific operational and logistical aspects of program implementation, whereas those who were less involved (providers or administrators) noted more general and system-level aspects of program implementation. Table 1 provides the classification of themes with relevant quotes. These main themes are discussed in detail in the following sections.

Table 1. Qualitative themes and supporting quotes[a].

Category and themes	Supporting quotes
Individuals and inner setting	
Patients	
Convenience	• "Patients are glad the photo can be done at the same place...the photo is quick. They often say thank you and that [they've] been meaning to [get screened]." [Participant 10, NP[b]] • "Issue comes when the patient has other things that get in the way [or] they're not able to follow instructions well." [Participant 1, RN[c]] • "We have taken pictures of patients who've never been to an eye doctor before." [Participant 9, RN]
Patient communication and arrangement	• "It's hard to get our patients in for a visit period, but when they're in for a visit and it's already taking long and then you have to do the eye screen afterwards, they may not have allotted themselves that much time here at clinic." [Participant 5, RN] • "Letting the patient know ahead of time [that they] have an opportunity to get an eye screen [important]." [Participant 2, PharmD[d]]
Staff and inner setting	
Motivation and buy-in	• "[Using the camera] made my job more enjoyable." [Participant 3, RN] • "It's cool to see the eye." [Participant 9, RN]
Limited resources (time and staff)	• "Even though the procedure itself doesn't take that long, to try to fit it in with a staff that's competent to do the screening [is a problem]." [Participant 6, NP, and participant 12, administrator] • "...Some slow buy-in by the nurses because then they were feeling like we're short staffed." [Participant 6, NP] • "...Currently short staffed three nurses [making it hard to support program]." [Participant 10, NP] • "...Challenge implementing, taking time and staff away from the normal flow to get it done." [Participant 8, MD[e]]
Characteristics of the intervention	
Camera ease of use	• "It's intimidating by looking at the machine, but it's actually a lot easier than it looks." [Participant 1, RN]
Technology and workflow complexity	• "[Technology didn't] work all the time, when operational it's great...You can send the results right away to [ophthalmology]." [Participant 9, RN] • "As routine...internal processes have been developed...entire screening process...reduced to [about] 10 minutes." [Participant 10, NP]
Referral and follow-up with eye care	• "How you make a referral is the more challenging part...don't have resources to be tracking every referral." [Participant 3, MD] • "...Nice if there was [more] follow-up from [ophthalmology department] to close the loop [with us]." [Participant 10, NP] • "...Biggest challenge to long-term sustainability is maintaining that relationship between 2 different departments." [Participant 3, MD] • "[Other similar programs exist in] New York State...but not as coordinated as we are doing it with Ophthalmology." [Participant 3, MD] • "[Ophthalmology Program staff]...good about follow-up and checking in." [Participant 11, MD]
Implementation processes	
Education and training	• "[What] motivates nurses is [regular] in-services [teaching] the importance of eye health [and use of system]." [Participant 1, RN] • "[Initial eye health, diabetes, and camera demo talks] engaged the physicians and the residents in the process." [Participant 3, MD] • "...cause we have so many resident physicians that if we had an in-service showing how important that eye health is then and how we have this machine and its capabilities I feel like it would get used so much more." [Participant 3, MD] • "...Brings PCPs[f] right into the mix, so there's a lot of benefits for the providers. Since we are a resident training clinic, I think there is a huge educational benefit." [Participant 3, MD] • "[We] felt competent to develop the workflow, and [use] the machine. We tried to solve barriers, but without nurse to staff it [we] added training for residents." [Participant 11, MD]

Category and themes	Supporting quotes
Hands-on experience	• "Yeah...everybody really enjoyed having it here. We tested a lot on the employees to just get the hang of things." [Participant 4, RN]
Champions	• "...Champions at site is key." [Participant 3, MD] • "[Champions who train others]...who know the program leaving clinic." [Participant 9, RN] • "It seemed like the reimbursement was very low so that part was difficult to make sustainable." [Participant 8, MD]
Outer setting	
Awareness and attitude	• "Some people just do not care [about their eyes]. Hopefully this program provides a prompt to keep up with eye care if they are not already doing so." [Participant 10, NP] • "Patients [don't] understand the gravity of how diabetes can affect their eye health...more education...need[ed]." [Participant 5, RN]
Financial	• "Well, a lot of our patients are Medicaid but I have no idea how it works on the insurance side of it." [Participant 1, RN] • "[For] patients that don't have any insurance, we have a program 'charity care'...cover [the costs]." [Participant 3, MD]

[a]Who said each statement is identified at the end of each quote.

[b]NP: nurse practitioner.

[c]RN: registered nurse.

[d]PharmD: Doctor of Pharmacy.

[e]MD: Doctor of Medicine.

[f]PCP: primary care provider.

Individuals and Inner Setting

This theme focuses on the characteristics, skills and self-efficacy, motivation, and perception of resources, namely time, by staff and patients.

Staff and Inner Setting of the Primary Care Clinics

Inner setting per the CFIR framework includes structural and cultural context through which the implementation process takes place [30]. In our analysis, we merged the themes related to staff characteristics with the inner setting in which they were embedded because of the substantial overlap between concepts.

Staff noted that having the program at their clinic brought a meaningful, novel way to help their patients. They were excited to have the camera and believed in the program's utility to screen their patients for retinopathy and vision loss in their clinics. This belief was a strong motivator and provided buy-in at the individual level to adopt this program for patients with diabetes. RN staff most often had comments about the daily workflow and camera use. As expected with the adoption of new technology or innovation, there was some preliminary hesitation because of perception of the technology, additional workflow elements, and preconceived notions of the complexity of the technology. However, once staff had training and a chance to use the camera on their own, they found that they could be more efficient at screening with the camera. Staff also saw value in being able to provide improved access to eye care as they could expeditiously obtain a review of retinal images and vision-screening information by an ophthalmologist for their patients and thereby reduce by at least 6 months the overall wait time for patients to see an ophthalmologist to obtain timely sight-saving treatment.

Another facilitator of program acceptance was a perceived educational advantage to the program in that it allowed primary care providers to discuss eye care as an ongoing topic with patients. Having the camera in the clinic increased conversations around eye care in patients with diabetes, especially among staff and resident physician trainees, and was something the practices would show off to their resident interviewees as an innovative intervention to help improve access to care.

Staff did express facing challenges with supporting the program as nurses felt that they were short-staffed and they did not always have the time to incorporate the teleophthalmology workflow into their typical workflow. An NP and physicians also frequently cited time constraints and nursing staff allocation as challenges to implement the program. Nursing staff specifically expressed that they did not have the time and resources to support the program as communicated. These comments highlight the anxiety generated among staff that felt that they had limited capacity and bandwidth to take on new responsibilities.

Patients

We have previously reported on patient perspectives obtained from surveys and focus groups [28]. Interviewed staff felt that their patients saw the camera-based evaluation as a convenient and valuable benefit for their health. Staff also commented that patients were grateful to have such a program in their primary care clinic as they had been putting off obtaining an eye examination with an ophthalmologist because of other priorities. Staff further noted that patients were more motivated to participate when they felt the images were captured quickly and conveniently and when their primary care providers recommended the teleophthalmology evaluation. The screening

did not seem to take long per the staff but did add additional time to visits. In addition, finding an available staff member who was trained to carry out the teleophthalmology evaluation was difficult at times as these staff members were occupied by other clinical tasks. Previous communication with patients about the longer process was also noted as important to staff. Patients may not have been prepared for the longer visit duration and often did not anticipate staying the extra 10 to 15 minutes needed to complete the teleophthalmology evaluation, which was mostly done at the end of the primary care visit.

Characteristics of the Intervention

This category included themes related to technology, tasks, and workflows. Staff believed that the usability of the camera was not a significant challenge. Nursing staff noted that the nonmydriatic camera seemed intimidating at first but was easy to use and worked well, although the camera software did not function smoothly all the time. A key facilitator of program adoption was that staff felt that the program was helpful in that evaluation of the eye for diabetes-related eye disease was available during the patient's primary care provider visit. Once an internal process to improve the workflow of the teleophthalmology project had been established, the screening process was reduced to approximately 10 minutes.

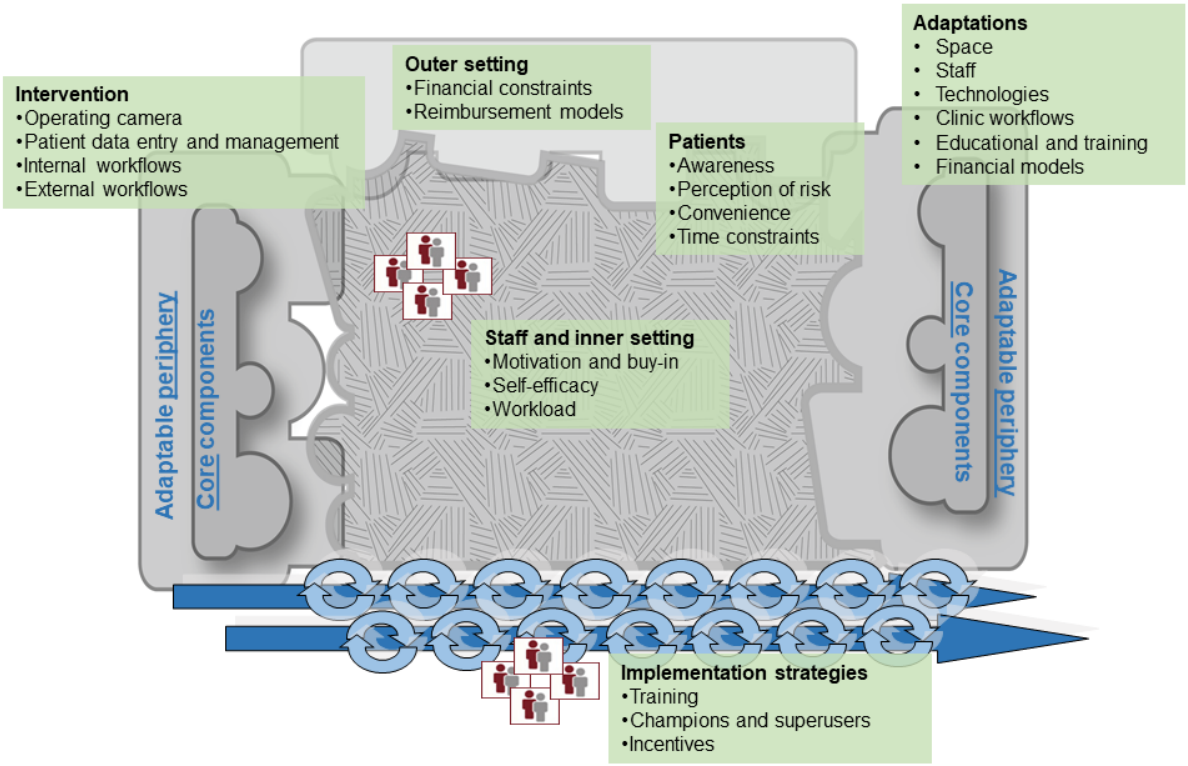
Tasks and workflows were seen as a significant challenge from the staff's perspective. The tasks included scheduling and patient notification, data entry into the teleophthalmology software, and tracking of the ophthalmologist referral. Both physicians and nurses said that nurses were an integral part of the workflow and that all nurses who could potentially conduct the camera-based evaluation should learn the workflow and process. In reality, there were certain superusers and a limited number of nursing staff assigned by the clinics for training in the teleophthalmology process, including using the camera.

Follow-up to eye care also remained a challenge. Staff expressed concerns in making and tracking each referral to ophthalmology as they did not have the necessary resources to do so. All cadres of staff felt that maintaining a long-term relationship between primary care and ophthalmology could pose a challenge in the future as they felt that there was not enough follow-up from the ophthalmology department to close the loop with the clinic; however, they acknowledged that the proponents of the program in ophthalmology worked at maintaining good communications and relationships.

Implementation Processes

This category included activities carried out at different levels to help establish the technology and teleophthalmology process in the clinic and incorporate it as part of routine care (Figure 1). It involved training and assigning champions, staff training to perform the teleophthalmology process, increasing awareness and visibility of the program among clinic staff and patients, and the process of referring patients who used teleophthalmology to ophthalmology from primary care at the recommended interval per their evaluation.

Figure 1. Mapping qualitative themes onto Consolidated Framework for Implementation Research domains (adapted from Damschroder et al [30]).



Training

Staff found that providing in-service training to learn the importance of eye health was key to keeping physicians and residents engaged in the process. In some clinics, staff complemented formal training with hands-on experience with peers and found this additional practice with the technology and process helpful. The training of multiple staff in conducting

the teleophthalmology process, including becoming very familiar with operating the camera and the web-based data entry platform, especially as new staff were hired by the clinic, was repeatedly mentioned as an essential aspect of implementing the intervention. Both the intensity and scope of training were cited as important. Physicians and nurses also viewed training and raising awareness of the program for primary care clinical, administrative, clerical, and physician staff as important.

Scheduling and front-desk clinic staff were responsible for contacting patients for a primary care appointment during which the camera-based evaluation would also be done. Thus, making this staff aware of the rationale and process of what the patient would experience so that they could clearly communicate this to the patient during conversations occurring for scheduling and checking in the patient to the clinic was deemed important by both nurses and physicians. Nurses and physicians also agreed that physicians, including residents, and NP providers should be made aware of the availability of the camera-based evaluation and of the process so that they could counsel their patients who needed such an examination on the process and need to have the evaluation before they left the clinic. Respondents felt that training should include both hands-on use of the camera and running through the workflow of the teleophthalmology evaluation process, along with didactic education on the effects of diabetes on the eye. Overall, personalized, live-human training was preferred. Respondents in all clinics requested periodic in-services and refresher sessions on using the camera, on how the program fit in the daily workflow, and on the rationale of performing the examinations in all clinics.

Champions

Another crucial implementation strategy was the identification and recognition of champions, who were superusers [31]. At each site, at least one RN was identified and trained as a superuser. These superusers were very adept at using the camera and electronic workflow, as deemed by the ophthalmology implementation team, before implementing the program. The superuser would train others in the clinic and champion the program by ensuring that patients were identified and taken through the camera-based eye examination process. When these champions were involved in the program, uptake was strong. However, these champions often did not remain at the clinic for >6 months. There was also a high turnover of clinic nurses, which also included those trained to use the camera and the electronic workflow by the ophthalmology implementation team and superuser RN. This high turnover was cited as a challenge to implementation by all cadres of staff.

Leadership

Leadership buy-in and motivation to implement the teleophthalmology program within the clinical setting served as vital components to achieve the support for workflow changes and sustainability of the program. Primary care physician leaders in the clinics were key to implementation. They helped emphasize the need for performing eye examinations to their colleagues, who were more apt to discuss the need for the examination with their patients. Physicians helped facilitate patient acceptance of teleophthalmology by discussing the importance of having an eye examination to determine their level of eye disease and describing the convenience of having the camera-based evaluation of their eye in lieu of an immediate eye examination with an ophthalmologist while they had come for their primary care visit. The physicians themselves saw the need for leadership buy-in across departments and medical specialties. Understanding how ophthalmology and primary care would work together to address patient needs and support the teleophthalmology initiative was one of the biggest challenges. Having physician champions translated into having administrative buy-in as physicians were often administrators themselves or had good relationships with nonphysician administrators. In addition, nonphysician administrators, who saw their role of helping physicians deliver quality care, also valued the teleophthalmology program as they felt it was an essential quality improvement program for the clinic.

Perceived Benefits

Primary care clinic leadership and administrators noted meeting the Healthcare Effectiveness Data and Information Set metric and elevating the profile of the clinic as a provider of the highest standard of care as 2 reasons for implementing the camera-based eye examinations. Meeting the eye examination metric gave 3 points out of 100 toward meeting the overall score considered in granting various quality distinctions by rating agencies. However, the exact dollar amounts to be gained by meeting these incentives could not be specifically identified. Clinic leadership acknowledged that the program could not be supported by existing monetary incentives and by qualifying as a quality center for health care by offering the program. At the end of the 2-year pilot at the clinics where the intervention was implemented as a community service, there was discussion of sustaining the program with the fee-for-service billing. However, physician champions and administrators at these clinics noted that the reimbursement was too low to make it sustainable, and they decided not to continue with the teleophthalmology program after the grant period ended.

Outer Setting

This category focused on external factors affecting the process of implementation, including financial constraints and community awareness of eye health. Staff expressed that they did not feel that patients knew the importance of how diabetes affected their eyes, so more education was needed in the community. The lack of awareness and recognition could potentially jeopardize the sustainability of the intervention and patients' participation in follow-up visits.

Staff noted that financial support was an important consideration, especially in the low-income population that their safety-net clinics served. The nursing and physician staff were not aware of the specific costs or financial implications of the program to the patient as these points were not discussed or fully vetted before the start of the program. Staff noted that financial support was an important consideration for patients, and a physician in the clinic who implemented fee-for-service billing did note that the health system provided funds to cover the health care costs of the teleophthalmology evaluation for those whose income level qualified.

Discussion

Principal Findings

Overview

This study identified several factors affecting the process of implementing teleophthalmology in primary care using the PRISM and CFIR frameworks. Figure 1 shows the main factors of implementing teleophthalmology identified in this study across CFIR domains [30]. These include the complexity of the teleophthalmology intervention, the need for and feasibility of active implementation strategies (such as training and champions), and the context-specific barriers related to inner and outer settings of primary care. Discussion of these main domains in the context of teleophthalmology occurs in the following sections.

Liu et al [18] conducted a qualitative study involving patients and primary care providers to learn about their experience with the implementation of teleophthalmology in rural primary care clinics. They classified factors associated with teleophthalmology implementation across different workflow stages, including the process of determining patient eligibility, patient referral, and activities during the patient appointment for the teleophthalmology evaluation. The main barriers to implementing teleophthalmology according to Liu et al [18] were the patients' unfamiliarity and negative attitude toward eye care and logistical challenges in attending their appointments, primary care physician lack of knowledge and data system capabilities in identifying eligible patients and making referrals, and lack of proper communication between patients and care providers. Our findings are consistent with the study by Liu et al [18] in terms of barriers viewed by the provider, such as time constraints and conflicts with existing workflows, which can negatively affect the implementation of the program. This study also complements the framework by Liu et al [18] by focusing on organizational structure and incentives and provides a holistic picture of clinical staff's experiences and perceptions. However, unlike Liu et al [18], we also interviewed the nurses who actually performed the teleophthalmology workflow in our settings. Thus, our findings may better reflect the perspectives of and challenges experienced by those actually conducting the teleophthalmology program in primary care clinics.

The Complexity of the Intervention

This study's qualitative findings highlighted the complexity of teleophthalmology as an intervention. In recent years, more attention has been paid to disentangling the dimensions of complexity [32] of interventions and developing strategies to facilitate their implementation by addressing the complexity [33]. Complex interventions have several interacting active ingredients and blurred boundaries between the intervention, implementation strategies, and contexts within which the intervention is being implemented [34]. We noted these considerations in our own program evaluation. Implementation of teleophthalmology involves several interacting moving parts, including the camera, its operation and software, the patient health information system, the internal workflow within the clinic, the external workflow between primary care and ophthalmology, and the feedback and follow-up system with patients and eye care. Several contextual factors influence these interacting components, including financial and time-based resource constraints, which affect the success of the implementation. We noted individual characteristics of the staff, human resources and workload, existing physical and information technology infrastructure within the clinic, and existing relationships with the eye care provider clinics as key areas to be addressed in implementing teleophthalmology as identified by primary care clinic providers, administrators, and staff. These are embedded in a larger context of the patient population, their knowledge and readiness, and financial incentives to promote service use, which are limited especially for low-resourced or low-income and, thus, more vulnerable populations. The noticeably increased administrative and staff resources, communication gaps, existing challenges of finding suitable candidates for the program, and heavy dependence on patients' involvement in the program, especially in terms of follow-up to eye care, have been seen to further complicate the implementation and success of teleophthalmology and are also consistent with the experience of implementing other eHealth interventions [35].

The Importance of Champions, Facilitators, and Continuous Training

Champions and superusers were identified in all our clinics to raise awareness of the program and train staff. This was necessary as not all staff could be trained to use the technology during the ophthalmology-led training sessions. Although this strategy usually worked, it induced challenges when the champion was not available, was not recognized by the staff as the go-to person, or left the organization. An alternative solution that was suggested by the interviewees was broader training and continuous engagement of the staff [31]. All staff felt that having educational lectures and hands-on training in a continuous manner, either with regular check-ins and in-person training sessions or by using recorded lectures and training videos on the web, was important. Identification of champions was correlated with improved implementation outcomes [36]. The literature also supports that staff may have more willingness to integrate the program and show interest and commitment to implementation activities after ongoing training [36].

There is growing evidence that champions play a crucial role in the successful implementation and positive outcomes of interventions and are an essential implementation strategy [37]. Thus, the identification, appointment, and preparation of champions contribute to the viability of teleophthalmology programs [31]. Champions require several skills and qualifications and enough motivation to lead the organizational change to be effective in facilitating the implementation [38]. Miech et al [31] recognized >26 different traits for effective champions, varying from being personable and well-liked among peers to having distinguished presentation and communication skills as well as the willingness to engage and lead the efforts according to the program goals and action plan. Champions should be intrinsically motivated and take the initiative in leading the implementation rather than being assigned by the leadership, as was often the case in our clinics, to accomplish

their role [37]. Our study found that champions assigned by the clinic administrators of physician leadership sometimes felt overwhelmed or were not intrinsically motivated or recognized by others for their roles. The lack of motivation and organizational recognition might hinder their impact on sustaining the implementation of teleophthalmology in clinics. We suggest that, to facilitate the implementation of teleophthalmology, more attention should be paid to the identification of internal champion staff that self-select into this role and to recognizing the importance of their roles in leading the implementation. As staff turnover is frequent in this context, using champions as an implementation strategy should be re-evaluated and adapted continuously, which may involve continuous training and replacement of champions or possible incentives to enable champions to stay in these roles.

The Role of the Inner and Outer Setting

The inner setting encompasses the structure and culture of the primary care clinics where the teleophthalmology program was implemented, whereas the outer setting connotes the external effects on the implementation process, such as patient needs and resources as well as external policies and incentives [39]. Our findings indicate that the clinical staff thought favorably of the implementation of the teleophthalmology program as it improved the quality of life and quality of care for patients with diabetes, which resulted in a more receptive implementation atmosphere [40]. These results are in parallel with the evidence suggesting that improving organizational receptivity toward change has a direct and positive correlation with the adoption, implementation, and sustainability of programs [41]. However, the lack of organizational incentives and substantial increase in burden and responsibilities for nurses negatively affected readiness and receptivity in our clinics. Unlike physicians, who may be paid based upon the pay-for-performance model, similar financial incentives did not exist for nurses in the primary care clinics. Thus, for nurses, the implementation of programs such as teleophthalmology may lead to an extra workload without concurrent proper increase in remuneration or other incentives or rewards.

Our study found that adjusting the primary care clinic workflow might be needed to successfully integrate the teleophthalmology program. Initially, staff felt that the intervention tasks did not fit well within their existing workflow when first introduced. In addition, the limited physical space of the clinics may have compounded the issue with the workflow. However, when clinic staff were given the ability to develop solutions to better modify the processes of the teleophthalmology intervention to allow it to become more seamless in the clinic workflow, they were more accepting and willing to carry out the process. Liu et al [18] also found that placing an excessive burden on the clinical personnel, as well as high staff turnover and insufficient staffing can directly result in a decrease in clinical personnel satisfaction and may also jeopardize the viability and success of teleophthalmology programs in the primary care setting. They stressed the importance of engaging with clinic staff to make mutually informed changes in the program to ensure that the program properly fits into the existing workflow [18]. Studies have shown that time and space constraints along with disruption of existing, well-ingrained processes are the main obstacles to fit a new program into the workflow [42]. Moreover, there are a variety of views regarding managing the workflow to successfully implement interventions [42]. One view states that interventions should be adjusted accordingly to fit into the predefined workflow. An opposing view suggests that alterations in the workflow are unavoidable and fundamental for the program to successfully achieve its goals [42]. These 2 drastically different opinions highlight the fact that, despite the consequential effect of workflow on the success of an intervention, there still appears to be no definitive approach to workflow standards.

Learning from experience and from the results of this study, our teleophthalmology program was modified to better integrate it with the existing workflow in the primary care setting. The space constraint was addressed by moving the camera to a clinic room only on the days of the week designated for carrying out the teleophthalmology program. This strategy allowed for flexibility in scheduling appointments and accessibility to the camera throughout the day. Furthermore, the electronic intake form was shortened and made easier to fill out on the web platform used for the teleophthalmology program. In addition, staff were asked to capture only 50% (2/4) of the images per eye (macular centered and anterior segment image) to reduce the time spent photographing the patients' eyes. These changes decreased the time to complete the teleophthalmology-based evaluation and increased its acceptance by staff and patients. This increased the number of patients evaluated through teleophthalmology. Finally, to ensure that the added responsibility of the intervention did not burden the nurses, primary care leadership suggested assigning and training data coordinators instead of nurses to carry out the teleophthalmology workflow. In doing so, the nurses were freer to attend to tasks that needed their skill set, which allowed for more efficient use of clinic resources. Web-based training modules on operating the camera and assessing visual acuity were made available to all staff participating in the teleophthalmology workflow to accommodate such transition and promote staff education. These changes have increased adoption of teleophthalmology by more primary care clinics in the health system and have increased the number of patients evaluated with teleophthalmology in currently participating clinics.

We also interviewed staff on their knowledge of the costs of the program to the patient and the financial feasibility of the program through financial incentives from meeting quality metrics and through fee-for-service insurance billing. Emphasis on constructing a sustainable business model was not the focus of the piloting of the program in the 3 clinics, and most of the staff we interviewed were not involved in insurance billing. Only 33% (1/3) of the clinics performed fee-for-service billing for the program. We were only able to interview 1 program administrator and a few physician leaders who knew more about the financial aspect of the program. Some did acknowledge that insurance reimbursement may not be enough to make the intervention sustainable as reimbursement for ophthalmic photography was inconsistent among the various insurers, especially the government-funded insurers Medicare and Medicaid, which insured most of the safety-net patient population [22]. In our program, Medicare did not reimburse

for instances where the photographs did not show any pathology. There are different limitations and guidelines in Medicaid programs for each state, and each regional Medicare governing body has their own rules for coverage of telemedicine interventions [43]. The uncertainty around reimbursement for this service is seen as a potential barrier to wide-scale implementation of teleophthalmology in the primary care setting [43].

In our study, nurses indicated that patients with diabetes had little knowledge of the severe impacts of diabetes on eye health, which reduced their adherence to eye care. In addition to lack of knowledge, several factors may affect patients' adherence. The absence of necessary information and recommendations about the significance of preventive eye health screening by the primary care providers to their patients is a known barrier to seeking timely preventive eye care [44]. Furthermore, the absence of primary care recommendations leads to low perceived vulnerability to diabetic retinopathy in patients with diabetes [44]. An et al [45] conducted a retrospective study to evaluate the long-term adherence of Americans with diabetes to the recommended retinal screening. They reported that patients with low socioeconomic indicators (income and educational attainment) and low diabetes-related health education were less likely to have annual dilated eye examinations [45]. They also determined an inverse association between the specialist's copayment and the patient's adherence to eye examinations [45]. Implementing teleophthalmology in primary care clinics as a convenient and affordable addition to routine primary care visits can potentially address many of the mentioned barriers to eye care, particularly for those at risk of missing their recommended eye care appointments [46]. However, lack of knowledge and negative or even indifferent attitudes toward teleophthalmology by primary care providers can be considerable barriers to its integration and effectiveness. Most patients with diabetes have still not heard about telemedicine. Their willingness to take part in teleophthalmology is often contingent upon their relationship with their primary care provider, their health status, the cost of receiving such care, and their opinion on its convenience [47].

Strengths and Limitations

This study focused on both provider and nursing staff, who were the ones to actually carry out the workflow of the teleophthalmology program. It identified the factors influencing adoption and use of teleophthalmology in urban primary care safety-net clinics with a large racial and ethnic minority population in 1 city. Consequently, the generalizability of the findings is limited to that population. As only 1 administrator at 1 clinic was interviewed, the perspectives presented in this study may not fully reflect the experience of administrative staff (who were responsible for coding and billing and were probably more familiar with the complexities of financial reimbursement), ophthalmologists, or patients (who were the focus of another published study [28]). Moreover, there are several factors beyond the clinic level that may affect the success of implementation, many of which are related to patients' needs and experiences (which are not the focus of this study) as well as the broad financial context of health care in the United States, which was not brought up by the participants. Further study of these elements to fully understand the factors leading to successful implementation of teleophthalmology for diagnostic eye care in primary care settings is needed.

Conclusions

Overall, in our study, primary care staff expressed that having a teleophthalmology program for patients with diabetes in their clinics was valuable. Ensuring standardization of processes, workflows, and knowledge among staff and patients; having adequate staff, space, and time; consistently well-functioning technology with robust customer support; financial viability (including understanding of the impact on patient finances); and continuous engagement with care coordination between primary care and eye care to improve timely follow-up to eye care are needed for ideal implementation.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Qualitative interview guide.
[DOCX File , 19 KB - diabetes_v7i1e32162_app1.docx]

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Abbreviations

CFIR: Consolidated Framework for Implementation Research
DRS: diabetic retinopathy surveillance
NP: nurse practitioner
PRISM: Practical, Robust Implementation and Sustainability Model
RN: registered nurse

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Original Paper

A 12-Month Follow-Up of the Effects of a Digital Diabetes Prevention Program (VP Transform for Prediabetes) on Weight and Physical Activity Among Adults With Prediabetes: Secondary Analysis

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Abstract

Background: The prevalence of diabetes is increasing rapidly. Previous research has demonstrated the efficacy of a diabetes prevention program (DPP) in lifestyle modifications that can prevent or delay the onset of type 2 diabetes among individuals at risk. Digital DPPs have the potential to use technology, in conjunction with behavior change science, to prevent prediabetes on a national and global scale.

Objective: The aim of this study is to investigate the effects of a digital DPP (Virgin Pulse [VP] Transform for Prediabetes) on weight and physical activity among participants who had completed 12 months of the program.

Methods: This study was a secondary analysis of retrospective data of adults with prediabetes who were enrolled in VP Transform for Prediabetes for 12 months of the program. The program incorporates interactive mobile computing, remote monitoring, an evidence-based curriculum, behavior tracking tools, health coaching, and online peer support to prevent or delay the onset of type 2 diabetes.

Results: The sample (N=1095) was comprised of people with prediabetes who completed at least 9 months of the VP Transform for Prediabetes program. Participants were 67.7% (n=741) female, with a mean age of 53.6 (SD 9.75) years. After 12 months, participants decreased their weight by an average of 10.9 lbs (5.5%; P<.001) and increased their physical activity by 91.2 (P<.001) minutes.

Conclusions: These results suggest that VP Transform for Prediabetes is effective at preventing type 2 diabetes through a significant reduction in body weight and increase of physical activity. Furthermore, these results suggest that the DPP remains effective 12 months after beginning the program. A prospective randomized controlled clinical study is warranted to validate these findings.

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KEYWORDS

mHealth; mobile health; diabetes; DPP; diabetes prevention program; digital health; longitudinal study; prevention; weight loss; physical activity

Introduction

Diabetes is associated with considerable economic and social burden [1]. It is one of the leading causes of mortality, disability, and decreased work productivity [2,3]. The global prevalence of type 2 diabetes has been increasing in recent decades [4] as well as the rate of prediabetes [5]. In 2015, 33.9% of adults 18 years or older in the United States had prediabetes [6]. According to an American Diabetes Association panel [7,8], up to 70% of adults with prediabetes will develop type 2 diabetes.

Type 2 diabetes can be managed and prevented using lifestyle change programs. Clinical trial efficacy data demonstrated a marked reduction in progression from prediabetes to type 2 diabetes mellitus among individuals who achieved modest weight loss through lifestyle change focused on dietary change and increased physical activity [9]. Based on these findings, the Centers for Disease Control and Prevention (CDC) launched the National Diabetes Prevention Program to help individuals with prediabetes achieve 5% to 7% body weight loss [10,11]. Diabetes prevention programs (DPPs) have been widely implemented and have been shown to be effective in helping individuals reduce their weight and improve health behaviors such as engaging in physical activity and eating a balanced diet [12-16].

DPPs can reduce the risk of developing type 2 diabetes and, if scaled effectively, have the potential to reduce the prevalence of diabetes [17,18]. Barriers such as transportation and time have been associated with in-person DPPs [19]. The use of digital therapeutics for the delivery of such programs may increase program accessibility and participation [20]. DPPs have also demonstrated a return on investment by preventing diabetes and reducing the need for later stage more costly interventions [21]. Due to their scalability, digital DPPs can be a cost-effective method to lower the risk of developing type 2 diabetes.

Smartphones can deliver effective interventions among various age groups and in many disease areas, including diabetes [22-24]. Mateo et al [24] conducted a systematic review and meta-analysis to compare the efficacy of mobile phone apps with other approaches that promote weight loss and increase physical activity. The authors concluded that mobile phone app-based interventions may be useful tools for weight loss [24]. Studies have shown that innovations in health technology demonstrated positive behavior changes among patients with type 2 diabetes [25,26].

DPPs delivered via mobile health technology can result in weight loss. Chin et al [27] reported 77.9% of participants had a reduction in weight due to the use of a digital DPP, with 22.7% reducing weight by 10%. Albright and Gregg [13] demonstrated the effectiveness of a digital DPP in reducing weight by 11 pounds after 4 months of beginning the program. A systematic review examining 28 studies determined that the average weight loss was approximately 4% [28]. Weight loss in the first 6 months has been associated with a decreased risk of diabetes and associated with a decreased cardiometabolic risk and predictive [27].

Virgin Pulse (VP), a global digital health company, adapted the CDC's Diabetes Prevention Program to a digital model to enable a highly scalable, convenient, and flexible delivery of the CDC program. VP Transform for Prediabetes integrates interactive mobile computing (ie, a smartphone app), wearable tracking devices (ie, activity tracker), remote health monitoring hardware (ie, digital scale), and professional health coaches to effectively address the complex factors that impact health behavior. The program components are described in detail later and outlined in Figure 1. Effectiveness of the digital DPP, VP Transform for Prediabetes (formerly known as Transform), was previously evaluated over a 4-month period resulting in an average weight loss of 13.3 pounds after 4 months [11].

Figure 1. Virgin Pulse Transform for Prediabetes components: a smartphone app with digital tracking and communication tools, a wireless scale, a professional health coach, a private peer community, and an activity tracker.

Current research has predominantly focused on either shorter-term effects of a digital delivery model or longer-term effects of a delivery model on a small sample. This study aims to build upon the 16-week study by examining a larger sample of participants over a longer study period to assess longer-term results from program completion. Using a 12-month study period may help assess the sustainability of the early (4-month) weight loss.

Methods

Design and Setting

The study is a secondary analysis of data collected via the VP Transform for Prediabetes program. Deidentified data were collected from baseline to 12 months. Two outcomes were assessed: weight loss and changes in levels of physical activity. Physical activity was calculated by adding the total reported weekly minutes of physical activity (measured from the Fitbit device).

Intervention: VP Transform for Prediabetes

VP Transform for Prediabetes is a 12-month intervention that uses the CDC's DPP program structure by delivering the program in two phases: the 4 months of high-frequency core intervention followed by 8 months of complementary maintenance programming to support the new health behaviors.

Curriculum

The DPP curriculum is presented in a digital format via a smartphone app and includes survey questions, quizzes, and open-response questions. The lesson curriculum includes topics like eating balanced meals that follow the MyPlate United States Department of Agriculture [29] guidelines, benefits of physical activity and methods to increase it, stress management, social support, and how to maintain healthy lifestyle changes.

The program matches individuals with DPP-certified health coaches who motivate and guide participants to reach their health goals. Health coaches keep participant discussions on track, provide personalized feedback on food logs and physical activity progress, and conduct individualized coaching sessions

using specialized techniques such as motivational interviewing through private messages, calls, and emails. Quiz responses and open responses are shared with the health coach. Lesson completion is defined as completing the quiz associated with each lesson that is delivered at the end of the content.

Group Support

Participants are placed into private chat groups within the smartphone app to recreate the experience of a group dynamic. An online group discussion allows participants to post questions, reply to comments, and share their experiences and progress. Group discussion is asynchronous, rather than live, to make the intervention more flexible and convenient.

Digital Tracking Tools

A wearable tracking device and digital scale are provided to participants. If a participant is active for more than 15 minutes, the amount of physical activity is automatically captured by the wearable tracking device. In addition, a photo-enabled food diary facilitates tracking of eating behaviors. Participants are asked to track their food by taking a picture of each meal, snack, or drink and uploading it to the app. The health coach reviews the tracking once a week and provides feedback.

Participant Recruitment

VP Transform for Prediabetes participants were recruited via a marketing channel partner. Participants received packages in the mail that included a wireless weight scale by BodyTrace, Inc and a wearable activity tracker by Fitbit, Inc (Flex 2 model).

Eligibility Criteria

Participants were eligible for the digital DPP if they met the following conditions: scored ≥9 on the online survey adapted from the CDC prediabetes screening tool or ≥5 on the American Diabetes Association risk screening tool and/or indicated prediabetes diagnosis through a recent blood test (self-reported, within the last 12 months); had a BMI of ≥25 kg/m^2 (≥23 kg/m^2 if self-identified as Asian); were ≥18 years of age; recorded their weight during the program; had a smartphone with an up-to-date operating system; had regular access to Wi-Fi; enrolled in the program between October 2017 and October 2018; had never previously participated in the program; did not have type 1 diabetes, type 2 diabetes, or end stage renal disease; and were not pregnant at the time of enrollment.

In addition to these, the following engagement criteria requirements were applied: time from the first lesson to the last lesson is at least 9 months, where a lesson is defined as completing the quiz or completing a remote session with their coach; has at least two weight readings: a baseline weight reading and a second weight reading, which takes place within a 2-week buffer from day 1 of month 12 and the last day of month 12; and engagement in the Core Phase and Maintenance Phase where engagement events include: stepping on the scale, engaging in a coaching session with a coach, posting in a group chat, logging in at least 3 meals in a lesson period, completing the quiz in 5 of the first 22 (core and biweekly) weeks. An individual had to have at least two engagement events in months 1 to 5, and at least two engagement events in 3 months between months 6 to 12.

The engagement criteria are adapted from the CDC's Diabetes Prevention Recognition Program (DPRP) requirements (2018). According to the DPRP, participant data must meet the following criteria to be qualified for preliminary or full recognition: attend at least 3 sessions in the first 6 months and whose time from the first session to the last session is at least 9 months, and at least 60% of participants attend at least 3 sessions in months 7 to 12.

Measures

Two outcomes were measured for this study: weight loss and physical activity. Weight loss was calculated in pounds and percent of initial body weight lost. A scale was used to measure weight, with weight loss being calculated as the weight measurement subtracted from the initial body weight. Physical activity was measured using a fitness tracker, which measured daily physical activity in minutes if the activity was at least 15 minutes long. For this study, physical activity was examined as total physical activity per week, calculated as the sum of physical activity each day for each week.

Ethics

The Health Research Ethics Board in Newfoundland and Labrador, Canada reviewed and approved this secondary analysis.

Statistical Analysis

Descriptive Statistics

Frequencies and percentages for categorical variables were used to describe participant demographics, with means and SDs for continuous variables. Analyses were conducted using SAS, version 9.4 (SAS Institute). A P value <.05 was considered statistically significant for all results.

Generalized Estimating Equations

Due to the longitudinal nature of our study design, we used a generalized linear regression with generalized estimating equations, with the exchangeable working correlation structure, to examine the significant association between time in weeks and weight and physical activity during the follow-up period. Weight loss was measured in pounds and percent of body weight lost. Data were analyzed at 6, 9, and 12 months.

Results

Sample Size

Of the 3184 individuals who enrolled in the Transform program, 2089 did not meet the inclusion criteria to be included in the study (Figure 2). After completing month 9 of the program, 13.7% (150/1095) of participants were lost to follow-up by month 12. This response rate is consistent with other studies using online surveys [30].

Figure 2. Participant flow diagram.

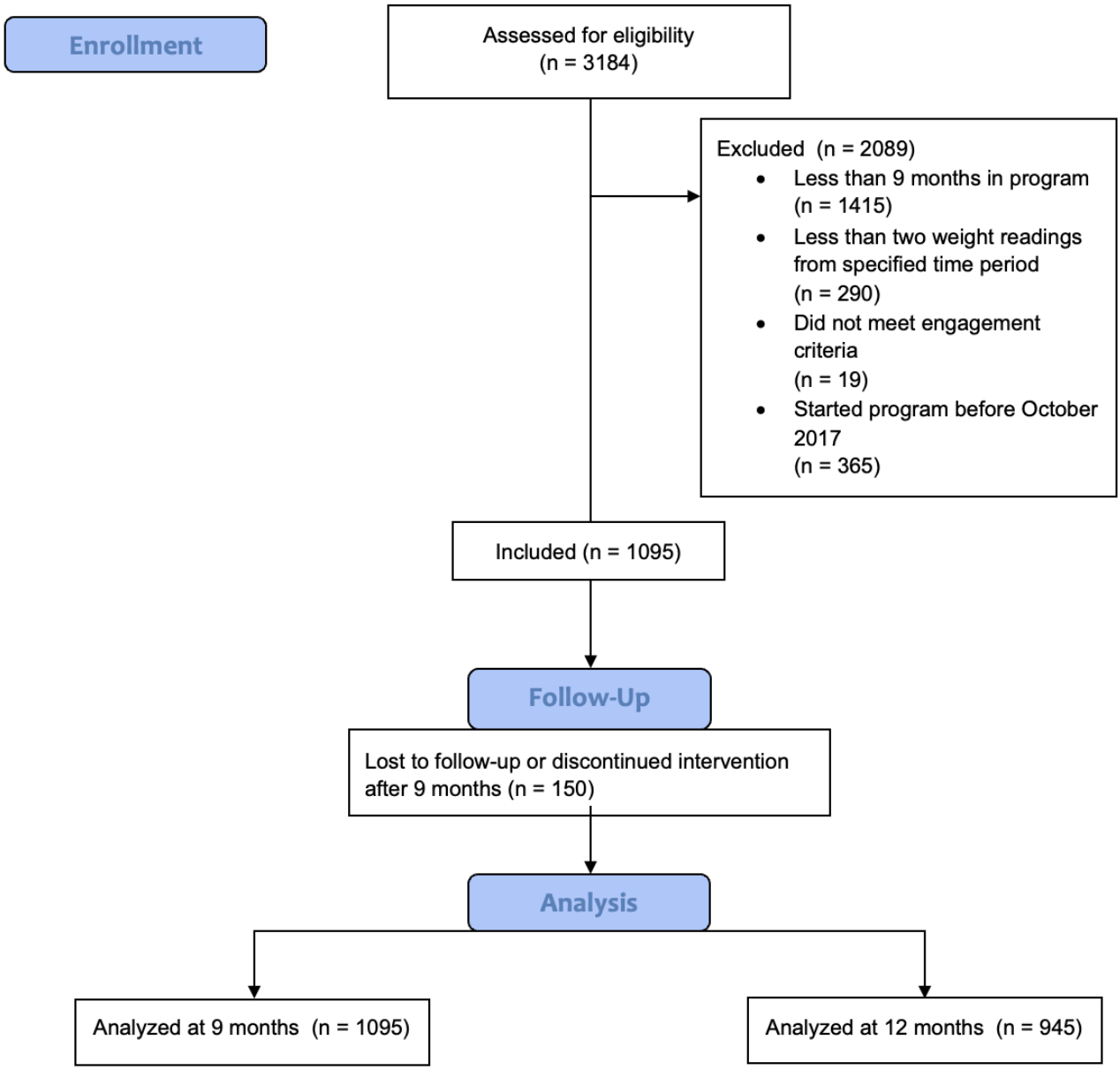
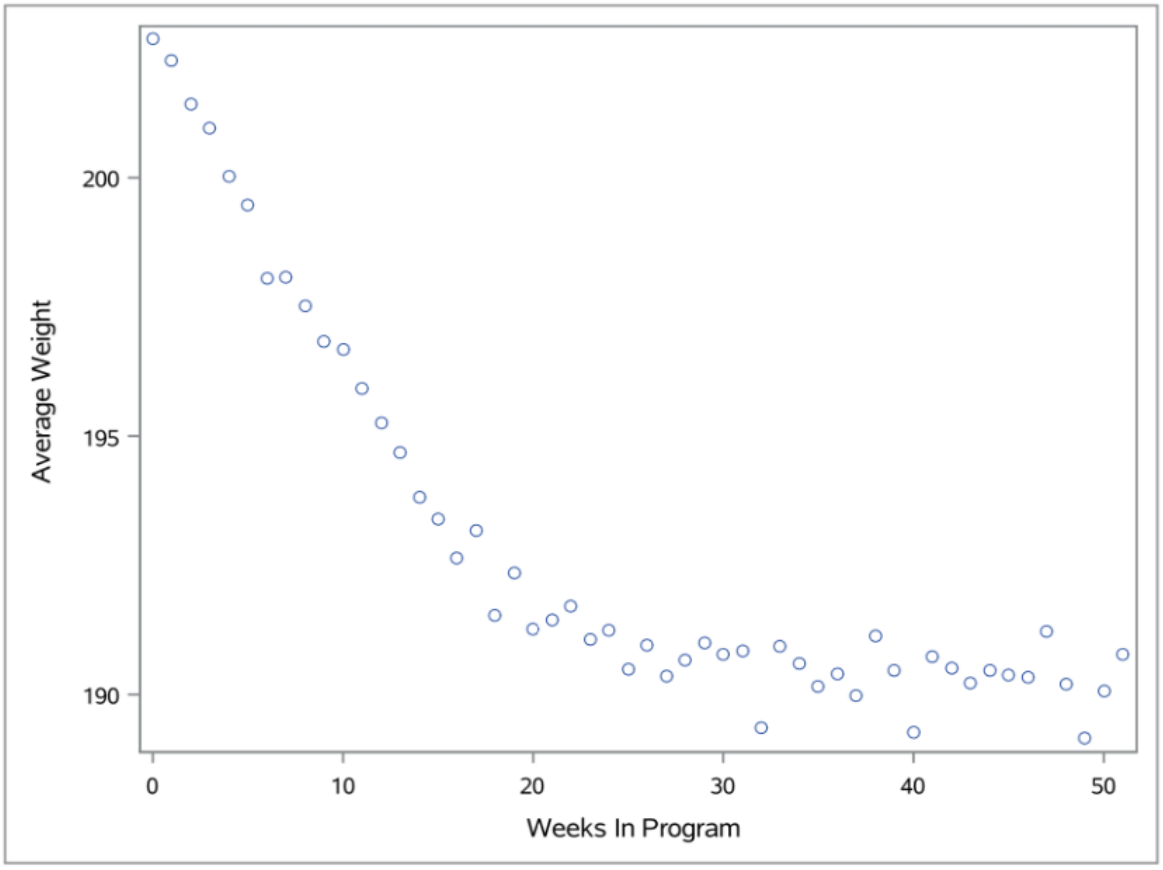


Figure 3. Graph of participants' average weight.



Demographics

A total of 1095 participants (1095/3184, 34.3%) were included in the analysis. Table 1 shows the sample demographics. Our sample had a mean age of 53.6 years and was 67.67% (n=741) female.

Table 1. Participant demographics.

Characteristic	Participants (n=1095)
Age (years), mean (SD)	53.6 (9.75)
Sex (female), n (%)	741 (67.67)
Ethnicity, n (%)	
White	682 (62.28)
Asian	73 (6.67)
Black	95 (8.68)
Other	195 (17.81)
Missing[a], n (%)	50 (4.57)

[a]These participants had missing demographic variables.

Weight Loss

At enrollment, the average starting weight was 204.5 (SD 42.9) lbs. After participation in the VP Transform for Prediabetes program for a minimum of 9 months, the average weight was 191.4 (SD 41.27) lbs, resulting in an average weight loss of 11.4 lbs and 5.5% weight loss. Table 2 shows the results from the generalized estimating equation. Physical activity was significantly associated with weight loss (Table 3).

Table 2. Weight loss and physical activity at 9 months and 12 months.

	Baseline	Mean change baseline to 9 months[a] (n=1095)	Mean change baseline to 12 months[a] (n=945)
Weight (lbs), mean (SD)	204.49 (42.92)	–13.30 (0.56)	–10.88 (0.62)
Weight loss (%), mean (SD)	N/A[b]	–6.60 (0.28)	–5.47 (0.31)
Participants with ≥5% weight loss, n (%)	N/A	639 (58.35)	552 (58.41)
Weekly physical activity (minutes)	66.97 (3.84)	116.45 (11.47)	91.22 (12.36)

[a]Adjusted mean and SE from generalized estimating equation models.

[b]N/A: not applicable.

Table 3. Results from generalized estimating equation.

Outcome measure and parameter	β (SE)	95% CI	*P* value
Weight loss (lbs)			
Intercept	–11.44 (0.29)	–12.02 to –10.87	<.001
Weight (lbs)			
Intercept	199.88 (1.28)	197.38 to 202.39	<.001
Weeks	–0.23 (0.012)	-0.2565 to –0.2085	<.001
Weight loss (%)			
Intercept	–5.47 (0.13)	–5.71 to –5.22	<.001
Weight loss (%)			
Intercept	–3.14 (0.089)	–3.26 to –2.91	<.001
Weeks	–0.11 (0.0054)	–0.1202 to –0.0989	<.001
Physical activity[a] (minutes)			
Intercept	132.94 (4.08)	124.94 to 140.95	<.001
Physical activity[a] (minutes)			
Intercept	167.80 (5.32)	157.38 to 178.23	<.001
Weeks	–1.64 (0.13)	–1.90 to –1.38	<.001
Weight (lbs)			
Intercept	200.43 (1.28)	197.91 to 202.94	<.001
Weeks	–0.24 (0.013)	–0.26 to –0.21	<.001
Physical activity[a]	–0.0032 (0.0010)	–0.0052 to –0.0013	.001
Weight loss (%)			
Intercept	–2.87 (0.12)	–3.05 to –2.59	<.001
Weeks	–0.11 (0.0056)	–0.1230 to –0.1012	<.001
Physical activity	–0.0016 (0.0005)	–0.0025 to –0.0007	.001

[a]Physical activity measured as total weekly physical activity in minutes.

At baseline (n=1095), participant's average total physical activity per week was 66.97 minutes. After participating in the 16-week core curriculum of the program, the average increased to 154.90 minutes per week (n=1095). At the end of the study period, the average number of physical activity minutes per week was 132.94 (n=945; Table 4).

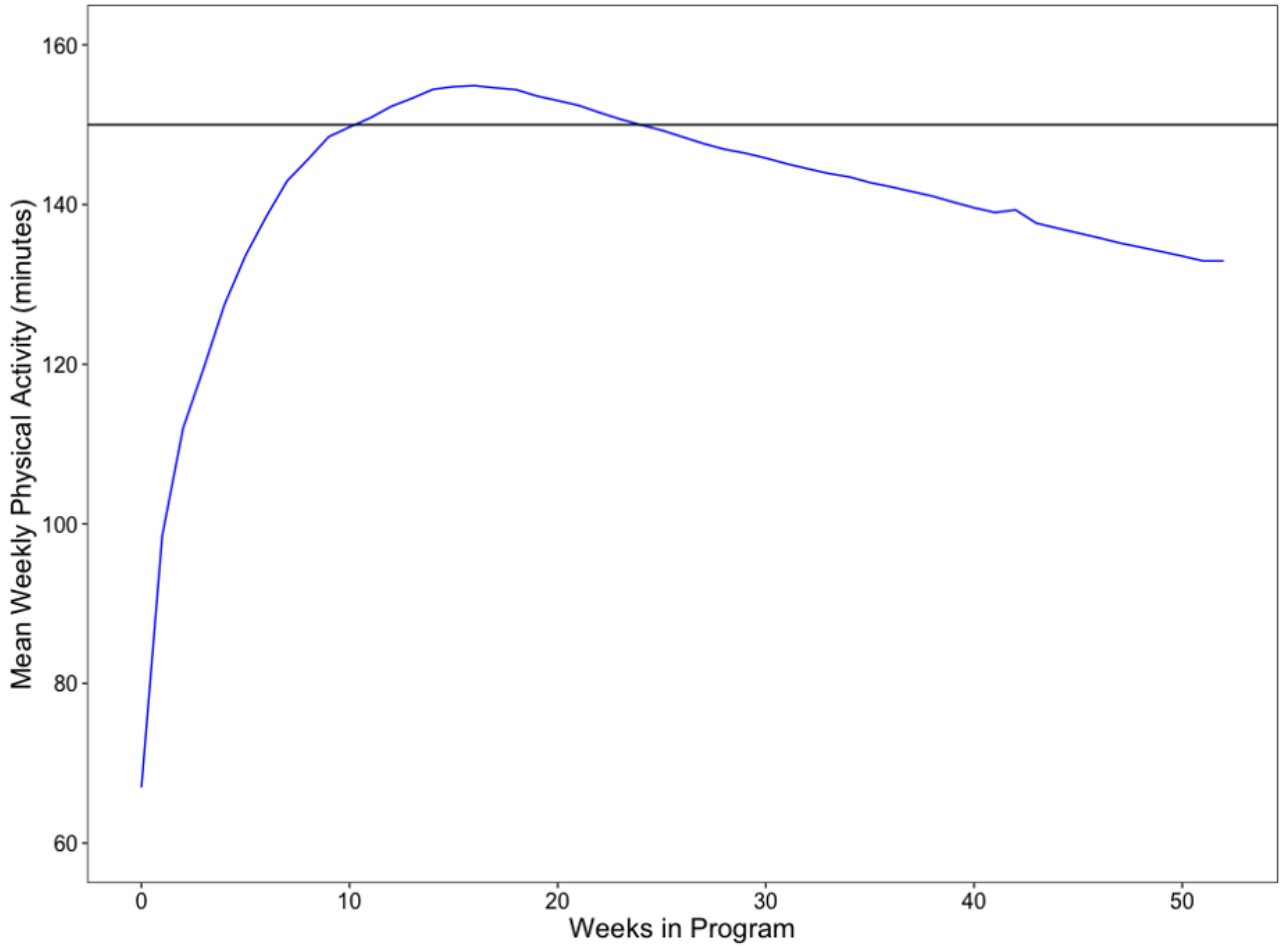
Table 4. Physical activity results.

Outcome measure and parameter	β (SE)	95% CI	*P* value
Baseline			
Physical activity			
Intercept	66.97 (3.84)	59.45 to 74.50	<.001
End of 16-week core curriculum			
Physical activity[a] (minutes)			
Intercept	154.90 (4.80)	145.49 to 164.31	<.001
Physical activity[a] (minutes)			
Intercept	126.11 (5.50)	115.32 to 136.90	<.001
Weeks	3.76 (0.68)	2.43 to 5.10	<.001
After 6 months (24 weeks)			
Physical activity[a] (minutes)			
Intercept	149.97 (4.54)	141.06 to 158.87	<.001
Physical activity[a] (minutes)			
Intercept	148.30 (4.99)	138.53 to 158.07	<.001
Weeks	0.15 (0.27)	–0.38 to 0.6852	.57
End point			
Physical activity[a] (minutes)			
Intercept	132.94 (4.08)	124.94 to 140.95	<.001

[a]Physical activity measured as total weekly physical activity in minutes.

At baseline, the mean physical activity was 66.9 minutes per week (n=1095). After completing the first 16 weeks of the program, participant's average physical activity per week exceeded the 150 minutes per week goal at 154.9 minutes per week (n=1095). At the end of the study period, the physical activity decreased to 132.94 minutes (n=945); however, participants improved their physical activity by 88 minutes per week compared to baseline after completing the program. Mean weekly physical activity is shown in Figure 4, with participants meeting or exceeding 150 minutes after completing the 16-week core curriculum then decreased during the maintenance phase of the program.

Figure 4. Graphical representation of physical activity.



Discussion

Principal Findings

Overall, participants either attained or surpassed the program goals. Weight and physical activity improved after completing 12 months of the VP Transform program. Mean weight decreased throughout the program (Figure 3). Similarly physical activity increased after participating in the 16-week core curriculum, with a slight decrease between month 4 and 12 after completing the program (Figure 4). After 12 months of completing the program, mean weight declined by 10.9 lbs (5.47% of total body weight, n=945), while physical activity per week increased by 65.97 minutes (n=945) compared to baseline. This illustrates that VP Transform for Prediabetes is effective at reducing body weight and improving physical activity after completing the program.

Comparison With Previous Work

Prior data demonstrated the effectiveness of VP Transform after 4 months of completing the program [11]. We extend these findings by reporting results 12 months after beginning the program among a larger cohort of participants (n=945) compared to the previously reported study (n=273).

The mean weight declined by 10.9 lbs (5.47% of total body weight) among VP Transform for Prediabetes participants (n=945) who completed 12 months of the program. These are similar to, but slightly higher than, results reported in some previous studies. Sepah et al [31] reported a weight loss of 10 lbs after 12 months or 4.7% weight loss (n=187), Moin et al [30] found a mean weight change of 8.8 lbs after 12 months or 3.7% weight loss (n=268), and Gilis-Januszewska et al [32] found an average weight loss of 4.9 lbs at the 12-month follow-up among 105 participants (average percentage of weight loss not reported).

A systematic review of 22 studies analyzing diabetes prevention lifestyle interventions concluded an average mean weight loss of 5.1 lbs after 12 months [33]. Clinically significant weight loss is defined as at least a 5% reduction in weight from baseline levels [34] and is associated with improvements in cardiometabolic risk factors, such as reduction in blood lipids and improved insulin response [35-37]. Our results suggest that VP Transform for Prediabetes is effective at reducing participants' risk of developing type 2 diabetes through sustained and clinically meaningful weight loss from baseline to 12 months.

It is difficult to compare the results of this study with previously published literature due to different interventions and duration examined. A systematic review by Cotterez et al [37] reported that only 1 study found statistically significant differences in activity levels for participants in web-based programs compared to those in a non–web-based control group. Furthermore, there

is limited objective data regarding the effect of digital DPPs on physical activity [37].

Limitations and Strengths

This study was a retrospective longitudinal cohort study. As a result, results from this study may be due to factors other than VP Transform for Prediabetes. Participants were predominantly female, which may affect the generalizability of the study to both sexes. Additionally, there was also no control group, which would minimize the effect of all confounding variables and would strengthen the correlation between the intervention and the outcomes.

Although physical activity was measured, the intensity level was not differentiated between moderate and vigorous. This affected the ability to evaluate VP Transform for Prediabetes against the physical activity goal of 150 minutes of moderate physical activity each week. Using a Fitbit for physical activity does not account for when an individual is not wearing it. As a result, a reading of 0 may respond to an individual not wearing the device.

The primary strength of this study was the use of objective measurements from activity trackers and a weight scale. This study had a large sample size, which increases the generalizability of the results. Additionally, the relative lack of attrition during the 12-month period indicates that the impact found in this study is likely sustainable over time, which is a key feature of success in impacting chronic conditions such as diabetes.

Future Studies

Future studies should examine other aspects of the digital DPP, such as work productivity metrics, sleep, and diet. An experimental study should be included to assess the impact of VP Transform for Prediabetes factors on additional health risk outcomes and potential confounding variables such as ethnicity, income, geography, and gender. Examining the effects of specific engagement data could also be included. Lastly, a study examining the economic impact of VP Transform for Prediabetes would be beneficial.

Conclusion

VP Transform for Prediabetes significantly reduces body weight and results in an increase in total weekly physical activity minutes. The study's findings highlight the effectiveness of the program in promoting meaningful changes to participants' behaviors, leading to a reduction in their risk for type 2 diabetes.

Conflicts of Interest

Virgin Pulse Inc funded this study through a partnership with a Mitacs Accelerate grant. MN and AB are full-time employees at Virgin Pulse, Inc. MN and AB were not involved in the analysis or reporting of the data.

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Abbreviations

CDC: Centers for Disease Control and Prevention
DPP: diabetes prevention program
DPRP: Diabetes Prevention Recognition Program
VP: Virgin Pulse

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