JMIR Diabetes

Contents

Original Papers

Original Paper

Use of a Mobile App to Facilitate Blood Glucose Monitoring in Adolescents With Type 1 Diabetes: Single-Subject Nonrandomized Clinical Trial

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Abstract

Background: Cloud-based glucose monitoring programs allow users with diabetes to wirelessly synchronize their glucometers to their mobile phones. They also provide visualization and remote access of their data through its mobile app. There have been very few studies evaluating their effectiveness in managing diabetes among adolescents with type 1 diabetes (T1D).

Objective: The purpose of this study was to assess the feasibility of using a mobile app to improve daily average blood glucose (BG) levels and increase BG monitoring frequency.

Methods: We used an ABA single-subject prospective study design. We recruited five participants aged 13 to 17 years with uncontrolled T1D, glycated hemoglobin A1c 9.0%-10.7%, self-monitoring behavior of ≤5 checks/day, and on multiple daily insulin injections. The study consisted of 4-week intervals of three phases: (1) phase A: usual glucose monitoring log (fax); (2) phase B: mobile app; and (3) phase A': second phase A. A certified diabetes educator and endocrinologist reviewed logs and provided recommendations weekly. Data were analyzed using a quasi-Poisson model to adjust for overdispersion among individual participants, and a generalized estimating equation model for overall intervention effect in aggregate.

Results: For mean daily BG (mg/dL) levels, participant 1 had decreased values on the mobile app (298 to 281, $P=.03$) and maintained in phase A'. Participant 4 had an increase in mean daily BG in phase A' (175 to 185, $P=.01$), whereas participant 5 had a decrease in mean daily BG in phase A' (314 to 211, $P=.04$). For daily monitoring (checks/day), participant 3 increased in phase B (4.6 to 8.3, $P=.01$) and maintained in phase A'. Participant 5 also had increased daily monitoring at each phase (2.1 to 2.4, $P=.01$; 2.4 to 3.4, $P=.02$). For the five participants combined, the overall mean BG and BG checks per day in phase A were mean 254.8 (SD 99.2) and mean 3.6 (SD 2.0), respectively, mean 223.1 (SD 95.7) and mean 4.5 (SD 3.0) in phase B, and mean 197.5 (SD 81.3) and mean 3.7 (SD 2.1) in phase A'. Compared to phase A, mean glucose levels declined during phase B and remained lower during phase A' ($P=.002$). There was no overall change in BG checks by phase ($P=.25$). However, mean BG levels negatively correlated with daily BG checks ($r=-.47$, $P<.001$). Although all participants had positive opinions about the app, its utilization was highly variable.

Conclusions: We demonstrated modest feasibility of adolescents with uncontrolled T1D utilizing a glucose monitoring mobile app. Further study is needed to better determine its effects on BG level and monitoring frequency. Psychosocial factors and motivational barriers likely influence adoption and continuous use of technology for diabetes management.

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Introduction

In adolescents with type 1 diabetes (T1D), barriers to appropriate self-management abound [1]. It is a period of transition from childhood to adulthood, which is associated with multiple psychosocial stressors. As a result, adolescents with T1D have the worst glycemic control of all age groups, averaging a glycated hemoglobin A_{1c} (HbA$_{1c}$) of 9% [2]. This finding is extremely worrisome because this increases the risk of long-term complications [3].

Self-monitoring is a critical component of T1D care. Multiple cohort studies show an association between frequency of glucose checks and better glycemic control when adjusted for age [4-6]. Although not a causal relationship, given that effective diabetes management includes insulin dosing, frequent blood glucose (BG) checking appears to be related to global self-care behavior, signifying that those who monitor BG more frequently are more likely to engage in good self-care [4]. Thus, there is compelling evidence to support self-monitoring with frequency depending on individual patient needs and goals [7]. Additionally, glucose monitoring is more likely to decline with age among adolescents with specific characteristics, such as residing in low socioeconomic households, having lower self-esteem, experiencing more stressful life events in the past year, and having a poorer quality relationship with parents or receiving less parental support [4].

Pediatric endocrinologists utilize manual logs of BG, insulin doses, and carbohydrate intake to determine insulin adjustments. However, if a patient uses multiple glucometers (eg, for use at home, school, daycare), in our clinical experience, it is unlikely that all the information will be logged to share with clinicians. Furthermore, based on our clinical experience, adolescents find that logging is an arduous task and thus will often not perform it of their own volition and less frequently as recommended by their physicians. Mobile phone apps can facilitate this process by automatically uploading BG, insulin dose, and carbohydrate intake data using wireless Bluetooth technology to a central Internet-based account accessible by authenticated providers. In fact, preliminary studies of Bluetooth-enabled self-monitoring devices in adults with type 2 diabetes and hypertension have shown promise of improved disease control [8].

Despite much publicity and marketing by app developers, there is very limited published data on the efficacy of mobile health apps in adolescents with T1D [9,10]. Additionally, rigorous research into clinical effectiveness of diabetes app designs in adolescents is lacking [11]. To date, there are at least two clinical studies that specifically evaluate mobile phone apps in adolescents with T1D. One pilot study showed an app with gamification incentives resulted in increased daily average frequency of BG measurements [9]; a second retrospective study of 81 adolescents showed that a glucometer mobile app increased monitoring frequency, particularly among those who synchronized their devices [12].

In this study, we prospectively evaluate a glucose monitoring system to determine feasibility, adoption, and impact, measured via monitoring frequency and BG levels, among adolescents with poorly controlled T1D.

Methods

Participants

Recruitment of low-income, minority patients with T1D occurred in an inner-city academic pediatric endocrinology clinic. Patients were screened before their appointment visit via chart review. Inclusion criteria were age 13 to 21 years, T1D diagnosed at least 1 year prior to study enrollment, on a multiple daily injection regimen, HbA$_{1c}$ of 8% to 12% within the previous 6 months, and a no-show rate to clinic of less than 50% in the prior 12 months. After their diabetes clinic visits, patients were approached by research staff for further screening requirements: average daily glucose checks five times or less per day over the prior 2 weeks and verification using the patient's glucometer(s). In addition, the patient and guardian were required to own compatible mobile phones with Internet access, a compatible glucometer, and report no prior use of the mobile app.

A total of five participants and guardians each received US $32 over the course of the study for their participation. Participant characteristics of the enrolled patients are included in Table 1. The University of Illinois at Chicago Institutional Review Board approved the protocol.

Table 1. Participant characteristics.

Participant	Sex	Age (years)	Race/Ethnicity	Years with T1D	Initial study HbA$_{1c}$ (%)	Baseline mean daily BG^a checks
1	Female	17	African-American	2	9.0	2.4
2	Female	14	African-American	4	10.7	1.9
3	Female	15	Hispanic	1	9.1	4.0
4	Male	14	Hispanic	8	9.0	4.5
5	Male	13	African-American/White	2	9.4	5.0

^{a}BG: blood glucose.

Materials

Glooko (Glooko, Mountain View, CA, USA; the "mobile app") is an online-based diabetes management system that incorporates automatic mobile phone reminders, allows for visualization of glucose trends and levels, and provides access of data by caretakers and clinicians [13]. The mobile app includes MeterSync Blue ("syncing device"), a Bluetooth-enabled attachment for patients to upload data from their glucometers to their mobile phone and online account. The syncing device is compatible with a majority of Food and Drug Administration (FDA)-cleared glucometers and with mobile phones utilizing iOS (Apple, Cupertino, CA, USA) and Android (Google, Mountain View, CA, USA) operating systems [14]. In 2012, the FDA cleared the mobile app for marketing as a Class II product after a 510(k) premarket notification review [15]. It is also HIPAA compliant [16].

At the start of the intervention period, participants opened an account online and on their mobile phone, and were loaned a syncing device. Participants returned the device at the end of the study.

Experimental Design

An ABA single-subject prospective study design was used. Each phase lasted 4 weeks. In phase A, participants performed usual BG monitoring and were instructed to notate BG levels, insulin dosing, carbohydrate intake, and relevant activity in the clinic's standard logbook. They were instructed to fax their logs to the clinic. A certified diabetes educator (CDE) called them once a week to discuss the log data and make recommendations as clinically indicated in consultation with the pediatric endocrinologist. At the end of phase A, participants and their guardians returned to the clinic to open the mobile app accounts. They downloaded the app onto their mobile phones, were taught the features of the program, and received the syncing device with instructions on use.

During phase B, participants performed usual BG monitoring but were instructed to synchronize their meter nightly and enter insulin dosing, carbohydrate intake, and relevant physical activities into the app. Each week, the CDE called participants to discuss the electronic log data and make recommendations as clinically indicated in consultation with the pediatric endocrinologist. The CDE and endocrinologist accessed an online dashboard that provided individual BG levels and descriptive statistics for review. The dashboard included graphical representations of BG logs, which included BG levels, carbohydrate intake, insulin administration, and percentage of time spent within BG goal.

At the end of phase B, participants were instructed to stop using the mobile app and restart manual logging with continued weekly CDE calls. Mobile app accounts were not suspended, but we were able to determine if the syncing device was being used. We emphasized to participants that the second phase A could not begin until cessation of synchronizing activity. A semistructured phone survey was also conducted to obtain feedback about their experience using the mobile app.

Statistical Analysis

Study data were collected and managed using REDCap electronic data capture tools (REDCap, Nashville, TN, USA) hosted at the University of Illinois at Chicago [17]. Mobile app data were downloaded from the app's clinician dashboard. Descriptive statistics for continuous variables were expressed as mean and standard deviation; categorical variables were presented as frequency and proportion. The intervention effect was reported as estimated mean and P values. All statistical tests were two-sided. First, we analyzed each of the five participants case by case. For each case, the scatterplots of both outcomes (BG level and number of BG checks) over time for the entire study period were generated to visually evaluate the patterns in the data with a smoother filter. The outcomes were analyzed using an interrupted time-series regression. We used both a quasi-Poisson and generalized least squares model. The quasi-Poisson model accounted for overdispersion by allowing the variance to be proportional rather than equal to the mean, whereas the generalized least squares model accounted for autocorrected residuals. Quasi-Poisson model results are reported. Then, we performed an overall correlation analysis for BG level and number of daily BG checks including all five participants together. Finally, we conducted a generalized estimating equation (GEE) analysis of intervention effect and association between BG level and number of daily BG checks through the SAS GENMOD procedure. GEE provides more robust inference to account for large variability [18]. All statistical analyses were conducted by R Core Team (R Foundation for Statistical Computing, Vienna, Austria) [19] and SAS version 9.4 (SAS Institute Inc, Cary, NC, USA).

Results

Nine patients fulfilled the inclusion criteria, but one patient declined participation due to lack of interest. Eight provided assent/consent, and five completed the study. One male patient believed the study was too intrusive and dropped out after 4 weeks. Two other male patients could not commit to regular contact with the CDE and each dropped out after 2 weeks.

Table 2 demonstrates the mean daily frequency of BG testing and mean daily BG levels. Figure 1 is a collection of time-series graphs showing both mean daily frequency of BG checks and BG levels for each participant.

Participant 1 had no significant changes in BG monitoring. However, BG decreased from phase A to B (298 to 281 mg/dL, P=.03) and was maintained in phase A'. Participant 2 had no significant changes in BG monitoring or mean BG levels. Participant 3 increased daily monitoring from phase A to B (4.6 to 8.3 checks/day, P=.01), and maintained in phase A'. However, there was no change in mean BG levels. Participant 4 had no significant changes in BG monitoring. However, mean daily BG levels increased from phase B to phase A' (175 to 185 mg/dL, P=.01). Participant 5 had increased daily monitoring from phase A to B (2.1 to 2.4 checks/day, P=.01) and again from phase B to phase A' (2.4 to 3.4 checks/day, P=.02). Furthermore, there was a decrease in mean daily BG levels from phase B to phase A' (314 to 211 mg/dL, P=.04). In aggregate,

there was no significant difference in BG monitoring across phases (*P*=.25).

The frequency of hypoglycemia (BG level <70 mg/dL) paralleled the participant's frequency of BG checks—the more checks, the more often hypoglycemia was discovered, as shown in Table 3. Data entry of insulin dosing, carbohydrate intake, and physical activity was inconsistent and limited, as shown in Table 3. Insulin adjustments were only made on two participants during phase A and phase A' predominantly because insulin and carbohydrate intake was more consistently noted on manual logs. The frequency of synchronization events in phase B are also shown in Table 3. There was maximum synchronizing in the first and second week, then it decreased thereafter.

For the five participants combined, the overall mean BG and BG checks per day in phase A were mean 254.8 (SD 99.2) and mean 3.6 (SD 2.0), respectively, mean 223.1 (SD 95.7) and mean 4.5 (SD 3.0) in phase B, and mean 197.5 (SD 81.3) and mean 3.7 (SD 2.1) in phase A'. Mean BG level was negatively correlated with daily BG checks (r=–.47, *P*<.001). GEE modeling confirmed the negative correlation between BG level and BG check frequency (*P*=.02); compared to the initial control period (A), the mean glucose values significantly decreased during the intervention phase (B; parameter estimate: –55.68, 95% CI –95.13 to –16.23) and maintained at reduced level (A'; parameter estimate –32.02, 95% CI –55.24 to –8.80, *P*=.002).

All five participants expressed a positive experience during interviews after phase A' period. Comments included: "I didn't have to fax stuff, the app was easy to use," "it's easier than writing the numbers and the amounts of insulin by hand," "it only takes about 3 minutes," and "I really like it and would recommend it to anyone." One participant indicated an increase in motivation to self-check glucose with automatic recording of levels, when previously she checked only at mealtimes. There were some technical issues, which affected the timeliness of the synchronizing process. Comments included: "I disliked that syncing takes too long," "sometimes the app messes up and I have to turn it off and on again," and "hard to Bluetooth it over because you have to hold it a certain way." One participant suggested having a pop-up reminder for input of insulin/carbohydrate data when synchronizing. The pediatric endocrinologist and CDE both noted that the mobile app clinician dashboard was convenient to use and appropriately summarized the relevant data.

Table 2. Mean daily blood glucose levels and daily blood glucose checks.

Measure	Participant				
	1	2	3	4	5
Blood glucose level (mg/dL), mean (SD)					
Phase A	298.2 (91.7)	295.9 (68.0)	175.1 (55.8)	190.1 (45.9)	325.4 (115.3)
Phase B	281.4 (83.0)	215.2 (58.6)	141.4 (36.2)	174.5 (47.4)	314.5 (110.7)
Phase A'	235.9 (119.6)	210.4 (57.5)	160.7 (38.5)	184.9 (50.0)	210.5 (112.7)
Difference, OR (95% CI)					
Phase B-A	0.71 (0.52-0.97)[a]	0.99 (0.77-1.26)	0.82 (0.61-1.10)	1.27 (0.99-1.62)	0.76 (0.52-1.11)
Phase A'-B	1.13 (0.70-1.81)	1.02 (0.77-1.37)	1.23 (0.94-1.60)	1.46 (1.12-1.90)[a]	0.63 (0.41-0.98)[a]
Blood glucose checks (checks/day), mean (SD)					
Phase A	2.7 (1.2)	3.0 (1.4)	4.6 (2.5)	5.3 (1.6)	2.2 (1.1)
Phase B	2.3 (1.0)	3.2 (1.1)	8.3 (3.4)	5.6 (1.2)	2.5 (1.4)
Phase A'	1.4 (0.7)	2.4 (1.1)	6.1 (2.0)	4.3 (0.9)	3.5 (1.9)
Difference, OR (95% CI)					
Phase B-A	1.34 (0.73-2.44)	0.97 (0.63-1.50)	2.42 (1.47-4.01)[a]	0.88 (0.69-1.14)	2.33 (1.33-4.11)[a]
Phase A'-B	1.33 (0.77-2.30)	0.83 (0.45-1.53)	0.83 (0.54-1.26)	0.83 (0.66-1.03)	2.24 (1.17-4.30)[a]

[a]*P*≤.05.

Figure 1. Mean daily blood glucose checks and levels over the course of the study period. The vertical lines denote the different phases.
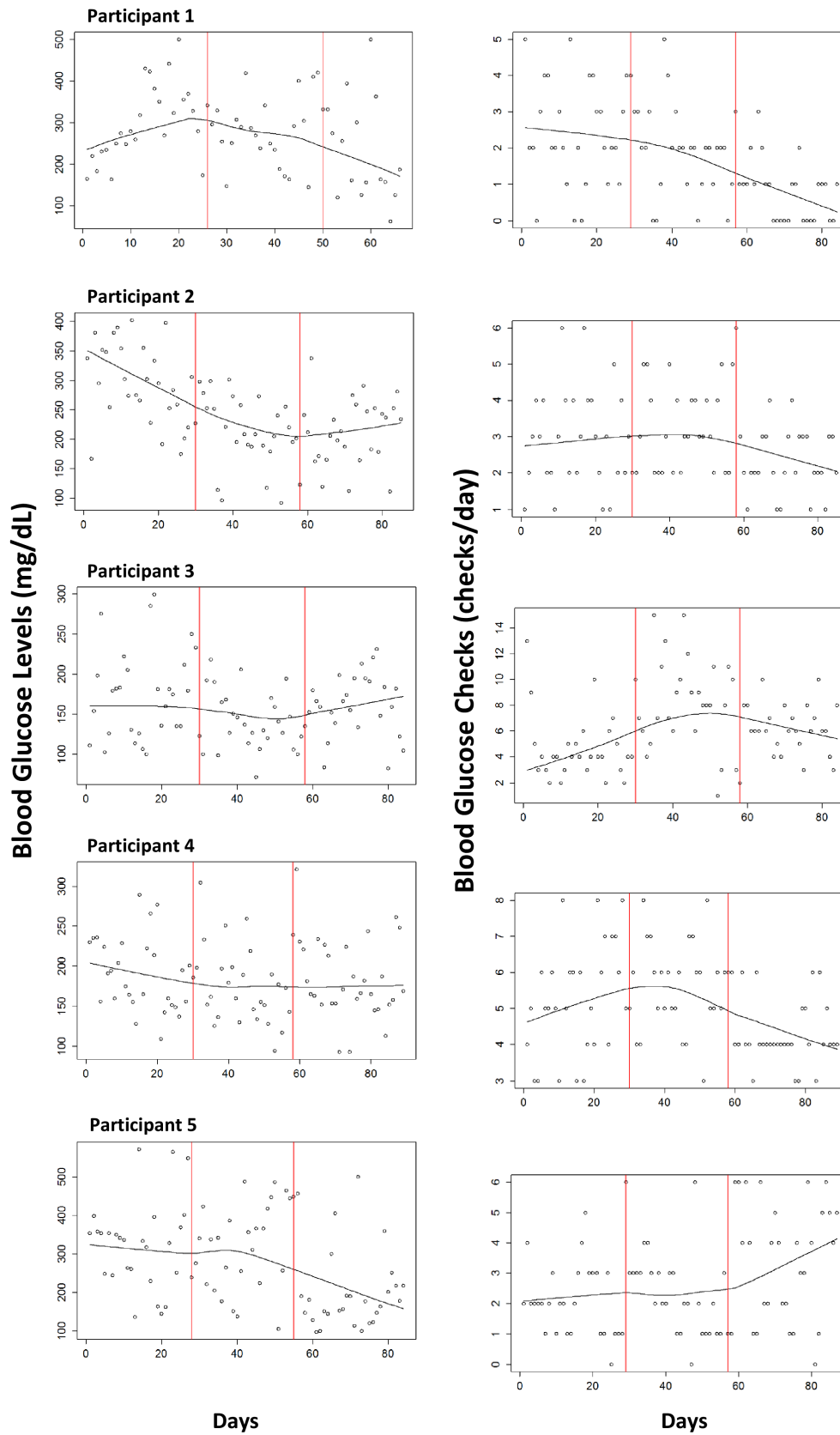
Table 3. Frequency of detected hypoglycemia, mobile app data input, and faxing and synchronization events.

Measure	Participant				
	1	2	3	4	5
Hypoglycemia detected, n					
Phase A	1	0	16	15	0
Phase B	2	3	41	26	2
Phase A'	1	4	22	10	0
Mobile app data input					
Total BG[a] checks, n	54	90	233	154	68
Insulin notation, n (%)[b]	0 (0)	34 (38)	47 (20)	0 (0)	19 (28)
Carbohydrates notation, n (%)[b]	2 (4)	71 (79)	58 (25)	3 (2)	29 (43)
Manual input (ie, exercise activity, meal description, notation of pre/post meal), n (%)[b]	1 (2)	0 (0)	10 (4)	39 (25)	59 (87)
Faxing and sync events					
Sent faxes (max 8), n	0	1	4	1	2
Sync events in phase B, total (n per week)	27 (10/6/10/1)	5 (2/0/1/2)	7 (2/3/1/1)	7 (2/2/2/1)	22 (9/5/3/5)

[a]BG: blood glucose.

[b]Percentages were determined using the number of notations divided by total BG checks.

Discussion

To our knowledge, this is the first ABA design to evaluate change in glucose monitoring frequency and BG levels from utilizing a mobile app in adolescents with T1D. A single-case (also known as "n-of-1") study design was used because it can provide an efficient way to evaluate the effects of a behavioral intervention [20]. This study demonstrated modest feasibility of adoption of the mobile app. Overall, BG levels of the five participants declined from phase A to B, and remained lower during phase A'. Furthermore, lower BG levels were associated with more frequent BG checks, which mechanistically supports the rationale for increased monitoring. However, it still remains uncertain if improvement in mean BG levels are secondary to Glooko monitoring versus time and regression to the mean in this limited sample. Visualizations of the ABA graphs (Figure 1) describe outcomes that reflect individual monitoring behavior but cannot reveal other challenges influencing behavior and motivation, including psychosocial stressors and mood conditions. Further study is needed to better determine the app's impact on BG levels and monitoring frequency.

Our study had mixed results with the usage of mobile app features. Although qualitative results suggest that participants preferred the mobile app to manual logging, there was variable use of app options and features. For example, participant 1 synchronized but rarely entered manual information. On the other hand, the rest of the participants preferably used either the insulin/carbohydrate function (manual numerical entry) or pre/post meal function (push button function). The effort required for manual data entry may inhibit complete logging [21]. The advantage of mobile apps is the elimination of certain tedious tasks (ie, logging). So for adoption of the technology, any steps that are substituted or added (ie, synchronizing, manual

entry of non-BG data) has to be sufficient to promote motivation for use. It was time consuming and challenging for some to routinely synchronize the device, requiring close proximity between Glooko and the meter while the app remained open. The use of smart glucometers that do not require a syncing device and even integrating Bluetooth-enabled insulin pens to automatically notate dosage administration can potentially increase adoption of mobile health devices in diabetes care.

In our cohort, due to incomplete logging and lack of clinical indication, there was limited insulin dosing change recommendations in phase B. Only participant 3 had a BG target adjustment due to her multiple hypoglycemic readings.

All participants preferred using the mobile app to manual logging and faxing. In fact, although participants were supposed to fax a total of eight times during the study, most were unable to do so due to difficulty accessing a fax, especially during the summer when the school's fax was not accessible. The most diligent participant faxed only 50% of the time recommended. This finding suggests that optimal use of Web-based apps can allow for more consistent review of data by clinicians.

This study demonstrates modest feasibility of adoption. Our cohort from populations of inner-city minority groups has the most to gain from effective technology as they typically experience worse outcomes.

Limitations of this study included the short length of the study (12 weeks). Furthermore, the study did not evaluate temporal effects (eg, school and other schedule changes) and confounders (eg, mood disorders, use of other diabetes apps management concurrently). Sampling bias, a limitation preventing generalizability, was also an intended feature of the recruitment process. The limited sample size also does not allow for definitive or even generalizable results. However, the results

provide a realistic representation of actual short-term device use in a systematic evaluation.

Mobile health is not a panacea for chronic disease management because device use is tied to individual motivation to use it, extra effort involved in its use, etc [22]. There are certain patients who will not want to engage with the system, as was the case with four patients who refused to participate or dropped out of the study. Of those for whom there is high enthusiasm with novelty, technology does not necessarily translate to meaningful utilization or behavioral change. These technologies still do not overcome the underlying discomfort and inconvenience of BG monitoring. For mobile health devices to be clinically useful, facilitation of management has to overcome motivational barriers. In other words, significant psychosocial barriers (eg, significant home chaos, poor mental health, low motivation) will reduce impact, even if there is ample access

to these devices. The patient has to be motivated sufficiently to improve his/her health if we are to expect them to use technology for such goals. In addition, to achieve benefit from increasing monitoring frequency, there must be subsequent motivated action, including better self-management. Patients must respond to feedback on hypoglycemia and hyperglycemia, adhere to lifestyle and treatment, and receive insulin adjustment under provider guidance.

The use of a mobile app by adolescents with T1D can be used in a low-income clinical setting, and provide important clinical information to caretakers and clinicians. There was observable variation in BG monitoring behavior, BG levels, and access of mobile app functions. The degree of behavior change is likely dependent on a host of psychosocial factors, and thus targeting the most appropriate patients who will benefit from this type of intervention may be key to maximize its effectiveness.

Acknowledgments

Conflicts of Interest

None declared.

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Abbreviations

BG: blood glucose
CDE: certified diabetes educator
FDA: Food and Drug Administration
HbA1c: glycated hemoglobin A1c
T1D: type 1 diabetes

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Original Paper

Change in Glycemic Control With Use of a Digital Therapeutic in Adults With Type 2 Diabetes: Cohort Study

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Abstract

Background: Intensive lifestyle change can treat and even reverse type 2 diabetes. Digital therapeutics have the potential to deliver lifestyle as medicine for diabetes at scale.

Objective: This 12-week study investigates the effects of a novel digital therapeutic, FareWell, on hemoglobin A_{1c} (HbA_{1c}) and diabetes medication use.

Methods: Adults with type 2 diabetes and a mobile phone were recruited throughout the United States using Facebook advertisements. The intervention aim was to effect a sustainable shift to a plant-based dietary pattern and regular exercise by advancing culinary literacy and lifestyle skill acquisition. The intervention was delivered by an app paired with specialized human support, also delivered digitally. Health coaching was provided every 2 weeks by telephone, and a clinical team was available for participants requiring additional support. Participants self-reported current medications and HbA_{1c} at the beginning and end of the 12-week program. Self-efficacy related to managing diabetes and maintaining dietary changes was assessed via survey. Engagement was recorded automatically through the app.

Results: We enrolled 118 participants with a baseline HbA_{1c} >6.5%. Participants were 81.4% female (96/118) and resided in 38 US states with a mean age of 50.7 (SD 9.4) years, baseline body mass index of 38.1 (SD 8.8) kg/m^2, and baseline HbA_{1c} of 8.1% (SD 1.6). At 12 weeks, 86.2% (94/109) of participants were still using the app. Mean change in HbA_{1c} was –0.8% (97/101, SD 1.3, P<.001) for those reporting end-study data. For participants with a baseline HbA_{1c} >7.0% who did not change medications midstudy, HbA_{1c} change was –1.1% (67/69, SD 1.4, P<.001). The proportion of participants with an end-study HbA_{1c} <6.5% was 28% (22/97). After completion of the intervention, 17% (16/97) of participants reported a decrease in diabetic medication while 8% (8/97) reported an increase. A total of 57% (55/97) of participants achieved a composite outcome of reducing HbA_{1c}, reducing diabetic medication use, or both; 92% (90/98) reported greater confidence in their ability to manage their diabetes compared to before the program, and 91% (89/98) reported greater confidence in their ability to maintain a healthy dietary pattern. Participants engaged with the app an average of 4.3 times per day. We observed a significantly greater decrease in HbA_{1c} among participants in the highest tertile of app engagement compared to those in the lowest tertile of app engagement (P=.03).

Conclusions: Clinically meaningful reductions in HbA_{1c} were observed with use of the FareWell digital therapeutic. Greater glycemic control was observed with increasing app engagement. Engagement and retention were both high in this widely distributed sample.

Introduction

Type 2 diabetes prevalence is at pandemic levels and continues to rise here in the United States and globally [1,2]. Medication costs are rising in parallel and threaten to bankrupt national health systems [3,4]. Despite increased use of medications and the advent of new pharmacological treatments, glycemic control among those with diabetes does not appear to be improving since 2010 [5].

While type 2 diabetes is currently considered a chronic progressive disease that typically requires increasing medications over time [6], there is also growing evidence that type 2 diabetes is treatable, and in some cases reversible, with comprehensive lifestyle changes alone [7-15]. Therapeutic lifestyle changes include substantial improvements in dietary pattern, activity, and exercise; avoidance of tobacco and excess alcohol; and additional behaviors that improve sleep, stress, mood, and social connection [9,13,16].

The practice of leveraging therapeutic lifestyle changes as medicine is often referred to as lifestyle medicine. The case for lifestyle as medicine has been detailed elsewhere and applies not just to type 2 diabetes but to many other lifestyle-related chronic diseases, which collectively account for roughly 80% of premature mortality and health care costs [16-19].

An intervention that successfully delivers lifestyle therapy has potential benefits over traditional therapeutics like medications and surgery. Potential benefits include a more favorable side-effect profile due to fewer adverse effects and additional non–disease-specific health benefits, lowered health care costs, and for many, greater acceptability [16-19].

Lifestyle therapy has been shown to outperform pharmacotherapy in diabetes prevention [20,21] although the challenge of translating that result to real-world populations persists [22,23]. For diabetes reversal, there is similar opportunity but less clarity about the preferred approach [10,15], and thus there are few widely accessible, cost-effective therapies available [16]. Digital therapeutics that deliver lifestyle therapy have potential to fill this therapeutic void because they are inherently scalable therapies that can be accessed outside of traditional brick-and-mortar constraints (ie, wherever a patient goes, at any moment in time).

A digital therapeutic has been described as an intervention for treating disease that is delivered continuously through digital means [24,25]. This study examines a digital therapeutic, called FareWell, that aims to effect a sustainable shift to a whole food, plant-based dietary pattern and regular exercise by advancing culinary literacy and lifestyle skill acquisition. It incorporates interactive mobile computing (ie, an app), remote sensors (eg, wearable devices and home monitors), and human care (eg, health coaching) delivered by digital means. This solution affords for population management and specialized care that can be made accessible to adults living in a vast geography, at

scale. As envisioned, it is intended as a stand-alone intervention that could replace or complement other interventions.

In this study, we sought to understand to what degree a novel, skill-focused, digital therapeutic could change HbA_{1c} and antidiabetic medication use in a geographically widely distributed sample of adults with type 2 diabetes. While the ultimate goal of the intervention is to be more cost effective than other interventions, this study examines effectiveness alone.

Methods

Trial Design and Participants

We conducted a 12-week, nonblinded, single-arm interventional study in a convenience sample of adults with a self-reported diagnosis of type 2 diabetes.

Participants were recruited online through advertisements listed on Facebook and to a lesser extent Craigslist, targeted to adults in any US state with an interest in type 2 diabetes. The study was described as evaluating a free 3-month lifestyle change program that uses digital tools, a plant-based dietary pattern, and health coaching.

Eligibility criteria included having a diagnosis of type 2 diabetes, age 18 years or older, and possession of an Android or iPhone mobile phone as demonstrated by the ability to download the intervention app. Type 2 diabetes status was presumed by the combination of a self-reported diagnosis and an initial HbA_{1c} of 6.5% or higher. Participants were excluded if they were not able to comply with the study protocol—for example, if they could not speak or read English or did not have sufficient computer literacy to operate the app successfully.

Enrollment was on a first-come-first-served basis and all data collection occurred online via electronic survey or directly through the app. Participants who were interested in the study were invited to download the app and enter a code to unlock the app. Participants were then instructed by the app to create an account using their email address. Upon creating an account, participants were emailed an informed consent document to review. Informed consent was obtained for each study participant via discussion with a study staff member prior to commencing their first coaching call. This phone call with study staff also ensured that each participant was unique.

An incentive of US $200 was offered to participants who participated in the program and completed data reporting at 3 months. The study was approved and overseen by Quorum Review Institutional Review Board [26], an independent ethics review board located in Seattle, Washington.

Intervention App Development

The intervention app was developed by a San Francisco–based startup of which the authors are founders and/or employees or scientific consultants. The first version of the app was developed as a Web app using responsive design and validated with usability testing, followed by a pilot clinical trial in adults with

class 1 obesity and elevated risk for metabolic disease [27]. It was then redeveloped as a native app for Android and iOS using human-centered software design principles [28] and subject to basic usability testing prior to the start of this study.

Periodic updates of the app were released during the study period. Study participants enrolled using version 1.3 of the app and completed the study on version 1.5. The vast majority of the changes in the app during the study period were minor experience improvements or bug fixes. One new feature—an artificially intelligent conversational bot—was released in the last month of the study in v1.5 along with the ability to enter home finger-stick readings. This bot enabled a new method for participants to report meals eaten and visualize the number of healthy meals eaten each week.

Intervention

The digital therapeutic consists of use of the intervention app paired with specialized human support, also delivered digitally. The content design of both app and human support incorporated evidenced-based dietary and lifestyle recommendations such as a dietary pattern consisting mainly of whole food plant-based meals and regular exercise meeting or exceeding national guidelines [9,13,19]. Since it is known that increased meals prepared at home is associated with decreased disease burden [29], additional content was developed with expert input to enhance culinary skill acquisition with the aim of increasing meals prepared at home.

Several theoretical models informed the design of app features, including the theory of planned behavior (eg, features were designed to alter intentions), social cognitive theory (eg, features were designed to enhance self-efficacy, enable experiential learning, and reinforce healthy behaviors), and behavioral economics (eg, use of default choices). Both the app and accompanying human support are designed as a learning platform, which aims to impart the lifestyle skills necessary to reverse cardiometabolic disease.

The app was designed primarily to facilitate the learning and adoption of plant-based meals, self-monitoring habits, and scheduling of coaching calls. It is intended to be used ad libitum, but expectations of use were established during the informed consent process as follows:

Use of the meal planning feature that facilitates advanced planning of meals and automated shopping lists (approximately 5 minutes per week). The meal planning feature uses default recipes that met prespecified criteria for ease-of-preparation, inclusion of easy-to-access, whole food, plant-based ingredients, and staged introduction of culinary techniques. Participants could easily swap meals or plan to eat a meal not in the recipe database. An interactive shopping list was autopopulated whenever a meal plan was created or modified.

Self-monitoring of weight daily (via digitally connected scale provided free to participants or by self-report in app) and the option of reporting meals made (approximately 1 to 2 minutes per day).

Reviewing of educational materials aimed at advancing culinary or health literacy (approximately 15 to 20 minutes per week).

An optional, private Facebook community was created to provide additional peer-to-peer and expert-to-peer support (ad libitum).

The app delivered reminders—for example, to schedule a coaching call or report meals made or eaten—in the form of in-app notifications and an ability to message the participant's health coach.

The primary form of human support was delivered by 30-minute telephonic health coaching calls, scheduled at the participant's convenience every 2 weeks via the study app. Health coaching is an evidence-based practice grounded in behavior change theory that uses guided conversational techniques such as motivational interviewing [30,31]. All study health coaches had completed training from accredited health coaching institutions and received additional training in lifestyle and culinary medicine, research methods, and training for coaching within a clinical team prior to the start of the study.

Health coaching calls were used to set and review personalized behavioral goals with each participant. These goals centered largely on the attainment of dietary skills and repetition for habit formation but also included setting physical activity goals and addressing barriers to these goals. For example, participants worked with their coach to establish an individualized plan to progressively reach or exceed a goal of 30 minutes of moderately intense physical activity per day.

During the intervention period, the health coaches were supported by a specialized team of lifestyle medicine experts including a nurse practitioner, internist, psychiatrist, chef-educator, and registered dietitian who were also available to speak to members on an as-needed basis via a care-escalation process. Participants were asked to continue managing all medications with their primary care team or endocrinologist during the course of the study.

Measures

Demographics

Participants reported age, gender, height, weight, and US state of residence as a part of the sign-up process for the study app.

Hemoglobin A_{1c} and Medication Use

Most recent HbA_{1c} and current diabetic medication use (name, dose, and frequency of medication) were self-reported in the study app by participants. Participants were encouraged by their coaches to report any changes to medications within their study app. In addition to in-app coach messages, email reminders were used to prompt entry of a follow-up HbA_{1c} and updated medications at 12 weeks. Medication and HbA_{1c} data were reviewed by 2 study authors (NLG, MAB). Participants were contacted by study staff (KLE, NLG) to help clarify potential reporting errors.

Engagement

Engagement with both the study app and coaching calls was measured automatically via the study app. Total engagement is defined as the average number of recorded app actions per day

(eg, planning or reporting meals, scheduling calls, building shopping lists).

Satisfaction

All participants were invited to fill out a Net Promoter Score (NPS) survey [32] at week 10 after sign-up. The NPS consists of 1 question "How likely are you to recommend FareWell to a friend?" rated on a 10-point scale (0-6=detractors, 7-8=passives, 9-10=promoters). The NPS is calculated by subtracting the percentage of detractors from the percentage of promoters.

Self-Efficacy

End of program self-efficacy to manage diabetes and maintain an optimal dietary pattern was measured via online survey questions using a Likert scale; survey was emailed to participants during their 12th week.

Statistical Methods

Statistical analyses were performed using SAS software version 9.4 (SAS Institute Inc). Change over time of continuous variables was analyzed using 2-tailed paired Student t tests with alpha set at .05 and chi-square tests for differences in categorical variables. The McNemar test was used to evaluate medication change.

To evaluate the combined effects of medication and HbA_{1c} change, we calculated a composite outcome measure defined as a decrease in diabetic medication use without an increase in HbA_{1c} or an improvement in HbA_{1c} of at least 0.5% without an increase in diabetic medication use.

We used mixed-effects modeling to test the effects of baseline body mass index (BMI), years since diagnosis of diabetes, net change in diabetes medications, total app engagement, and baseline HbA_{1c} on the mean change in HbA_{1c}. To evaluate the intent-to-treat effect, we used a last-value-carried-forward approach for the missing data from participants who did not report follow-up HbA_{1c} levels. Since effect-size can be modulated by baseline HbA_{1c} [33], we also tested the effects of a log transformed HbA_{1c}.

To investigate the relationship between engagement with the program and HbA_{1c}, we first defined tertiles of app engagement using the sum of all actions taken in the app during the study. A general linear regression was used to test the effect of app use tertile with the change in HbA_{1c}. Change in HbA_{1c} was set as the dependent variable with tertile of app engagement and the log transformed baseline HbA_{1c} as independent variables. Using the least square means pairwise comparison, we tested the differences in changes in HbA_{1c} by the tertiles of app engagement.

Results

Participants

A total of 123 individuals with self-reported type 2 diabetes and an initial HbA_{1c} of 6.5% or higher downloaded the intervention app, of which 118 (95.9% of downloads) consented to participation in the study. Of the consented participants, 113 were recruited from Facebook and 5 from Craigslist. There were 9 dropouts (7.6% of consented) during the study. Reasons for dropping out were participant not feeling ready to make lifestyle changes (5), difficulty using the app (2), and no reason given (2). Of the remaining 109 participants, 94 (86.2%) were still using the app at 12 weeks, and 101 (92.7%) provided some or all end-study data.

There were no adverse events observed thought to be related to the study intervention. However, 2 adverse events were reported during the first month of study period. One participant reported suicidal ideations to a coach, and another participant was hospitalized briefly for dehydration after a flu-like illness. Both participants recovered fully from their events and were able to continue participating in the study.

Baseline characteristics are summarized in Table 1. Participants from 38 US states consented to participate; 81.4% (96/118) were female, with a mean age of 50.7 (SD 9.4) years, mean BMI of 38.1 (SD 8.8) kg/m^2, and mean HbA_{1c} of 8.1% (SD 1.6) at baseline. There were no statistical differences in baseline characteristics between those who consented and those who submitted end-study data.

Table 1. Sample characteristics at baseline by program completion.

User characteristics	Total n=118	Completed program n=109	Submitted end-study data[a] n=101	P value[b]
Female, n (%)	96 (81.4)	87 (79.8)	80 (79.2)	.14
Age (years), mean (SD)	50.7 (9.4)	50.4 (9.6)	50.4 (9.7)	.85
Geographic distribution, # US states	38	37	37	.71
Hemoglobin A_{1c} (%), mean (SD)	8.1 (1.6)	8.2 (1.6)	8.2 (1.7)	.81
Body mass index (kg/m^2), mean (SD)	38.1 (8.8)	38.4 (9.0)	38.1 (8.9)	.99
Time since diabetes diagnosis (years), mean (SD)	2.6 (1.6)	2.6 (1.5)	2.6 (1.5)	.99
Diabetes medications (count), mean (SD)	1.4 (0.9)	1.5 (0.9)	1.5 (0.9)	.73

[a]Participants who submitted an end-study hemoglobin A_{1c} and/or self-efficacy survey.

[b]P value comparing total sample to those submitting end-study data.

Hemoglobin A$_{1c}$

Among participants who reported an end-study HbA$_{1c}$, 80% (78/97) had improvement of HbA$_{1c}$, with 59% (57/97) having a decrease of 0.5% or more, 39% (38/97) having a decrease of 1% or more, and 23% (22/97) having a follow-up HbA$_{1c}$ <6.5%. The mean change was –0.8% (SD 1.3, P<.001) over a mean interval of 3.5 (SD 0.9) months. This change remained statistically significant in our mixed-effects model (P=.003). Substituting the log transformed baseline HbA$_{1c}$, we found that the impact of baseline HbA$_{1c}$ was modulated and the significance of the mean change in HbA$_{1c}$ was improved (P<.001). Using a last-value-carried-forward approach for the missing data from participants who did not report follow-up HbA$_{1c}$ levels, the mean change remained statistically significant (118/118, –0.6%, SD 0.9, P<.001).

Among those with a baseline HbA$_{1c}$ >7%, the mean change was –1.0% (n=69, SD 1.4, P<.001). Excluding those who experienced a change in glycemic medication midstudy (2/69), the mean change in HbA$_{1c}$ was –1.1% (67/69, SD 1.4, P<.001).

Medication Use

At the start of the study, participants reported taking an average of 1.4 (SD 0.9) diabetic medications with a self-reported average time since diagnosis of 2.6 (SD 1.6) years. Of those reporting follow-up medication data, 4% (4/97) changed medications or dosages within the 12-week study (ie, their medication changes were likely to impact follow-up HbA$_{1c}$). In conjunction with reporting an end-study HbA$_{1c}$, 17% (16/97) of participants reported decreasing or stopping 1 or more diabetic medications and 8% (8/97) increased or added 1 or more diabetic medications. The frequency of decreased medication use (either decreasing dose or stopping a medication) compared to baseline medication use was statistically significant (P<.001).

Using the composite outcome measure defined above, 57% of participants (55/97) met the composite outcome of reducing HbA$_{1c}$, reducing diabetic medication use, or both.

Program Engagement and Satisfaction

Of the individuals who consented to participate, 92.4% (109/118) were active in the study at the end of the 12-week intervention period and 86.2% (94/109) were still using the app. Total distinct app engagements averaged 4.3 (SD 2.5) per day, and average number of coaching calls completed was 4.1 (SD 1.8) during the 12-week period.

We explored the relationship between app use and HbA$_{1c}$ change. There was a stepwise decrease in HbA$_{1c}$ as app engagement level increased. For example, as displayed in Figure 1, in those with a baseline HbA$_{1c}$ >7.0% who did not change medications during the study period, the lowest tertile of engagers reduced HbA$_{1c}$ by 0.9% (SD 1.3), whereas the highest tertile of engagers reduced HbA$_{1c}$ by 1.3% (SD 1.0, P=.03 using log transformed baseline HbA$_{1c}$).

The NPS survey was completed by 47.7% (52/109) of participants with 82.7% (43/52) of respondents giving a promoter score (9 or 10), 11.5% (6/52) a neutral score (7 or 8), and 5.8% (3/52) a detractor score (6 or below). The calculated NPS was 76.9%.

Figure 1. Change in hemoglobin A$_{1c}$ by tertile of engagement in subset of participants with baseline HbA$_{1c}$ >7.0% and no midstudy medication changes. Bars represent means and standard errors. Star indicates P=.03 between groups.
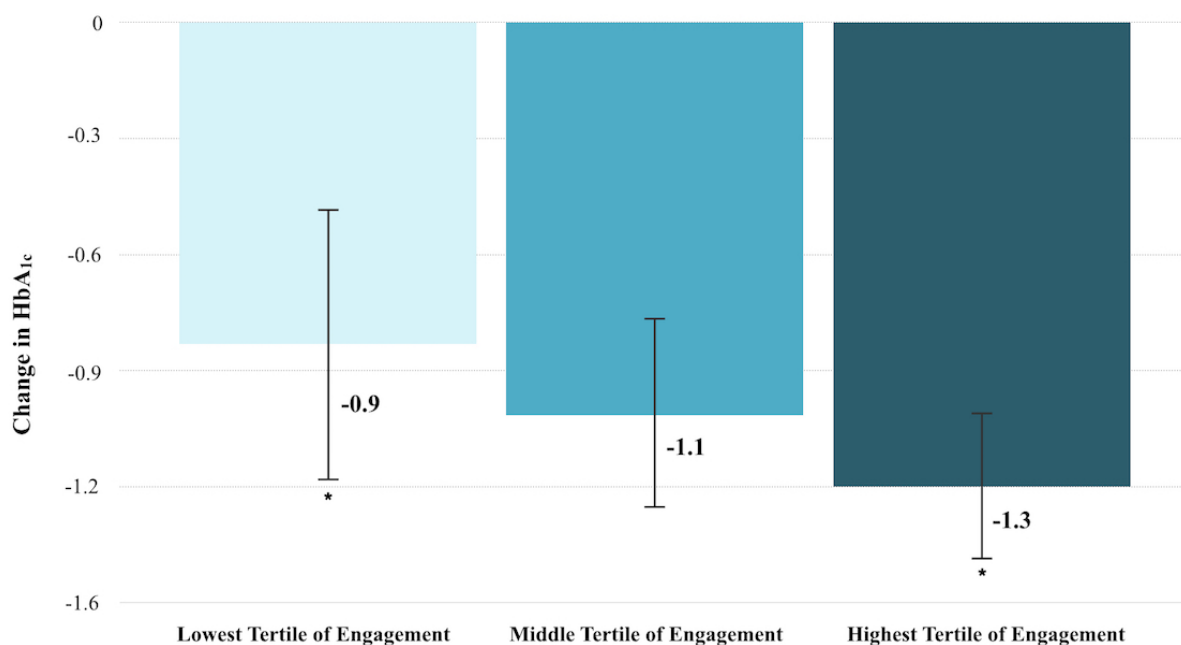
Table 2. Changes in hemoglobin A_{1c}, diabetes medications, and self-efficacy.

Measures	Value	n	P value[a]
Hemoglobin A_{1c} (%), mean change (SD)	−0.8 (1.3)	97	<.001
Duration (months)[b], mean (SD)	3.5 (0.8)	97	
Decrease by 0.5% or more, %	58.8	57	
Decrease by 1.0% or more, %	39.2	38	
Decrease in diabetes medication use[c], %	16.5	16	<.001
Increase in diabetes medication use[c], %	8.3	8	
Daily mobile app engagements[d], mean (SD)	4.3 (2.5)	109	
Diabetes self-efficacy[e], mean (SD)	4.5 (0.6)	98	
Dietary change self-efficacy[e], mean (SD)	4.4 (0.8)	98	

[a]Comparison of baseline and end-study values by paired Student t test for HbA_{1c}, by McNemar test for medication use.

[b]Time between the baseline and end-study HbA_{1c} values.

[c]Includes those who changed dose and/or number of medications used.

[d]Includes use of all features in the mobile app; does not count log-in.

[e]Rated on a 5-point Likert scale with 5=a lot more confident and 1=a lot less confident.

Self-Efficacy

Of the participants answering questions pertaining to self-efficacy, 92% (90/98) of those responding reported greater confidence in their ability to manage their diabetes compared to before the program, and 91% (89/98) reported greater confidence in their ability to maintain a healthy dietary pattern. Table 2 summarizes change in HbA_{1c}, diabetes medications, and self-efficacy.

Discussion

Principal Findings

In this study, we examined the effectiveness of a digital therapeutic delivered to participants with type 2 diabetes distributed across the United States. We found clinically meaningful reductions in both HbA_{1c} and the proportion of participants who reduced diabetic medication use at the conclusion of the 12-week study period. We also observed greater glycemic control in participants with higher levels of engagement with the app.

The magnitude of HbA_{1c} reduction observed was comparable to those found with commonly prescribed medications [33,34] and successful intensive lifestyle interventions delivered in person [10]. In addition, a meaningful percentage (28%, 22/97) of participants achieved an HbA_{1c} value below the diabetic range, 23% (5/22) of whom reported no diabetic medication use, indicating potential for partial or complete remission of diabetes as defined by the American Diabetes Association consensus definition [35]. However, the short duration of this trial and lack of knowledge of the temporal sequence of lab test versus medication change does not allow us to evaluate remission status.

While this study supports the findings of others [36,37] who have demonstrated the efficacy of digital health apps, this is the first digital therapeutic study to our knowledge that emphasized a skill-building process according to the principles of lifestyle medicine rather than calorie or macronutrient counting or restrictions, meal replacements, or mandatory finger-stick monitoring. This is important because many situations that are not conducive to long-term health can ameliorate glycemic measures in the short term, among them starvation and serious infectious disease [38]. Part of the novelty of this intervention was use of a lifestyle approach to treat and reverse diabetes in the short term that is known to be compatible with overall health [18,19] and diabetes prevention [20,21] in the long term.

Strengths and Limitations

The main limitations of this study stem from its single sample, nonrandomized design, self-selection of participants, and reliance on self-reported biometrics. As such, this study cannot establish causation nor can it rule out all potential confounders. In addition, in this short duration study, we did not independently quantify exercise or calorie-nutrient profiles and therefore cannot comment on the precise mechanisms of action.

The strength of this study is a design that closely mirrors real-world implementation of the intervention. The same clinical team and processes used in the study are used in real-world implementation of this digital therapeutic. And just like in the real world, the app continued to develop and experience bugs and bug fixes during the course of the study. This pragmatic study design in concert with recruitment of participants in 38 US states suggests generalizable findings. Other strengths of this study include high rates of retention and successful data collection.

Conclusions

Future research in the form of randomized controlled trials will be needed to establish comparative effectiveness. In addition,

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longer duration trials will be needed to assess the durability of the lifestyle, biometric, and medication changes observed among diverse socioeconomic populations. Equally important will be research evaluating cost effectiveness. Finally, because this study evaluated an early version of a rapidly evolving digital therapeutic, it will be important to understand to what degree feature enhancements and additions modify the outcomes observed in this study.

Acknowledgments

Authors' Contributions

MAB, NLG, KLE, KJA and DLK, who are also employees of the study sponsor, participated in the development of the intervention, drafted the study protocol, managed data collection, conducted primary data analysis, and prepared the manuscript.

Conflicts of Interest

MAB, NLG, KLE, KJA, and DLK are employees and equity owners of Better Therapeutics LLC. DME is a paid scientific consultant of Better Therapeutics. VYN, an independent scientific consultant, was provided the raw deidentified data to perform statistical analyses.

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Abbreviations

BMI: body mass index
HbA$_{1c}$: hemoglobin A$_{1c}$
NPS: Net Promoter Score

Original Paper

Mobile App for Simplifying Life With Diabetes: Technical Description and Usability Study of GlucoMan

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Abstract

Background: Patients with diabetes can be affected by several comorbidities that require immediate action when occurring as they may otherwise cause fatal or consequential damage. For this reason, patients must closely monitor their metabolism and inject insulin when necessary. The documentation of glucose values and other relevant measurements is often still on paper in a diabetes diary.

Objective: The goal of this work is to develop and implement a novel mobile health system for the secure collection of relevant data referring to a person's metabolis and to digitize the diabetes diary to enable continuous monitoring for both patients and treating physicians. One specific subgoal is to enable data transmission of health parameters to secure data storage.

Methods: The process of implementing the system consists of (1) requirements analysis with patients and physicians to identify patient needs and specify relevant functionalities, (2) design and development of the app and the data transmission, and (3) usability study.

Results: We developed and implemented the mobile app GlucoMan to support data collection pertaining to a person's metabolism. An automated transfer of measured values from a glucometer was implemented. Medication and nutrition data could be entered using product barcodes. Relevant background knowledge such as information on carbohydrates was collected from existing databases. The recorded data was transmitted using international interoperability standards to the MIDATA.coop storage platform. The usability study revealed some design issues that needs to be solved, but in principle, the study results show that the app is easy to use and provides useful features.

Conclusions: Data collection on a patient's metabolism can be supported with a multifunctional app such as GlucoMan. Besides monitoring, continuous data can be documented and made available to the treating physician. GlucoMan allows patients to monitor disease-relevant parameters and decide who accesses their health data. In this way, patients are empowered not only to manage diabetes but also manage their health data.

Introduction

According to the International Diabetes Federation, approximately 642 million people worldwide will suffer from diabetes in 2040 [1]. Diabetes mellitus poses enormous challenges for patients and health carers. Once diabetes is diagnosed, lifelong self-management is critical for glycemic control with direct impact to long-term prognosis for the patients. Diabetes self-management includes self-monitoring of blood glucose, weight management, eating, and taking and managing medications. Furthermore, preventing and controlling diabetes complications (eye, foot, and renal) is important and requires regular checkups with physicians [2]. Care costs for

chronic diseases are immense. Research showed that these costs can be reduced by supporting the self-management capabilities of patients [3]. Studies have proven that self-management allows patients to effectively deal with the challenges of chronic diseases and their treatment by reducing complications and symptoms, thus maintaining the level of quality of life [4]. With the rapid and ongoing growth of wireless connectivity and mobile phone availability, apps are increasingly considered interesting for supporting disease management. There is evidence from small studies that app use may have a beneficial effect on health outcomes [5]. The American Diabetes Association guidelines confirmed that apps may be a useful tool for monitoring diabetes and preventing complications [2]. With this in mind, we designed an app supporting diabetes self-management and digitized the existing paper-based diabetes diary.

Even though thousands of diabetes apps are available in the iTunes App Store and Google Play store for Android [6], these have limitations, which we address with our diabetes manager, GlucoMan. For example, the app mySugr allows a user to document blood sugar and other values uploaded from measurement systems [7]. DiaFit [8] supports uploading data from gadgets such as Apple Watch for fitness activity and glucose monitoring. Lithgow et al [9] claim that existing apps often do not support synchronization with a glucometer, although this feature is desired by patients. Existing apps support data export via email or sharing in social media platforms [10], but secure data export to a database that physicians can easily access through their information systems is not at all supported [10]. Arnhold et al [11] performed a systematic review on diabetes apps and found out that most of the 656 apps they reviewed provided only one function, such as documentation, information gathering, data forwarding, reminder, or therapy support. Further, they concluded that data transmission of health parameters to physicians is an important issue for future systems and is currently not well established.

The goal of this work is to develop and implement a novel mobile health system that digitizes the diabetes diary, enabling continuous monitoring of relevant data regarding a person's metabolism, and addresses the limitations of existing systems. A multifunctional app was developed aimed at supporting patients with diabetes in managing their disease by enabling documentation, data communication, and information gathering. Data is stored on a health platform where it can be accessed by physicians and researchers after patient authorization.

Methods

Requirements Analysis

We developed GlucoMan within the context of the Hospital of the Future Live (Spital der Zukunft Live, or SDZL), a Swiss project involving 16 companies and 6 hospitals that focused on eHealth technologies to develop information technology (IT) solutions for future optimized health care processes [12]. The Institute for Medical Informatics of the Bern University of Applied Sciences executes SDZL on behalf of GS1 Switzerland to study to what extent IT can optimize public health sector processes such as information flow and logistics in a system

that starts and ends at home and involves the patient, carers, family doctor, specialists, and the hospital and rehab clinic. The project SDZL runs from June 2016 to June 2018. Several partners from the project were involved in the development of GlucoMan through provision of technology (hospINDEX, MIDATA, see below) and assistance with the requirements analysis. This particular subproject ran from September 2016 to June 2017.

We developed the concept and collected requirements based on interviews and discussions with 3 doctors from the university hospital in Bern, 2 representatives from Diabetes Switzerland, the national diabetes association, and 2 patients with diabetes recruited from the authors' personal environments. In this way, we assessed and considered the needs of health professionals and patients during the app development phase. Additional information was collected by reviewing scientific literature and teaching materials retrieved by searching PubMed using combinations of the keywords "mobile app," "diabetes," "diabetes management," "patient empowerment," "mobile health," and "self-management." The existing paper-based diabetes diary was used as a basis for app development and deciding on functionalities to be integrated.

Knowledge and Technological Resources

Drug information was retrieved from hospINDEX (HCI Solutions AG) based on the Global Trade Item Number. hospINDEX contains article and partner data in XML format, and the referenced articles are linked to commercial and scientific data. The selection of the data covers around 220,000 articles. Additionally, hospINDEX provides clinical decision support data. The database contains information on allergies, interactions with food, use during pregnancy, maximum dosages, and more.

We used the open food databases openfoodfacts.org, openfood.ch, and fddb.info to import the values of carbohydrates of nutrition products. The current version of the prototype supports communication and data exchange with the MyGlucoHealth (Entra Health Systems) wireless Bluetooth glucose meter. We selected this device since it provides a wireless interface. Other devices such as FreeStyle Libre (Abbott Laboratories) have been assessed for integration but were excluded due to proprietary data formats or missing data transmission interfaces.

Data is stored on the MIDATA IT platform [13]. MIDATA.coop has developed an open source IT platform for the secure storage, management, and sharing of personal health data of any sort. The platform underwent 3 independent security checks before the first personal data were stored. MIDATA.coop has also established a clear trust-promoting governance framework. A developer's guide is available [14] that explains the general architecture of the platform and how apps and plugins can interact with it.

Our app is developed with the Ionic v2 Framework and Cordova (HTML, Cascading Style Sheets, Typescript); therefore, it can be built for multiple platforms (Android, iOS, Windows Phone, Blackberry, etc). The runnable version was only created for

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Android because the iPhone Bluetooth interface could not be used as required.

Usability Study

The objective of the usability study is to identify usability problems and refine the design of the system to address the identified problems. Two subjects suffering from diabetes, 1 diagnosed with type 1 (male, age 57 years) and 1 with type 2 (male, age 60 years), were recruited from the author's personal environment for the study. They also contributed to the requirements analysis. Diagnosed 12 years ago and 8 years ago, respectively, both test persons already have some years of experience with living with the disease. Additionally, 4 persons who are not diagnosed with diabetes were included in the study: 2 females, aged 73 and 38 years, and 2 males, aged 73 and 56 years, from the author's broader environment (friends and relatives of colleagues who were not involved in the app development). All test persons use their mobile phones daily. None of them had medical training. For the usability test, they were asked to use the app installed on a separate device so the test conditions would be the same for all participants. They had no time in advance to get familiar with the app. Instead, they had to complete the tasks with only a brief verbal introduction to the functionalities by the study coordinator.

The usability test comprises 81 tasks concerning the different functionalities of the app. For example, the test persons had to navigate to the monitoring screen and add a new appointment or remove it. Another task required manually entering measurement values such as weight or pulse or importing data from the glucometer. From the nutrition screen, the test persons manually entered carbohydrate values for their meals or scanned products to import the carbohydrate data into the app.

The number of trials per task was recorded (ie, how often the task had to be started to finish it—immediately, second try, more than 2 trials). Additionally, the number of clicks needed to fulfill each task was collected. For each task, we assessed the optimal number of clicks beforehand and compared this number to the measured values. The test persons were asked to think aloud when problems occurred. After participants completed the tasks, overall feedback on usability of the app was assessed with an 8-question questionnaire.

Even though the number of participants in the study was low, previous studies from the human-computer interface literature found that 80% of usability problems can be found with only 5 research subjects [15,16]. Turner et al [15] even claims that the most serious usability problems can be revealed with only 3 subjects. The problem space determines the estimated required sample size [11]. The tasks to be supported by GlucoMan are well defined, and the problem space is limited compared to other software systems. Thus, the 6 persons included in our study are expected to be sufficient to determine the main problems related to usability of the app.

Results

Requirements

Based on the requirements engineering, literature reviews, and interviews, we identified the following features to be implemented in GlucoMan:

- Patient can access personal medical data related to metabolism independently from time and location.
- Defined members of a patient's care team can view the measured values documented and shared by the patient regardless of time and location.
- Data such as glucose levels are transmitted automatically from measurement devices to the app.
- Patient can specify target rates as control measures for specific values and get immediate feedback on the last added measurement value relating to a defined target range.

Architecture and System Functionalities

All collected data is made available to selected physicians and researchers when the patient provides access rights. The app connects to nutrition and medication Web services for carbohydrate and drug information (see section on technological resources). Data from medical devices are collected via Bluetooth. The concept underlying GlucoMan comprises a mobile phone app, data collection from medical devices or gadgets, and data storage (see Figure 1; the following numbers in the descriptions pertain to numbers in the figure).

To add new measurement values, Bluetooth-capable devices can be connected to the app (1). Upon data request, the actual measurements are imported to GlucoMan (2). In the current prototype, the glucose meter MyGlucoHealth is integrated as an example. Other devices can be added easily. Food names or data on nutrition (3) can be entered manually by the patient, and barcodes on food labels can be scanned. Current medication names (5) can be added manually or the drug barcode can be scanned by the patient. The scanned or entered products are searched in the drug or food databases, and relevant parameters are stored. For food items, information on carbohydrates (4) is retrieved, and for medications, article details such as product number and images (6) are retrieved. All collected and relevant data are uploaded to the personal account of the patient on the MIDATA platform (7).

The data exchange between GlucoMan and the platform MIDATA is realized using the Health Level Seven International (HL7) Fast Healthcare Interoperability Resources (FHIR) standard. This standard is based on resources, so-called observations, which are formatted in JavaScript Object Notation. Due the multiply encrypted data, MIDATA ensures a high safety standard, which is indispensable for personal medical data. The encryption of the key guarantees that the data are exclusively controlled by the owner. Without the key, the data can no longer be decrypted and are thus lost. Additional health data servers can be integrated easily as data sources via Bluetooth (8). From the MIDATA server, GlucoMan can retrieve relevant data for visualization (12). The data collected by the app and transferred to the MIDATA server can be made available by the patient for anonymized use in studies (9) or for monitoring purposes by

the personal health care team (10). With the authorization of the patient, physicians are able to upload additional data like diagnoses, treatment, and personal notes to the account of a patient (11), which can be imported to GlucoMan where the patient can access it (12). GlucoMan shows all stored data aggregated in graph-like representations.

Figure 1. Concept and functionalities of the mobile app GlucoMan.
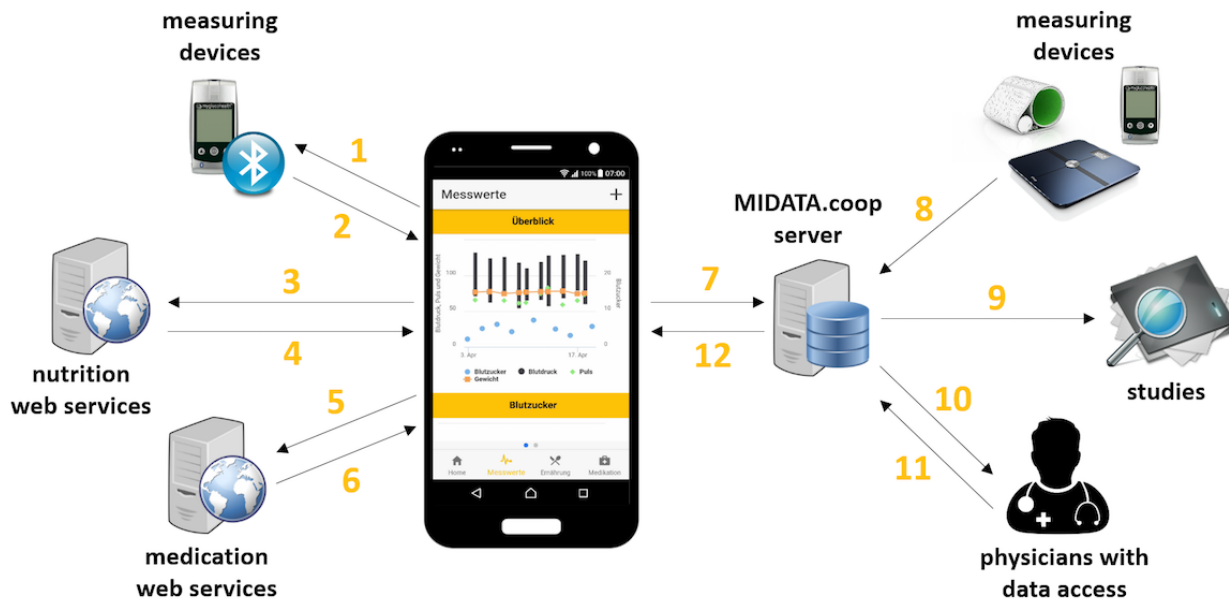
The app allows specifying a measurement scheme comprising ranges for specific types of values and provides emergency support for persons who find a diabetic person in a situation of low blood sugar, advice for traveling with diabetes and on diabetes self-management, measurement values for HbA_{1c}, blood pressure, and weight as measured in the monthly or bimonthly checkups. Different types of measured values such as blood sugar, blood pressure, pulse, and weight can be uploaded via Bluetooth (Figure 2). Information on nutrition and medication can be entered to enable monitoring (Figure 2). The app provides the functionality to import the carbohydrate value by scanning the bar code of a product to retrieve nutritional values from food databases. If the database also contains the information on portion size, it is imported instead of the normal 100 g portion data. Before data are saved, the nutrition description, portion size (in grams), and carbohydrates (in grams) are displayed in an alert so that the user can still make changes. All measured values are visualized in an intuitive manner, enabling a user to monitor the changes in values. The different colors in the nutrition visualization represent the time of day. The size of the bar is determined by the number of carbohydrates (Figure 2). In order to record medication data, 4 types of medications are distinguished to enable a better overview: prescription medications, over-the-counter medications and supplements, insulin, and drug allergies. New drugs can be added by scanning the product bar code.

Usability Study Outcomes

In general, the app has been rated as easy to use by the 6 subjects. The descriptions of buttons were understandable. Some interactive functionalities were not recognized: checkboxes that could be selected or that a further view could be obtained by swiping. Surprisingly, the 2 oldest study participants (aged 73

years) had no problems identifying the swiping to change the view.

Most of the features were instantly recognized and completed in the desired number of clicks. Five out of 6 test persons managed to complete the majority of tasks in 1 trial. One test person completed 8 tasks in 3 trials, 15 tasks in 2 trials, and the other tasks in 1 trial. For tasks related to adapting the visualizations or defining ranges for values, more than the expected number of clicks were made. The reason was that the desired functionality was captured in the Options menu which was hard to find. The test persons desired explanations on the possible options that could be adapted in the app (eg, changing the measurement schema) and mentioned that it would be helpful to get more obvious hints when pages can be swiped. The 2 oldest test persons requested a larger font size and larger checkboxes.

The 4 test persons who did not have diabetes were impressed with the possibilities of the app and in particular liked that the information was provided in a clear manner and no irrelevant data were presented or collected.

The 2 test persons with diabetes had different types and considered certain functions more or less relevant and evaluated them differently. In the case of type 1 diabetes, several blood glucose measurements have to be made per day. This requires monitoring the measured values more often than with type 2 diabetes, where glucose is measured only 1 or 2 times daily.

The test person with type 2 diabetes stated that he would use the app in future if the diet in his therapy gains in importance. This person considers the data import by Bluetooth or barcode very practical.

The test person with type 1 diabetes currently measures his blood glucose level with a continuous measuring device. In order for the app to be used by him, a connection of his current measuring device needs to be enabled to import the values. In general, he considers the barcode detection a very helpful option. It would be beneficial if not only carbohydrates of ready-made meals could be calculated and recorded because this test person normally eats self-cooked food or in a restaurant.

Figure 2. Left: GlucoMan screen showing glucose and blood pressure readings. Right: GlucoMan nutrition overview. Carbohydrates per meal are shown graphically and in a table for 3 continuous days.
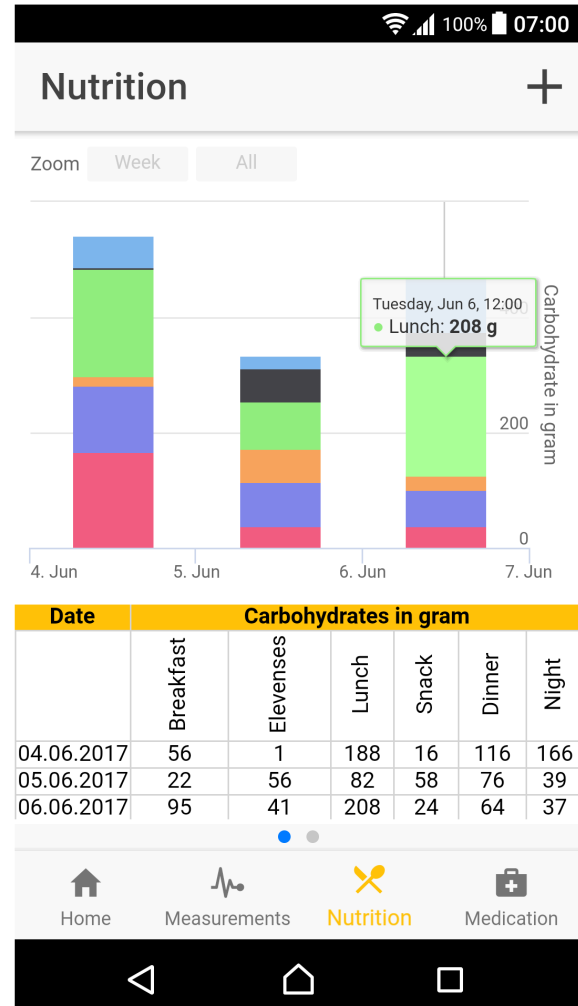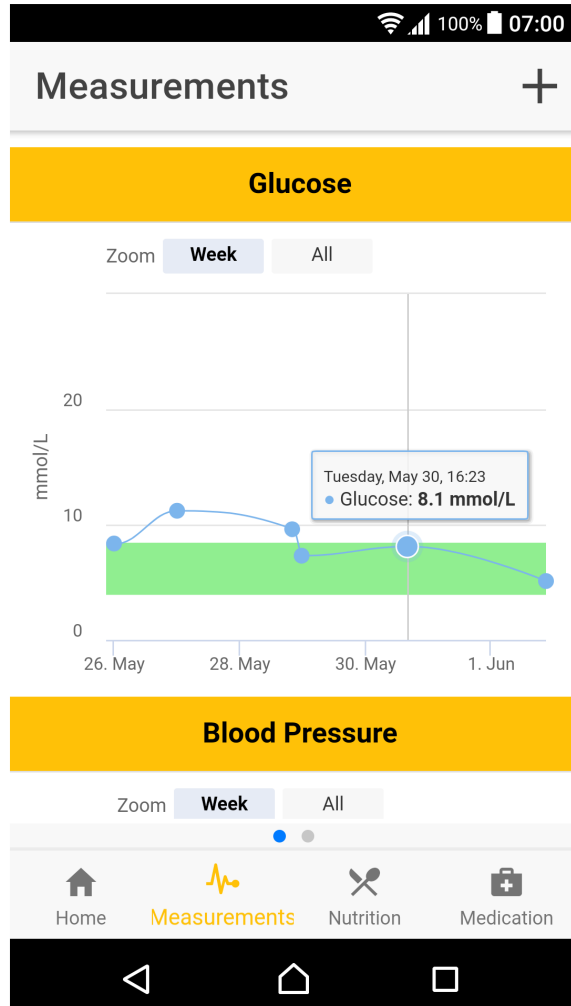
Discussion

Principal Findings

The purpose of the proposed app GlucoMan is to relieve the patient from the duty of entering or manually documenting measured data for monitoring purposes and provide a user-friendly overview of available measurements. In this way, the patient is put into the position of managing and monitoring his or her diabetes—the patient is empowered to understand the disease. The data collection feature was confirmed to be useful by the person with type 1 diabetes; he currently has to record such values manually in the diabetes diary.

GlucoMan stores the data on the MIDATA IT platform. For further use of the stored data, it is possible to authorize other users of the platform to access the data or open it for use in studies. For example, researchers can use the data for finding hidden patterns in the diabetes data of a larger population. In this way, scientists can have access to anonymized data of a large population in the future. The treating physician with an account on MIDATA can inspect the recorded measurements and add treatment- and diagnosis-relevant data regardless of location and time.

By scanning the barcode of a food product or drug, the patient can obtain additional information on carbohydrates or medication doses. Data entry is simple and easy to use with the barcode scanner. Bluetooth-connected measurement devices transfer data directly to the system without any media break.

Comparison With Prior Work

Functionalities of existing diabetes apps vary. Hood et al [17] distinguished apps that support monitoring tasks (diabetes-specific self-management tasks, weight and blood pressure tracking) from those that have educational purposes. Few apps provide personalized feedback or content. Most apps are equipped with glucose tracking, calorie counting, activity tracking, and education. Lithgow et al [9] found out that collecting data directly from a glucose meter is a feature missing [9] or supported only by a few apps [8]. Our app addresses this limitation.

Measurement devices normally support uploading values to the user's account. Often, this data can neither be used from these platforms by external parties nor easily analyzed by a physician. Furthermore, existing diabetes management apps support data-sharing only in social networks or by export via email. By storing data on MIDATA, the patient remains the owner of his data and can provide access rights to selected physicians or even offer the data to clinical studies. This is in contrast to portals from hardware providers such as Whitings or Fitbit that store the data on proprietary platforms without giving any rights to the patient. Storing data on MIDATA can be recognized as a first step toward an electronic health record that integrates clinical and personal health data. All treating physicians can access the personal health data of a patient. This is a unique feature compared to existing apps. Additionally, no other app could be identified that uses HL7 FHIR for data transmission even though it is obvious that the use of standards is important for achieving interoperability and data reuse.

Whereas several Bluetooth and Internet of Things measuring devices already on the market for common vital signs like blood pressure, pulse, and weight give access on the measured data, many manufacturers of blood glucose meters are implementing proprietary protocols. For this reason, it is impossible for third-party systems to access or process the data. Our concept allows easily integrating data from gadgets or medical devices when accessible data protocols are provided. A future extension of the app would be the integration of an insulin pen such as inPen (Companion Medical) which would enable the person to also track insulin doses.

The open question for our app and also for many other available systems is the usefulness for patients in managing their diabetes. Studies by Hou et al [18] showed that mobile phone apps have the potential to improve glycemic control in the self-management of diabetes. However, they also concluded that younger patients were more likely to benefit from the app use. Additionally, a randomized controlled trial by Quinn et al [19] found that traditional intervention methods could not provide adequate blood glucose control, but a mobile diabetes intervention method improved clinical outcomes. The US Food and Drug Administration has approved some apps for diabetes management. This shows that apps can be useful in this context.

Jo et al [20] tested the app Healthy-note with patients and found out that effective support can be achieved when the app provides suggestions for lifestyle adaptations and helps in monitoring those. According to their results, interaction with the patient is important for setting goals and providing continuous encouragement. Through the specification of ranges for the values in GlucoMan, a patient is enabled to set goals for specific measurement values. Including features for encouraging a patient to work toward achieving the goals is still open for future work.

Limitations

The user study involved 2 persons diagnosed with diabetes and 4 persons not diagnosed with diabetes. The latter could judge and test the functionalities but not the relevance of the app for diabetes management. However, we were able to identify main usability problems during the tests. Even though we involved the national diabetes association, it was not possible to recruit more patients in the short time available for this project. Even though the test persons were recruited from the personal environment of the authors, we are convinced that this does not affect the results of the usability study; the test persons completed defined tasks and number of clicks were counted, which is an objective measure. A comprehensive clinical study for testing the impact of GlucoMan on the self-management capacity and studying the usability of the system is currently planned.

Even though the concept enables data access by physicians, a corresponding user interface or data integration with existing information systems was not implemented as part of this work. This remains open for future work. We developed the connection to one specific glucose meter. To connect another medical device to the app, technical documentation needs to be available for the device that provides details on data requests and corresponding responses. For using the app in other countries than Switzerland, the underlying drug database would need to be changed. The hospINDEX only allows recognizing drugs that are approved on the Swiss market.

Currently, GlucoMan only enables entering data from products that have a barcode or where the patient enters the carbohydrates manually. A future extension is the integration of the GoCARB [21], a mobile system that allows taking a photo from a plate with food and calculates the carbohydrates automatically. This would clearly simplify the collection process for self-cooked meals.

Conclusion

Collection of data on a patient's metabolism can be supported with a multifunctional app such as GlucoMan. Besides monitoring, continuous data can be documented and made available to the treating physician. GlucoMan allows patients to monitor disease-relevant parameters and decide who accesses their health data. In this way, patients are empowered not only to manage diabetes but also to manage their health data.

Conflicts of Interest

None declared.

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Abbreviations

FHIR: Fast Healthcare Interoperability Resources
HL7: Health Level Seven International
IT: information technology
SDZL: Spital der Zukunft Live (Hospital of the Future Live)

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Original Paper

Health Care Professionals' Clinical Perspectives on Glycemic Control and Satisfaction With a New Blood Glucose Meter With a Color Range Indicator: Online Evaluation in India, Russia, China, and the United States

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Abstract

Background: We previously demonstrated in patients with diabetes that displaying blood glucose results in association with color improved their ability to interpret glucose results.

Objective: The objective of this study was to investigate the perceptions of health care professionals (HCPs) in specific countries about the value of color on a new glucose meter and to determine if HCP perspectives among countries differ on the value of this approach in clinical practice.

Methods: A total of 180 HCPs, including 105 endocrinologists, 34 primary care physicians, 25 diabetes educators, and 16 pharmacists, were recruited from India (n=50), Russia (n=50), China (n=50), and the United States (n=30). These HCPs experienced the OneTouch Select Plus Simple glucose meter online from their own office computer using interactive demonstrations (webpages, meter simulator, and video clips). After providing demographic and current clinical practice insights, HCPs responded to questions about the utility of the color-enhanced glucose meter.

Results: Mean age and years in their current professional role for the 180 HCPs was 41.3 (SD 8.1) and 13.3 (SD 6.8) years for endocrinologists, 41.3 (SD 8.3) and 14.1 (SD 6.8) years for primary care physicians, 37.5 (SD 8.7) and 12.7 (SD 6.8) years for diabetes educators, and 35.9 (SD 5.3) and 9.5 (SD 5.2) years for pharmacists. In all, 88% (44/50) of Russian and 83% (25/30) of American HCPs said their patients find it easy to recognize low, in-range, or high blood glucose results compared to 56% (28/50) of HCPs in China and 42% (21/50) in India. Regardless of country, HCPs had less confidence that their patients act on blood glucose results with 52% (26/50) in Russia, 63% (19/30) in the United States, 60% (30/50) in China, and 40% (20/50) in India responding positively. During the interactive online meter experience, HCPs from all countries responded positively to questions about a meter with color features. After reflecting on the value of this meter, most HCPs strongly agreed or agreed their patients would be more inclined to act on results using a meter with color features (Russia: 92%, 46/50; United States: 70%, 21/30; China: 98%, 49/50; India: 94%, 47/50). They also said that color was particularly useful for patients with lower numeracy or education who may struggle with interpreting results (Russia: 98%, 49/50; United States: 77%, 23/30; China: 100%, 50/50; India: 82%, 41/50).

Conclusions: This multicountry online study provides evidence that HCPs had high overall satisfaction with the OneTouch Select Plus glucose meter, which uses color-coded information to assist patients with interpreting blood glucose results. This may be especially helpful in patient populations with low numeracy or literacy and limited access to health care and direct interaction with HCPs.

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KEYWORDS

color range indicator; blood glucose meter; self-monitoring of blood glucose; health care professionals

Introduction

Guidelines suggest that when prescribing self-monitoring of blood glucose, health care professionals (HCPs) should ensure patients with diabetes receive ongoing instruction on interpreting blood glucose data so they may make lifestyle or therapy changes [1]. However, evidence from clinical practice in many countries, including China, Russia, and India, suggests patients struggle to achieve glycemic targets. A study in China found that 55% of 2819 insulin-treated patients with type 2 diabetes (T2D) had a glycated hemoglobin A_{1c} (HbA_{1c}) greater than 8%, with 59% of patients reporting that they only occasionally follow their HCP's instructions regarding self-monitoring of blood glucose [2]. A pharmacoepidemiological study observed a similar pattern of poor glycemic control in patients with T2D from 45 different towns in Russia reporting that 36% of patients had an Hb A_{1c} greater than 8% [3]. Furthermore, a mobile diabetes project in rural Russia in patients with T2D found that access to HCPs and ongoing support for patients is problematic in these areas [4]. Lack of consistent contact with HCPs and limited understanding of self-monitoring of blood glucose can have a negative effect on maintaining positive self-care behaviors in these countries. For example, in one rural area of India only 25% of patients had performed even a single blood glucose test in the time between face-to-face doctor visits, a finding partly attributed to a lack of knowledge about how to perform the test [5]. In addition, even for patients who regularly attended a tertiary care hospital in India, self-care practices were found to be unsatisfactory and the authors recommended that more effort be directed toward educating people with diabetes in India [6].

Appropriate education addressing how to interpret self-monitoring of blood glucose information and how to respond to "out-of-range" results have been identified as important requirements for useful self-monitoring of blood glucose practice [7]. However, lack of the ability to interpret or act on self-monitoring of blood glucose can be compounded by other factors. For example, disparities in literacy, presence of literacy but lack of health literacy, and low numeracy across patients in various countries can impede efforts to support patients who struggle to comprehend self-care guidance or use the self-monitoring technologies provided by HCPs. For example, low diabetes-related numeracy skills are associated with fewer self-management behaviors [8] and poor numeracy is also associated with suboptimal glycemic control in patients with T2D [9] and type 1 diabetes (T1D) [10]. In addition to issues with numeracy, a recent UNESCO report found only 29% of countries are expected to achieve universal adult literacy targets with the number of illiterate adults worldwide projected to be 743,000,000 by 2015 [11]. Therefore, providing patients with glucose monitoring tools that are easy for HCPs to teach

and easy for patients to interpret is important, especially in countries where both low numeracy and literacy are barriers to diabetes self-management. We previously reported that glucose meters utilizing color range indicators (ColorSure technology) improved the ability of patients with T1D and T2D to interpret glucose results [12]. In this study, we solicited feedback from HCPs in China, India, and Russia regarding a glucose meter that has features targeted to areas with diverse patient populations facing challenges in terms of access to health care (eg, in rural areas) or barriers to self-management (eg, lower literacy or numeracy). For comparison purposes, we also surveyed a cohort of HCPs providing diabetes care within the US health care environment.

Methods

Materials

The OneTouch Select Plus Simple meter (LifeScan, Wayne, PA, USA) is intended for self-testing by people with diabetes as an aid to monitor the effectiveness of diabetes control. It is simple to use, has a small and slim design, no buttons to push, and a large visual display with big, easy-to-read numbers. The meter automatically lets patients know if their blood glucose result is below, above, or within a target glucose range by displaying the current blood glucose result with a range indicator arrow (ColorSure technology) pointing to a corresponding color bar below the meter display (blue for low; green for in range; red for high) (Figure 1). The meter also emits a fast audible beep when the blood glucose result is low and a slow audible beep when the blood glucose result is high for an added level of safety. The system comes with a paper-based reference card guide that the doctor, diabetes educator, or other HCP can fill out with individualized reminders of when to perform glucose tests and how a patient should respond to certain blood glucose results.

Procedure

This multicountry online survey study was conducted by individual HCPs from institutions and clinical practices within each country. Webpages were provided to the HCP that summarized the features and benefits of the meter. In addition, short video clips pertaining to the setup and test process when using the meter were provided. An interactive computer simulation of the actual meter was provided online to allow each HCP to control and experience the various key features of the meter (Figure 2). A total of 180 HCPs from four countries (50 each from Russia, India, and China, and 30 from the United States) were recruited and included endocrinologists, primary care physicians, diabetes educators, and pharmacists.

Before the online experience with the meter, all HCPs provided demographic and clinical practice metrics with respect to the number and types of patients they routinely advised or treated.

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Figure 1. OneTouch Select Plus Simple blood glucose monitoring system components. An arrow pointing to the color bar on the meter casing indicates if the current blood glucose result is low (blue bar), in range (green bar), or high (red bar) to a target blood glucose range. The system uses OneTouch Select Plus blood glucose test strips and Delica lancing devices and contains a reference information card in the system kit that has space for health care professionals to write instructions and advice to their patients.

Figure 2. Methodology for the online health care professional (HCP) study. The HCPs interacted with webpages online describing features of the OneTouch Select Plus Simple, a reference card that was contained in the meter kit, an interactive simulation of use of the meter, and an online video demonstrating the proper use and features of the meter.
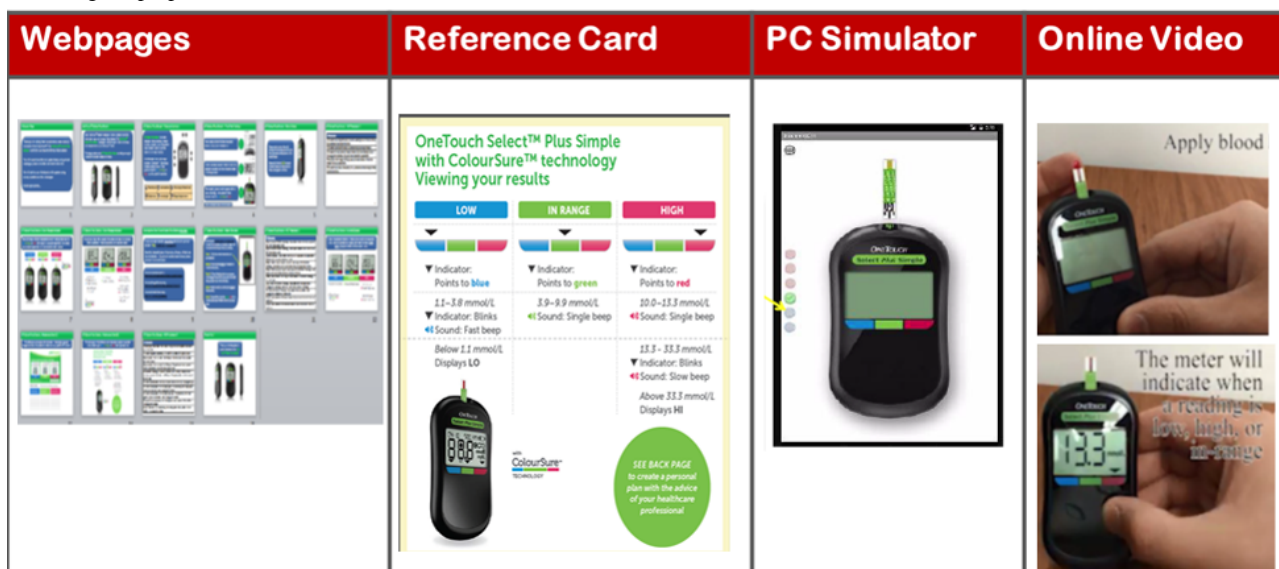
The HCPs were then asked four clinical practice questions to determine the confidence they had in the ability of their patients to interpret or act on blood glucose results and to determine how often they provided insight on these topics to their patients. Participating HCPs then used the interactive online tool to experience the identical capability, functionality, and navigation as the intended product. The meter simulator was preloaded with representative low, in-range, and high blood glucose results or information that provided examples of the meter screens that appeared whenever HCPs (or patients) reviewed information. The HCPs interacted online with a series of 19 webpages displaying both text and visuals of the meter, with embedded links at various points which automatically gave the HCP a hands-on interaction (via mouse) with the meter simulator

([Figure 2]). In addition, participants viewed two videos showing real-time meter setup and routine glucose testing with the meter. At various stages during these activities, 25 survey questions were presented to assess the HCP's opinions of the value of various functions and features of the meter to them and their patients. After completing the meter experience activities, the HCPs were asked three clinical practice-based questions pertaining to the value of the meter in supporting their patients with diabetes self-management and whether the meter might have particular benefits for patients with low numeracy.

Statistical Analyses

Continuous demographic variables were described as median and range or mean and standard deviation. Categorical demographic variables were described as percentages within categories and are presented with both numerator and denominators. Patient responses to survey statements were recorded using a five-point Likert scale with a favorable response (4 or 5) deemed statistically significant if the lower 95% one-sided confidence limit for the percentage of participants providing a favorable response per item was greater than 50%.

Results

Health Care Professionals' Demographic and Clinical Practice Information

A total of 180 HCPs took part in the study with 50 HCPs each in Russia, India, and China, and 30 HCPs from the United States. Professional background of the HCPs included 105 endocrinologists, 34 primary care physicians, 25 diabetes educators, and 16 pharmacists ([Table 1]). Pharmacists were not recruited as part of the US cohort of HCPs. Mean age across all four countries was mean 41 (SD 8) years (endocrinologists), mean 41 (SD 8) years (primary care physicians), mean 37 (SD 9) years (diabetes educators), and mean 36 (SD 5) years (pharmacists). Mean time in current role was mean 13 (SD 7) years (endocrinologists), mean 14 (SD 7) years (primary care physicians), mean 13 (SD 7) years (diabetes educators), and mean 10 (SD 5) years (pharmacists). The proportions of patients with T1D and T2D, respectively, typically seen by each professional in routine clinical practice was 20% and 80% (endocrinologists), 18% and 82% (primary care physicians), 32% and 69% (diabetes educators), and 23% and 77% (pharmacists). Country-specific variations in HCP demographics and clinical practice parameters are shown in [Table 1].

Health Care Professionals' Current Clinical Practice Feedback on Patient Self-Care

Of the HCPs in the United States and Russia, 90% (27/30 and 45/50, respectively) responded that their patients were either aware or very aware about what represents a low, in-range, or high glucose result when testing at home with their current meter compared to only 78% (39/50) in China and 64% (32/50) in India. A total of 83% (25/30) of HCPs in the United States and 88% (44/50) in Russia responded that most of their patients

could immediately recognize when results were low, in range, or high when testing at home with their current meter compared to only 56% (28/50) or 42% (21/50) in China and India, respectively. Regardless of country, HCPs had similar responses when asked how often they personally provided their patients with specific target levels for their glucose results with 90% (27/30) of American, 100% (50/50) of Russian, 90% (45/50) of Chinese, and 88% (44/50) of Indian HCPs responding they provided this information most or every time they met. Furthermore, HCPs across all countries had low confidence that their patients took action when they got low or high glucose results at home, with only 63% (19/30) of American, 52% (26/50) of Russian, 60% (30/50) of Chinese, and 40% (20/50) of Indian HCPs having confidence their patients took action ([Figure 3]).

Health Care Professionals' Feedback During Online Interaction With the Meter

During the interactive online meter experience, 92% (46/50) of Russian, 90% (45/50) of Indian, 88% (44/50) of Chinese, and 63% (19/30) of American HCPs agreed that the easy-to-understand ColorSure technology could support patients' ability to know when to act on their blood glucose results. In addition, 92% (46/50) of Russian, 90% (45/50) of Indian, 88% (44/50) of Chinese, and 63% (19/30) of American HCPs agreed a meter with color could help their patients feel more confident about managing their diabetes compared to receiving number results alone ([Table 2]). In all countries, HCPs often do not have ample time to teach patients about new technology. Therefore, it was valuable to 92% (46/50) of Russian, 86% (43/50) of Indian, 92% (46/50) of Chinese, and 67% (20/30) of American HCPs that this meter was so simple that the majority of their patients could start using it without additional training. Additionally, 96% (48/50) of Russian, 86% (43/50) of Indian, 86% (43/50) of Chinese, and 67% (20/30) of American HCPs agreed this meter could be used right out of the box without any additional instructions from them. Simple paper-based reminder tools to assist individual patients on how to react to different blood glucose results can support positive decision making. This meter comes with a paper reference card that allows HCPs to include personalized information on how individual patients should interpret or act on different levels of glucose results. All (100%, 50/50) of Russian, 84% (42/50) of Indian, 90% (45/50) of Chinese, and 73% (22/30) of American HCPs agreed such recommendations from them written on the reference card guide could help their patients know what to do next. Furthermore, 94% (47/50) of Russian, 82% (41/50) of Indian, 94% (47/50) of Chinese, and 80% (24/30) of American HCPs responded that recommendations from them in this paper guide could help their patients make the right decisions about their blood glucose results. In terms of overall benefits, 90% (45/50) of Russian, 86% (43/50) of Indian, 88% (44/50) of Chinese, and 60% (18/30) of American HCPs agreed that the meter itself provides patients with the added security of understanding their blood glucose numbers and provides reassurance about managing their diabetes.

Table 1. Health care professionals' status and clinical practice information.

Health care professional information	Russia (n=50)	India (n=50)	China (n=50)	United States (n=30)	Total (N=180)
Profession, n (%)					
Endocrinologist	30 (60)	30 (60)	30 (60)	15 (50)	105 (58)
Primary care physician	8 (16)	8 (16)	8 (16)	10 (33)	34 (19)
Diabetes educator	7 (14)	7 (14)	6 (12)	5 (17)	25 (14)
Pharmacist[a]	5 (10)	5 (10)	6 (12)	—	16 (9)
Gender (male), n (%)					
Endocrinologist	2 (7)	22 (73)	12 (40)	9 (60)	45 (43)
Primary care physician	4 (50)	4 (50)	6 (75)	7 (70)	21 (62)
Diabetes educator	0 (0)	3 (43)	1 (17)	0 (0)	4 (16)
Pharmacist[a]	2 (40)	5 (100)	4 (67)	—	11 (69)
Age (years), mean (SD [b])					
Endocrinologist	41 (10)	42 (4)	39 (6)	47 (11)	41 (8)
Primary care physician	38 (7)	43 (4)	36 (8)	47 (9)	41 (8)
Diabetes educator	33 (7)	37 (5)	42 (12)	40 (9)	37 (9)
Pharmacist[a]	34 (8)	39 (3)	35 (3)	—	36 (5)
Years in current role, mean (SD)					
Endocrinologist	14 (9)	12 (3)	14 (7)	16 (8)	13 (7)
Primary care physician	12 (7)	14 (4)	13 (7)	17 (8)	14 (7)
Diabetes educator	11 (7)	10 (2)	18 (6)	14 (10)	13 (7)
Pharmacist[a]	11 (9)	10 (2)	7 (3)	—	10 (5)
Patients with diabetes, T1D%/T2D% [c]					
Endocrinologist	18/82	30/70	8/92	28/72	20/80
Primary care physician	21/79	32/68	6/94	14/86	18/82
Diabetes educator	46/54	27/73	18/82	34/66	32/69
Pharmacist[a]	34/66	21/79	16/84	—	23/77
Patient therapy, % [c]					
Medications and insulin	25	33	35	33	31
Insulin only	29	23	15	25	23
Medications only	40	28	41	35	36
Not on any medications/insulin	5	14	7	6	9
Other (eg, lifestyle)	1	2	2	1	1

[a] Pharmacists were not recruited as part of the US cohort of HCPs.

[b] SD: standard deviation

[c] Percentages shown are estimates given by the HCPs.

Figure 3. Response to prestudy clinical practice questions from 180 health care professionals (50 each from Russia, India, and China, and 30 from the United States). Responses are the top two positive responses (1 or 2) on a five-point scale for each question corresponding to (A) very confident or confident, (B) every time or most times, (C) very easy or easy, and (D) very aware or aware.
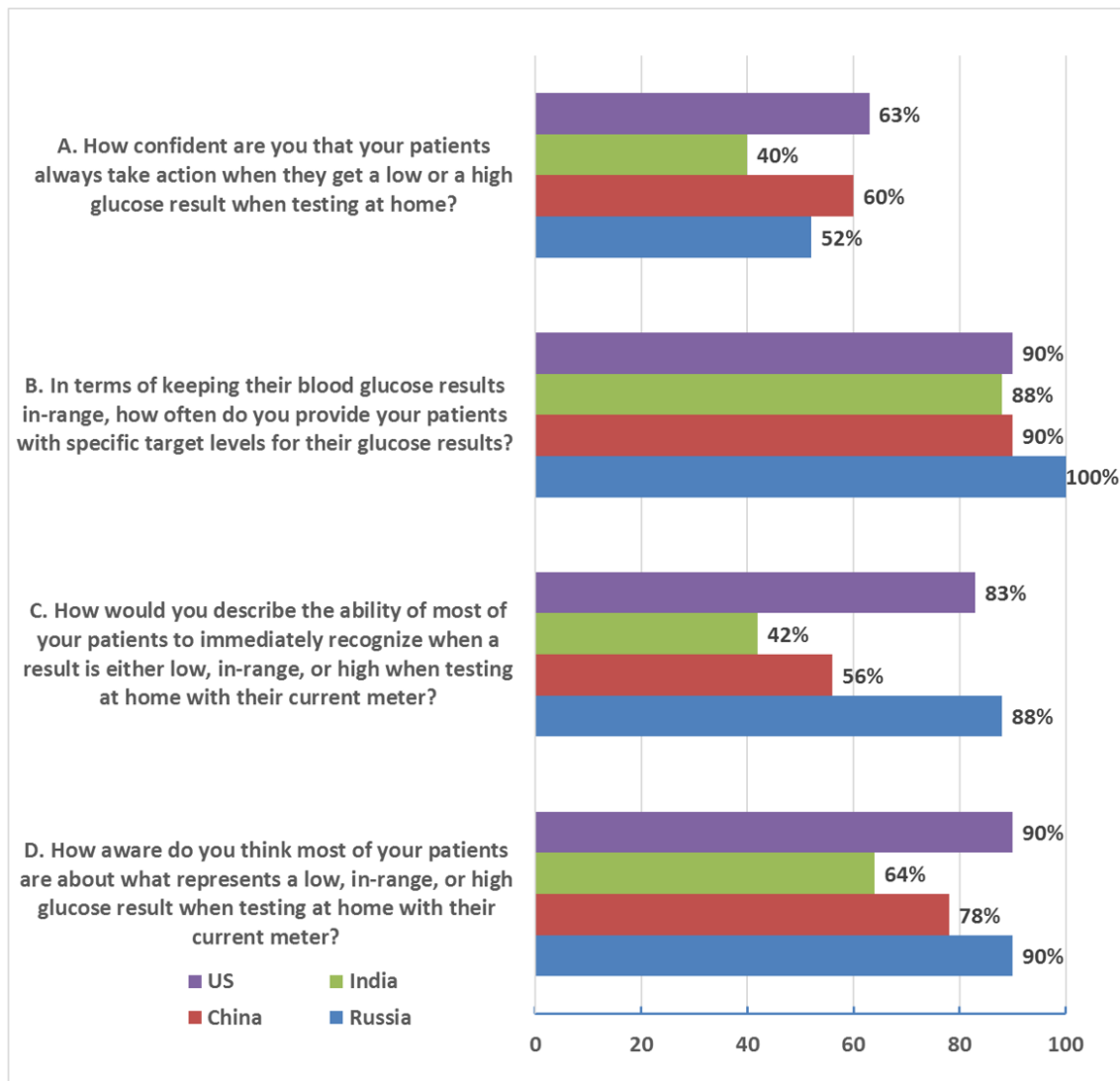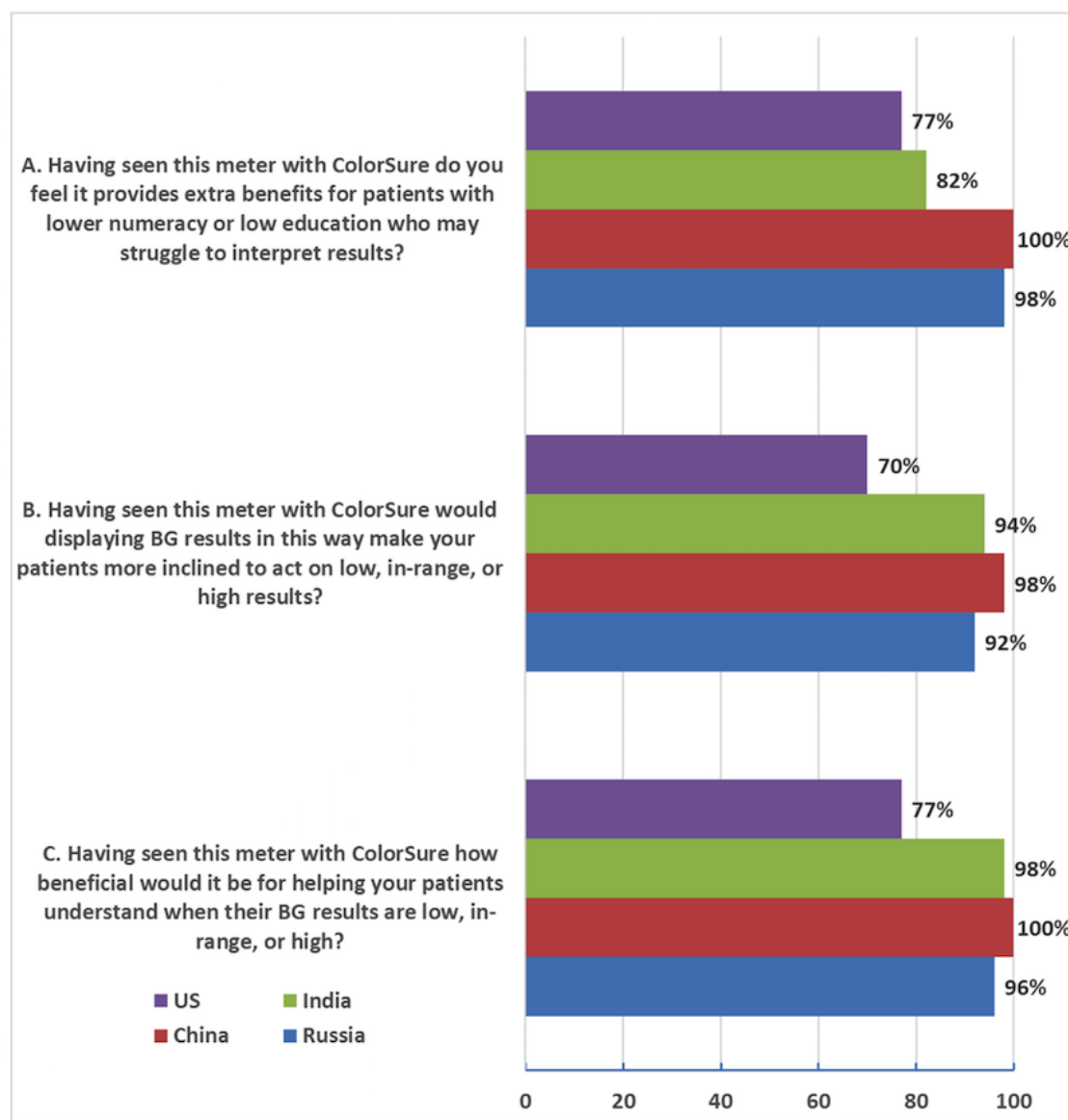
Table 2. Health care professionals' responses to 25 survey statements about the OneTouch Select Plus Simple meter. Results shown are percentage favorable responses ("strongly agree" or "agree") on a five-point scale where 1=strongly agree, 2=agree, 3=neither agree nor disagree, 4=disagree, and 5=strongly disagree. All percentage favorable responses are statistically significant (ie, lower bound of 95% confidence limits >50%)

Survey statements	Favorable response, n (%)				
	Russia (n=50)	India (n=50)	China (n=50)	United States (n=30)	Total (N=180)
With security from understanding their blood glucose results, patients will feel confident in managing their diabetes	45 (90)	41 (82)	39 (78)	18 (60)	142 (79)
ColorSure technology shows patients when they are in range (green) and gives positive feedback which may help to keep them on track	43 (86)	37 (74)	46 (92)	21 (70)	148 (82)
Patients will feel reassured using this meter because of the ColorSure technology, audio signals, and it is so simple and easy to use right out of the box	49 (98)	41 (82)	42 (84)	22 (73)	155 (86)
Recommendations from me, written in the Reference Card Guide could help my patients know what to do next	50 (100)	42 (84)	45 (90)	22 (73)	158 (88)
This meter with ColorSure technology helps patients feel more confident about managing their diabetes than numbers alone	47 (94)	40 (80)	44 (88)	25 (83)	157 (87)
With this meter, patients can feel secure because they can see and hear when they may need to act	48 (96)	41 (82)	47 (94)	22 (73)	158 (88)
With ColorSure technology to help them understand their numbers, a beep to tell them when they may need to take action, and reference card, patients can feel reassured	47 (94)	42 (84)	44 (88)	18 (60)	151 (84)
This meter helps tell patients when they may need to act and when they may be good to go	42 (84)	45 (90)	47 (94)	19 (63)	153 (85)
The small and slim design with large, easy-to-read numbers will help this meter fit into my patient's life	44 (88)	41 (82)	45 (90)	18 (60)	148 (82)
Easy-to-understand ColorSure technology could support patients to know when to act on their blood glucose results	46 (92)	45 (90)	44 (88)	19 (63)	155 (86)
Patients would feel secure when using this meter because it has ColorSure technology and audio signals	41 (82)	42 (84)	42 (84)	18 (60)	142 (79)
With this meter, patients can feel reassured because they can see and hear if they may need to act	43 (86)	40 (80)	44 (88)	18 (60)	146 (81)
This meter provides patients with the added security of understanding their blood glucose numbers and reassurance about managing their diabetes	45 (90)	43 (86)	44 (88)	18 (60)	149 (83)
The meter is so straight forward, it could be used right out of the box without any additional instructions from me	48 (96)	43 (86)	43 (86)	20 (67)	155 (86)
This meter will help patients to feel confident about their blood glucose result/about managing their diabetes, they just insert a test strip to get started	47 (94)	42 (84)	46 (92)	19 (63)	155 (86)
Easy-to-understand ColorSure technology helps patients to know when they may need to act on their blood glucose results	44 (88)	41 (82)	45 (90)	20 (67)	149 (83)
Patients will feel a sense of security using this meter because of the ColorSure technology, audio signals, and it is so simple and easy to use right out of the box	44 (88)	39 (78)	48 (96)	21 (70)	151 (84)
The audio signal makes it clear when results are high or low so that patients can consider when to take action	47 (94)	44 (88)	46 (92)	25 (83)	162 (90)
Recommendations from me written in the reference card guide could help my patients make the right decisions about their blood glucose results	47 (94)	41 (82)	47 (94)	24 (80)	158 (88)
This meter is so simple, the majority of my patients could start using it without additional training	46 (92)	43 (86)	46 (92)	20 (67)	155 (86)
Using a meter with ColorSure technology helps patients feel more secure about managing their blood sugar levels than a meter without ColorSure technology	48 (96)	43 (86)	47 (94)	18 (60)	157 (87)
This meter provides patients with the added reassurance of understanding their blood glucose numbers and confidence about managing their diabetes	47 (94)	42 (84)	44 (88)	18 (60)	151 (84)
This meter brings clear understanding of results for my patients with sight and sound	47 (94)	40 (80)	47 (94)	18 (60)	151 (84)

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Survey statements	Favorable response, n (%)				
	Russia (n=50)	India (n=50)	China (n=50)	United States (n=30)	Total (N=180)
With the reassurance from understanding their blood glucose results, patients will feel confident in managing their diabetes	45 (90)	47 (94)	45 (90)	19 (63)	157 (87)
The meter is a simple first step to understanding blood sugar results	46 (92)	39 (78)	46 (92)	20 (67)	151 (84)

Figure 4. Response to clinical practice questions from 180 health care professionals after online experiences with a glucose meter with ColorSure (50 each from Russia, India, and China, and 30 from the United States). Responses are the top two positive responses (1 or 2) on a five-point scale for each question corresponding to (A) very beneficial or beneficial and (B and C) strongly agree or agree.

Health Care Professionals' Clinical Practice Outlook for Patients Based on Meter Experience

After experiencing the meter, 100% (50/50) of Chinese, 98% (49/50) of Indian, 96% (48/50) of Russian, and 77% (23/30) of American HCPs responded that their patients would find it beneficial to help them understand when their glucose results were low, in range, or high (Figure 4). In terms of taking action, 98% (49/50) of Chinese, 94% (47/50) of Indian, 92% (46/50) of Russian, and 70% (21/30) of American HCPs responded that displaying results with a color range indicator would make their patients more inclined to act on low or high glucose results. Finally, with respect to patients with low numeracy or low education, 100% (50/50) of Chinese, 98% (49/50) of Russian, 82% (41/50) of Indian, and 77% (23/30) of American HCPs agreed that a meter with a color range indicator could provide extra benefits for those patients who may struggle to interpret glucose results.

Discussion

The methodology of this online study represents a novel, interactive approach to rapidly obtaining clinical insights from a diverse group of HCPs across multiple countries. The data provide evidence that HCPs from four countries had high overall satisfaction with this new glucose meter and specifically confirmed that using color-coded information to assist patients with interpreting their blood glucose information is a strategy that resonates universally with HCPs working in a variety of different health care environments.

The findings also highlight similarities and differences among HCPs from these countries regarding their patients' basic comprehension of diabetes self-management, particularly glucose monitoring. The HCPs in the United States and Russia were more positive regarding their patients' awareness of what constituted a low or high result than those in either India or China. Similarly, there was a higher confidence expressed by HCPs in the United States and Russia compared to those in India or China concerning the ability of patients to immediately recognize low, in-range, or high blood glucose results. The factors influencing regional differences are likely complex, but may relate to access of patients to health care, self-monitoring of blood glucose training, or issues relating to education, health literacy, or socioeconomic status. These issues are often barriers to health outcomes in different geographic regions [2-6,13-15]. Interestingly, regardless of country, HCPs provided similar positive responses with respect to their own efforts to consistently provide their patients with glycemic targets during routine visits suggesting that HCPs across these countries believe they are doing well with respect to goal setting and delivery of care. However, HCPs in India and China gave appreciably lower scores regarding their patients' ability to recognize low or high blood glucose results than those in the United States, which may reflect underlying shortcomings in self-care behaviors, educational level, or numeracy in these countries, particularly in rural areas.

Another common finding related to patient behavior was that HCPs had limited confidence that their patients take action at home in response to low or high results. Regardless of country, HCPs believe that their patients display a reluctance to act on self-monitoring data and this remains a barrier to progress. The glucose meter that HCPs experienced in our study was designed to overcome such barriers to patient understanding by using a simple color range indicator to improve patient interpretation and awareness of glucose results [12].

One of the goals of this study was to discover which aspects of this color-enhanced glucose meter resonated most with HCPs and would be most beneficial for their patients. The HCPs agreed that the color range indicator could help patients feel more confident about managing their diabetes than simply numbers alone and could support patients knowing when to act on results. The HCPs felt their patients may not know whether a result is low, in range, or high; therefore, immediate reinforcement using color coding could help patients recognize the significance of their blood glucose results. Furthermore, over time patients may become more familiar with how color-coded glucose results relate to glycemic risk and may become better able to tell their HCP when they experienced low or high results and what actions or behaviors coincided with these results.

Clinicians understandably focus predominantly on low or high glucose fluctuations for reasons of patient safety. But highlighting in-range (green) results could stimulate patient motivation and reinforce beneficial behaviors. This resonated with HCPs in that they agreed that such positive feedback might help patients feel more secure and could be more helpful in managing their glucose than a meter without color. Patients are receptive to praise and encouragement; however, this does not always occur during office visits. A US study found only 77% of noninsulin and 83% of insulin-using patients regularly received encouragement to check blood glucose, with only 58% and 63% regularly receiving any congratulations from their HCP for checking blood glucose [16]. Achieving blood glucose results within the green zone might provide recognition for patients of positive behavior between relatively infrequent HCP visits. The HCPs agreed that personal recommendations from them, hand-written in the OneTouch Select Plus Simple reference guide, could help patients know what to do next or to make the right decisions between office visits.

Even within health care systems in developed countries, encounters with HCPs are of short duration. An analysis of 46,250 adult visits to primary care physicians in the United States between 1997 and 2005 calculated a mean visit duration of 18.9 minutes for a general examination, extended by only 4.2 minutes on average for patients with diabetes [17]. Furthermore, an International Diabetes Foundation report cautioned that the burden on endocrinologists employed in large Russian cities will be inappropriately heavy (up to 1500 patients for each endocrinologist), which would reduce the time that each physician could allow for one patient to approximately 10 minutes [18]. An additional issue was highlighted in a study in Russia, which found 63% of people with diabetes had not participated in any diabetes education compounding the effects of lack of access to a HCP [19]. It is likely that access to and time with an HCP is probably diminished even further for patients in rural areas and/or developing countries such as India or China, although reliable data on provision of care in these regions is scarce. These circumstances may partly explain why HCPs were so positive regarding the simple paper reference card supplied with the OneTouch Select Plus Simple meter containing HCP reminders for patients about what to do in response to low, in-range, or high glucose results. This could become a valuable educational tool for the HCP to reassure patients between relatively infrequent and short face-to-face consultations.

After participation in the online meter experience, all 180 HCPs were asked to consider how color-coded information might benefit their patients. There was universal appreciation that color could help patients better understand when results were low, in range, or high, and agreement that associating results with color might make patients more inclined to act on results. It is worth noting that HCP responses in Russia, India, and China to both closing questions were consistently between 92% and 100% (46/50-50/50), whereas HCPs in the United States gave

positive, but appreciably lower, responses at 70% to 77% (21/30-23/30). The lower responses from American HCPs might be explained by a higher confidence in their ability to deliver care given greater access to resources, new technologies, and educational support to patients. Therefore, they may feel the benefits of color coding glucose information is less a priority in their own clinical practice compared to the circumstances faced by HCPs in other countries. A similar picture emerges with respect to the benefit of color for patients with low education and/or numeracy skills. American HCPs were less positive than the three other regions regarding these benefits. It is clear from the UNESCO report on education [11] and data specific to diabetes numeracy [8-10] that health inequality is an issue not only for those living in rural or developing regions with poor access to health care advice or technologies, but also

for those who have access but simply lack the ability to interpret the results shown on these technologies.

The study recruited a lower number of American HCPs because the meter is not planned to be available in the United States. The inclusion of HCPs from the United States was intended predominantly for comparative purposes as an example of HCP attitudes and perceptions in a country with more consistent care provision.

In conclusion, this multicountry online study provides evidence that HCPs had high overall satisfaction with the OneTouch Select Plus glucose meter, which uses color-coded information to assist patients with interpreting blood glucose results. This may be especially helpful in patient populations with low numeracy or literacy and limited access to health care and direct interaction with HCPs.

Conflicts of Interest

MG is an employee of LifeScan Scotland, Ltd. LBK and BLL are employees of LifeScan, Inc.

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Abbreviations

HCP: health care professional
T1D: type 1 diabetes
T2D: type 2 diabetes

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Original Paper

An Interactive Simulation to Change Outcome Expectancies and Intentions in Adults With Type 2 Diabetes: Within-Subjects Experiment

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Abstract

Background: Computerized simulations are underutilized to educate or motivate patients with chronic disease.

Objective: The aim of this study was to test the efficacy of an interactive, personalized simulation that demonstrates the acute effect of physical activity on blood glucose. Our goal was to test its effects on physical activity-related outcome expectancies and behavioral intentions among adults with type 2 diabetes mellitus (T2DM).

Methods: In this within-subjects experiment, potential participants were emailed a link to the study website and directed through 7 tasks: (1) consent; (2) demographics, baseline intentions, and self-reported walking; (3) orientation to the diurnal glucose curve; (4) baseline outcome expectancy, measured by a novel drawing task in which participants use their mouse to draw the expected difference in the diurnal glucose curve if they had walked; (5) interactive simulation; (6) postsimulation outcome expectancy measured by a second drawing task; and (7) final measures of intentions and impressions of the website. To test our primary hypothesis that participants' outcome expectancies regarding walking would shift toward the outcome presented in the interactive simulation, we used a paired t test to compare the difference of differences between the change in area under the curve in the simulation and participants' two drawings. To test whether intentions to walk increased, we used paired t tests. To assess the intervention's usability, we collected both quantitative and qualitative data on participants' perceptions of the drawing tasks and simulation.

Results: A total of 2019 individuals visited the website and 1335 (566 males, 765 females, and 4 others) provided complete data. Participants were largely late middle-aged (mean=59.8 years; standard deviation=10.5), female 56.55% (755/1335), Caucasian 77.45% (1034/1335), lower income 64.04% (855/1335) $t_{1334}=3.4$, $P \leq .001$). Our second hypothesis, that participants' intentions to walk in the coming week would increase, was also supported; general intention (mean difference=0.31/7, $t_{1001}=10.8$, $P<.001$) and minutes of walking last week versus planned for coming week (mean difference=33.5 min, $t_{1334}=13.2$, $P<.001$) both increased.

Finally, an examination of qualitative feedback and drawing task data suggested that some participants had difficulty understanding the website. This led to a post-hoc subset analysis. In this analysis, effects for our hypothesis regarding outcome expectancies were markedly stronger, suggesting that further work is needed to determine moderators of the efficacy of this simulation.

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Conclusions: A novel interactive simulation is efficacious in changing the outcome expectancies and behavioral intentions of adults with T2DM. We discuss applications of our results to the design of mobile health (mHealth) interventions.

Introduction

Background

Type 2 diabetes mellitus (T2DM) affects 29 million people in the United States and is associated with significant morbidity and early mortality [1]. Regular physical activity is considered one of the cornerstones of diabetes self-management [2] and has been shown to improve glycemic control [3], reduce blood pressure [4], and improve cardiorespiratory fitness in individuals with T2DM [5]. These intermediate outcomes have been associated with reduced diabetes-related morbidity and mortality [6]. Despite these benefits, most people with T2DM do not perform recommended amounts of physical activity [7].

By virtue of their potential for scalability and personalization, Web-based interventions have great potential to facilitate self-management in individuals with diabetes. However, to date, most interventions have demonstrated only small to moderate effects on self-management behaviors [8]. One reason for this may be that most interventions have used only a limited number and palette of behavior change techniques (BCTs) [9] (the smallest observable and replicable *active ingredient* in a behavioral intervention [10]). Several prominent theorists have proposed that, before deploying complex multicomponent mobile health (mHealth) interventions, designers and investigators should first demonstrate that each of the interventions' components have demonstrated efficacy [11,12].

Objective

In this study, we sought to test the efficacy of a novel BCT; an interactive Web-based simulation that demonstrates the immediate positive consequences of behavior change. The power of an interactive simulation is that it allows the user to experiment with possible actions and learn by vicariously experiencing the outcomes of those actions [13]. Simulations are now regularly used for the training of health care providers (HCPs) [14], but little research has addressed their use as an education and behavior change tool for patients.

Outcome expectancies are an individual's belief regarding the likely outcome of a given behavior (eg, what will happen to my blood sugar if I walk) [15]. Prior work has shown that outcome expectancies are related to self-care behaviors in individuals with T2DM [16] and that individuals with T2DM generally have low outcome expectancies regarding the effect of exercise [17]. Outcome expectancies are usually measured using Likert type scales (eg, "walking will improve my blood sugar control" strongly disagree—strongly agree). In this study, we used an electronic drawing task to measure participants' outcome expectancies. This electronic method allowed us to directly compare people's beliefs with the outcome presented by the simulation using area under the curve (AUC).

Prior Related Work

In prior work, we used daily glucose curves to change outcome expectancies regarding the immediate glycemic effects of exercise in adults with T2DM [18,19]. In this study, we sought to build on and improve upon our prior work in several ways. First, in our earlier work, the demonstration of the immediate positive consequences of behavior change was combined with other BCTs (eg, demonstrating negative consequences of failure to change behavior, guiding the individuals in action planning, and providing social support modeling the target behavior). In this study, we deliberately isolated the demonstration of the immediate positive consequences of behavior change to estimate its stand-alone efficacy. Second, in our prior work, the demonstration of the immediate positive consequences of behavior change reflected the average effect for an average person. Because the true effect of physical activity on blood glucose varies significantly across individuals [20], a personalized estimate of the effect is preferable and more accurate. In this study, we took a first step toward true personalization by presenting the effect for someone with similar blood glucose control (hemoglobin A_{1c}, HbA_{1c}) as the participant. Finally, because our prior work involved in-person interventions, the sample sizes were necessarily small and limited in diversity. In this study, we made a concerted effort to recruit a large and diverse sample of adults with T2DM.

Hypotheses

We hypothesized (1) that use of the simulation would shift users' outcome expectancies toward the outcome presented in the simulation and (2) that use of the simulation would lead to an increase in intentions to be physically active.

Methods

Human Subjects Protection

This study was reviewed and approved by the University of Utah Institutional Review Board.

Recruitment

Recruitment for this study was done simultaneously with a parallel study (manuscript in process) conducted with HCPs who treat individuals with T2DM. For both studies, we recruited participants via email.

An email invitation was disseminated directly to patients via the email list of clients of Alliance Health; a national provider of diabetic testing supplies.

An email invitation was also sent to the following groups of clinicians: a listserv of providers and diabetes educators from the Utah Department of Health; listservs of faculty and students at the University of Utah schools of medicine, nursing, and

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physical therapy; faculty and students of New York University schools of nursing and medicine; colleagues at Stanford University and at the Cancer Prevention Institute of California; and several community collaborators. The email invitation included the statement "please feel free to share this link with patients with type 2 diabetes and clinician colleagues." In this way, we intended to indirectly invite patients with T2DM. This snowball sampling approach aimed to recruit as geographically, ethnically, and socioeconomically diverse a sample as possible. Study participation was incentivized by including participants in a lottery for one of five US $100 gift cards.

Screening

After opening the website, participants self-sorted by clicking one of three statements (hyperlinks):

- "I am a person with Type 2 Diabetes" (participant directed to study website)
- "I am a healthcare provider or trainee who treats patients with Type 2 Diabetes" (participant directed to provider-facing website)
- "I am neither a person with Type 2 Diabetes nor a Healthcare provider" (participant thanked and dismissed)

Study Website

Participants completed all study tasks during a single session on the study website.

The study website leads participants through seven tasks (in fixed order):

1. Consent cover letter
2. Participant characteristics, past week walking, and presimulation intentions to be active. Participants completed 13 questions regarding demographics, diabetes-specific data (eg, self-reported HbA_{1c} and treatments), self-reported days and minutes of walking in the last week, and general intentions to be active (7-point Likert scale).
3. Orientation to the diurnal glucose curve (Figure 1). This task displayed a static graph showing a diurnal glucose curve with icons indicating when the person ate and some brief, simple language to orient individuals naïve to this type of graph. The glucose values in this graph, the subsequent drawing task, and the interactive simulation are based on prior work in which we developed "average" daily glucose curves for each HbA_{1c} value from 5.9 to 10.1 (in increments of 0.1) [21]. Using these curves allowed us to personalize the simulation, to some degree, for each participant.
4. Presimulation outcome expectancies. First drawing—using their cursor, participants drew what they believed the glucose curve would have looked like had they walked for 30 min at 9 AM (Figure 2).
5. Simulation. Participants could move two sliders, one to change the time of day and the second to vary the duration

of exercise to see what effect walking at different times of day and for different durations of 15, 30, 45, or 60 min might have on their glucose curve (Figure 3). To calculate the effect of exercise on glucose, we estimated the glucose value 30 min after exercise using a predictive model we developed in prior work, [20] and conservatively estimated that glucose would return to non-exercise levels over the following 6 hours [22].

6. Postsimulation outcome expectancies. Second drawing—After exploring the simulation, participants again drew what they believed the glucose curve would have looked like had they walked for 30 min at 9 AM. The interface for this drawing task was identical to the first (Figure 2).
7. Intentions to be active and feedback on website and study. On the final tab of the website, participants indicated their intentions to be active: general intentions to be active on a 7-point Likert scale and numeric values for planned minutes and days of walking in the coming week. They also rated the website's utility and informativeness (7-point Likert scales to rate how useful ["This website was useful" 1=strongly agree to 7=strongly disagree] and informative ["This website was *not* informative" 1=strongly agree to 7=strongly disagree]). Finally, a free text box titled "Please provide any feedback you have on this website or study" allowed participants to optionally provide qualitative feedback.

Analysis

To calculate the AUC for the "no walking" curve (Figure 1), we took the vector of values for the curve corresponding to the participant's self-reported HbA_{1c} and multiplied by 15 to get the total AUC in milligram/deciliter×minutes (this was necessary because the blood glucose values for the curve represent values in increments of 15 min).

To calculate the AUC for the drawing tasks, we first combined the vector of glucose values for the "no walking" curve (Figure 1) from 12 AM to 9 AM with the values that the participant drew. In cases where participants' drawings ended before the end of the day, we interpolated values between their last drawn point and the value at the end of the day (12 midnight) from the "no walking" curve. We then multiplied that vector by 15 (for our 15-min intervals) to get the total AUC in milligram/deciliter×minutes.

We used a similar process to calculate the AUC for the interactive simulation. In this case, we combined the vector of glucose values for the "no walking" curve (Figure 1) from 12 AM to 9 AM with the estimated postexercise glucose, (based on our predictive model) and interpolated a proportional return to the value of the "no walking" curve at 3 PM (6 hours after the start of walking).

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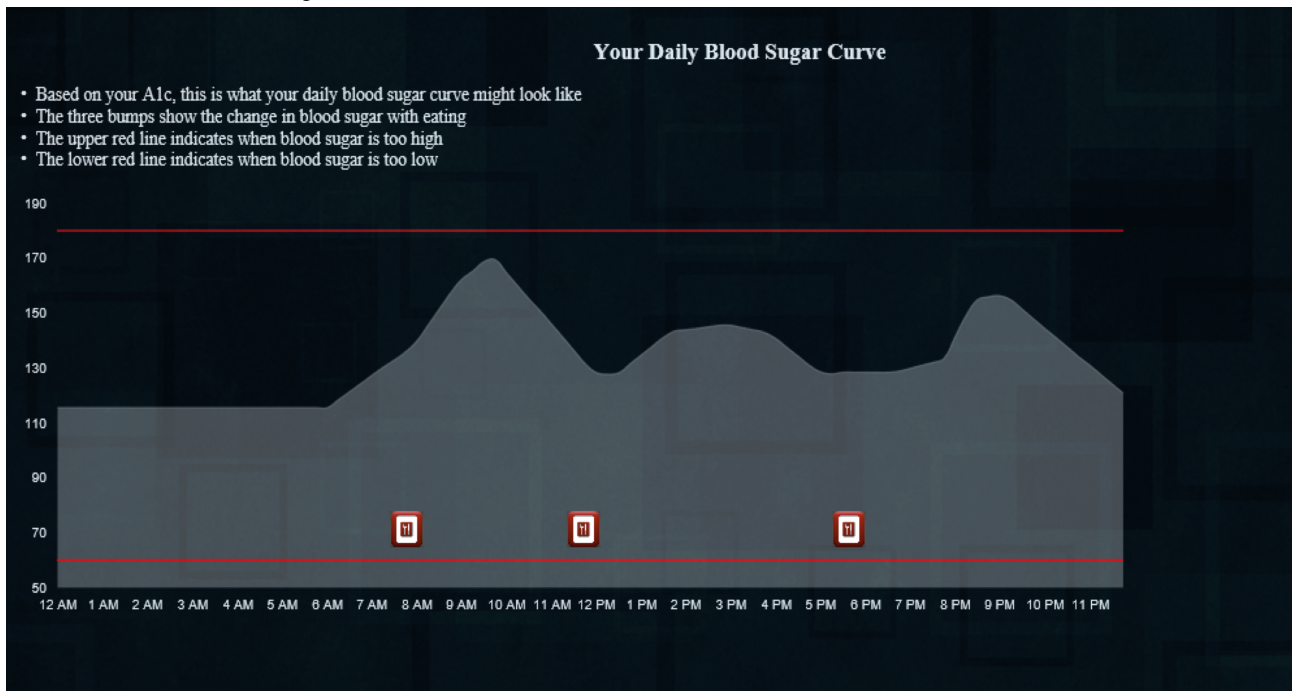**Figure 1.** Orientation to the diurnal glucose curve.
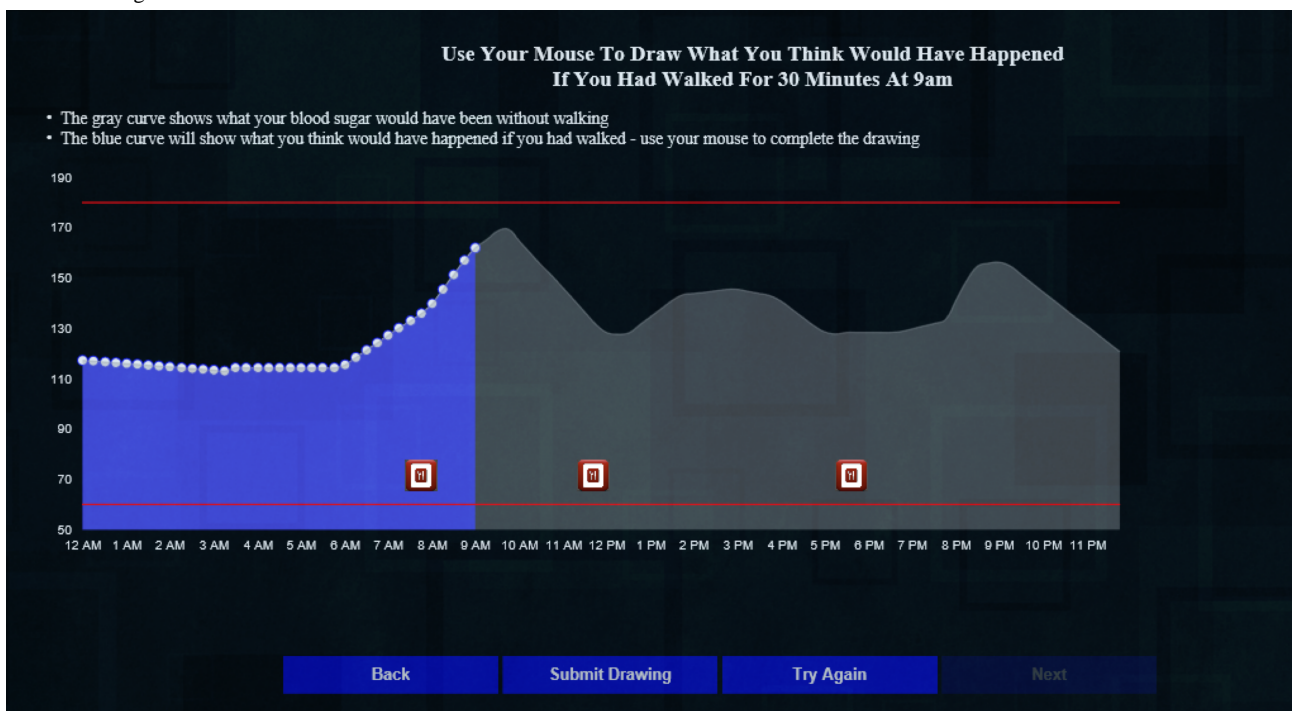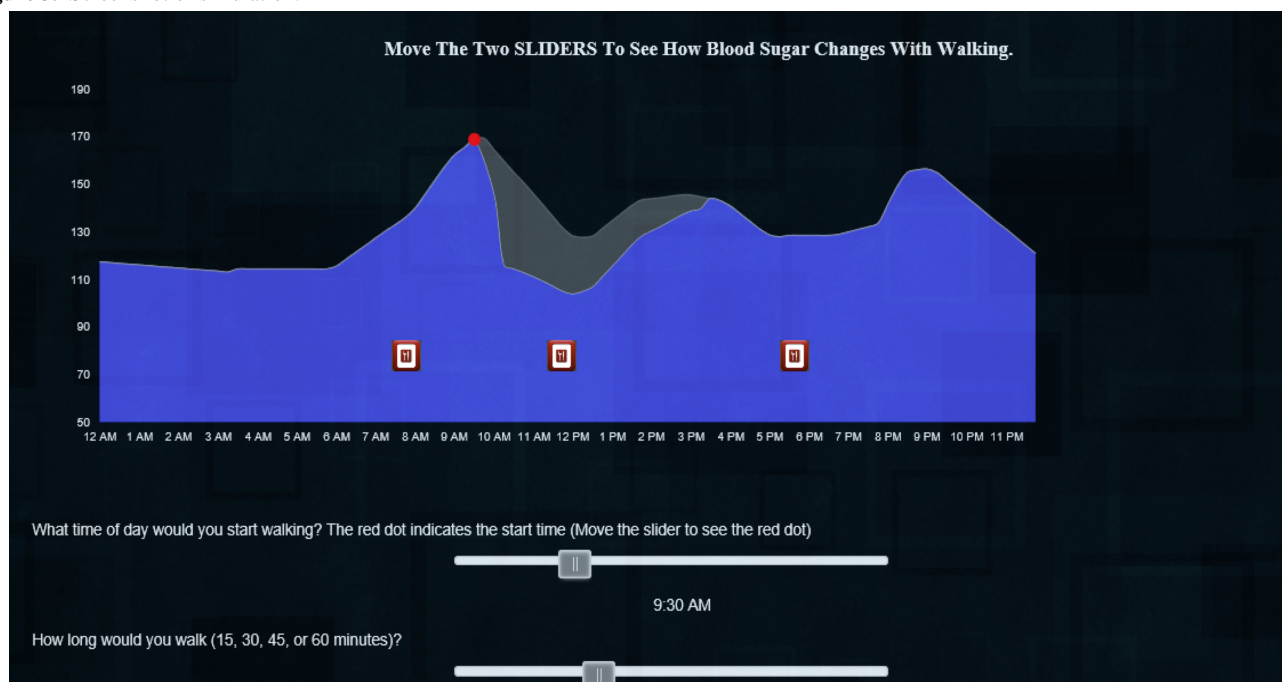

Figure 2. Drawing task.

Figure 3. Screenshot of simulation.

Analysis for Hypothesis 1: Participants' Outcome Expectancies Will Shift Toward the Outcome Presented in the Simulation

We calculated the differences in the AUC between the participants' counterfactual (no walking) glucose curve and their two drawings (presimulation and postsimulation). We then calculated the differences between these drawn beliefs (outcome expectancies) and the simulation. To determine if outcome expectancies changed as a result of using the simulation, we compared these differences using a paired *t* test.

Analysis for Hypothesis 2: Use of Simulation Will Increase Intentions

To test whether intentions to walk in the coming week changed, we used paired *t* tests. For the minutes of walking/week, we simply compared the participants' reported minutes of walking in the last week with their planned minutes of walking in the coming week and their pre- and postsimulation rating. To test whether ratings on a 7-point Likert scale to the statement "I intend to walk in the coming week" changed, we also used a paired *t* test.

To address missing data, we used *t* tests on only the complete cases (discarding individuals with missing data) and on two types of imputed data: first we replaced missing points data with mean values for postsimulation intentions, and second, we replaced missing values with the individuals' presimulation intentions. We report the most conservative of these findings.

Participants' Perceptions of the Website

We calculated the mean and standard deviation (SD) for participants' ratings of the website's informativeness and usefulness.

Next, we conducted standard qualitative analyses of participants' free text feedback. Three investigators (BG, LY, and VD)

reviewed this feedback and independently coded participant comments according to eight categories determined by the coders to encompass feedback relevant to our website design and to future research: positive feedback (on content or functionality), negative feedback on content, negative feedback on understandability, negative feedback on the relevance of the site's content to the participant, negative comment on usability, spontaneous mention of barriers to physical activity, suggestion for additional content or functionality, and miscellaneous comments. Participant comments could be associated with more than one code. After initial coding, the three investigators reviewed initial coding and reconciled until they reached >85% agreement for each quote.

Subset Analysis

The results of our primary quantitative and qualitative analysis led us to perform a post-hoc subset analysis looking at the effects of the intervention, in which we removed individuals who either self-reported a lack of understanding of the drawing tasks or simulation or whose drawings were extreme outliers.

Post-Hoc Analysis

Finally, we created a set of four post-hoc regression models to determine if the baseline measures we had collected on participants were associated with their baseline outcome expectancies or with intervention efficacy—changes in outcome expectancy, changes in planned minutes in walking/week, or changes in intentions to walk.

Results

Participants

Of the 2019 unique individuals who visited the website, 1335 (566 males, 765 females, and 4 others) provided complete data. As described in Tables 1 and 2, participants were predominately late middle-aged (mean=59.8 years, SD=10.5), female 56.55%

(755/1335), Caucasian 77.45% (1034/1335), lower income 64.04% (855/1335) <US $40,000/year annual household income), and geographically diverse (52 US states and territories).

Participants were nearly equally split between treatment with oral medications 48.76% (651/1335) and injectable medications 44.57% (595/1335); most had previously attended diabetes education 82.39% (1100/1335) and most reported generally well-controlled glucose (mean HbA_{1c} 7.3%, SD=1.2). More than half 57.83% (772/1335) reported walking for exercise in the previous week.

Hypothesis 1: Participants' Outcome Expectancies Will Shift Toward the Outcome Presented in the Simulation

Presimulation Outcome Expectancies

Compared with the simulation, which was conservative in its estimate of the expected effect (mean decrease in AUC of 5712 mg/dl×min, SD=2033 mg/dl×min), most individuals' presimulation outcome expectancies were overly positive (mean decrease in AUC of 12,265 mg/dl×min, SD=20,253).

Postsimulation Expectancies

As hypothesized, participants' postsimulation outcome expectancies shifted toward the outcomes presented by the simulation; mean decrease in AUC of 10,582 mg/dl×min, SD=19,117 mg/dl×min.

A paired *t* test comparing the difference of differences between the first drawing and the simulation (mean difference 6553 mg/dl×min, SD=19,230) and the second drawing and the simulation (mean difference 4869 mg/dl×min, SD=18,270) indicated a statistically significant shift in outcome expectancies toward the outcome presented by the simulation (mean of the differences=1683.4, t_{1334}=3.4, $P \leq .001$).

Hypothesis 2: Use of Simulation Will Increase Intentions

Pre-and Postsimulation Intentions to Be Active

Our second hypothesis, that participants' intentions to walk in the coming week would increase, was supported in both measures; general intention increased (mean difference=0.31, t_{1001}=4.53, $P<.001$).

Similarly, when assessing whether minutes of walking planned for the coming week increased over minutes of walking reported in the past week, the intervention had a positive effect (mean difference=33.5 min, t_{1334}=13.2, $P<.001$).

Table 3 presents the presimulation and postsimulation means and standard deviations for the measures for these two hypotheses.

Feedback on Website

Multimedia Appendix 1 contains the results of analysis of responses to the statements "This website was informative" and "This website was *not* useful" (1=strongly agree to 7=strongly disagree), as well as the result of our qualitative analysis of individuals free text feedback on the study or website.

Subset Analysis

We conducted a subset analysis to determine whether our findings regarding changes in outcome expectancies and intentions held true after excluding individuals for whom the drawing task may not have accurately reflected their beliefs (because of suboptimal understanding) or who reported significant difficulty understanding the simulation.

This yielded two categories of potential individuals to exclude (1) participants whose first and second drawings were marked outliers from the expected effect and (2) individuals who directly commented in the final comments text box that they did not understand either the curves or the simulation. These latter groups of individuals were excluded only, if, on a subsequent independent review, all three coders agreed to exclude.

The resulting subset included 1194 individuals. Table 4 summarizes the mean and SDs for outcome expectancies, general intentions, and minutes walking (reported vs planned) for this group of participants. From this table, it is clear that for intentions, the results for this subset of participants are nearly identical to the full group; however, for outcome expectancies, the efficacy of the simulation is stronger, and individuals' postsimulation beliefs are on average almost identical to those presented in the simulation (mean decrease in AUC of 5712 mg/dl×min, SD=2033 mg/dl×min).

Post-Hoc Analysis: Were Baseline Outcome Expectancies or Intervention Efficacy Associated With Demographics or Treatment Class?

Multimedia Appendix 1 contains the results of the post-hoc regression models we created to determine whether demographics (sex and age) or clinical variables (treatment type and HbA_{1c}) were associated with either baseline outcome expectancy or intervention efficacy: changes in outcome expectancy, planned walking minutes /week, or behavioral intentions to walk.

Table 1. Continuous demographics.

Characteristic	Mean (SD[a]) or n (%)
Age (in years), mean (SD)	59.9 (10.5)
Hemoglobin A_{1c} level, n (%)	7.3 (1.2)

[a]SD: standard deviation.

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Table 2. Categorical demographics.

Characteristic	n (%)
Sex	
Female	755 (56.55)
Male	566 (42.39)
Other	4 (0.003)
Race	
Caucasian	1034 (77.45)
Hispanic	63 (4.72)
Asian or South Asian	27 (2.02)
African American	124 (9.28)
American Indian or Native American	12 (0.89)
Native Hawaiian or Pacific Islander	3 (0.22)
Multiethnic	15 (1.12)
Annual income (in US dollars)	
<20,000	582 (43.59)
20,000-39,999	273 (20.44)
40,000-59,999	183 (13.70)
60,000-79,999	123 (9.21)
80,000-99,999	174 (13.03)
Region of residence	
Northeast	184 (13.78)
South	503 (37.67)
Midwest	326 (24.44)
West	317 (23.74)
US territories	5 (0.37)
Health insurance coverage	
Yes	1335 (100.00)
No	0 (0)
Primary care provider established	
Yes	1335 (100.00)
No	0 (0)
Primary language	
English	1335 (100.00)
Other	0 (0)
Previous diabetes education	
Yes	1100 (82.39)
No	235 (17.60)
Diabetes treatment type	
Injectable medications	595 (44.57)
Oral medications	651 (48.76)
Diet and exercise	81 (6.06)
Walked for exercise last week (presimulation assessment)	
Yes	772 (57.82)

Characteristic	n (%)
No	563 (42.17)

Table 3. Behavioral intentions and outcome expectancies before and after simulation.

Outcome measure	Presimulation	Postsimulation
Outcome expectancy (glucose levels)	12,265 mg/dl×min (20,253)	10,582 mg/dl×min (19,117)
Intentions to walk in next week[a], mean (SD[b])	5.16 (1.8)	5.47 (1.6)
Minutes walking, mean (SD)	67.1 (88.0) in last week	100.5 (100.4) planned

[a]"I intend to walk in the coming week" rated on a 7-point scale from 1="strongly disagree" to 7="strongly agree."

[b]SD: standard deviation.

Table 4. Intentions before and after simulation (subset of 1194 participants).

Outcome measure	Presimulation	Postsimulation	t score, P value
Intentions to walk in next week[a], mean (SD[b])	5.2 (1.8)	5.46 (1.7)	9.7, <.001
Minutes walking, mean (SD)	68.6 (89.4) in last week	98.7 (100.4) planned	11.2, <.001
Outcome expectancy (glucose levels)	7852 mg/dl×min (15,284)	5890 mg/dl×min (12,536)	4.2, <.001

[a]"I intend to walk in the coming week" rated on a 7-point scale from 1="strongly disagree" to 7="strongly agree."

[b]SD: standard deviation.

Discussion

Principal Findings

This study tested whether an interactive Web-based simulation would change participants' outcome expectancies regarding the acute effects of behavior change and whether use of the simulation would also be associated with an increase in participants' intentions to engage in the behavior. Specifically, we conducted a within-subjects experiment to determine if an interactive simulation that shows the acute effects of physical activity on the diurnal glucose curve would affect outcome expectancies and intentions to be active in adults with T2DM. We found that use of the simulation shifted individuals' outcome expectancies (measured by a novel drawing task) toward the outcome presented by the simulation and that users' general intentions to be active and their planned minutes of walk in the coming week both increased. We are encouraged by these results but also believe that they suggest the need for several areas of further work, which we discuss below.

The results of this study are in line with our prior work, which found that using glucose curves to demonstrate the acute positive effects of physical activity improves outcome expectancies, self-efficacy, behavioral intentions to be active in the future, and activity in the short term [18,19,23]. This study tested this simulation in isolation from other BCTs (in contrast to our prior work that employed many BCTs) and recruited a large and diverse sample. Taken together, we believe these studies provide evidence that demonstrating to adults with T2DM the acute positive effects of behavior change is efficacious and should be included in more behavioral interventions.

Despite our positive finding on the efficacy of the intervention in increasing behavioral intentions, our expected mechanism of action was not supported. We expected that participants would underestimate the effect of physical activity on blood glucose in the first drawing task, and then, after they used the simulation, participants' outcome expectancy would become more positive. Consistent with several models of health behavior change [15], we expected this increase in positive outcome expectancies would lead to greater intentions to be active. This is not what we found. On average, participants overestimated the effect of exercise in the first drawing task, and the simulation shifted toward the outcome presented but in the opposite direction expected (becoming less positive instead of more). Despite this decrease in outcome expectancies, participants' intentions to be physically active increased. We believe the most likely explanation for this finding is that in the first drawing, participants were uncertain about their belief (the diurnal glucose curve is unfamiliar to most individuals with T2DM and drawing their expectations of the effects of behavior on the curve is novel), and the first drawing was a "guestimate." When the simulation confirmed the positive effects of physical activity on glucose, participants' certainty in the positivity of the effect increased, and therefore, their intentions to be active increased. This hypothesis is supported by research from educational psychology showing that certainty is a moderator of the relationship between students' expectancies and task performance [24], and that certainty influences the efficacy of persuasive messages [25] and moderates the relationship between attitudes and behaviors [26]. It is worth noting that in searching the literature related to certainty and beliefs, we did not find any studies that measured certainty related to health-related outcome expectancies. Therefore, in addition to investigating this hypothesis for our own work, we suggest that it may be worthwhile to measure participants' certainty regarding their beliefs more broadly in health-related studies.

Strengths

This study has several strengths. First, our novel electronic drawing task as a measure of individuals' outcome expectancies allows for a finer grained quantitative representation of the individual's belief (AUC). We believe this method warrants further investigation. Future analyses using this drawing method could address questions such as: are measures other than AUC (eg, the coefficient of variation of postexercise glucose or the total AUC under 70 mg/dl) associated with intentions to be active? In addition, this drawing method could be used to understand patient's beliefs about other measures that are relevant to patients' self-management of chronic disease, including both those for which a "ground truth" is available (eg, ambulatory blood pressure and heart rate) and those that are entirely subjective (eg, mood and pain).

A second strength of this study is that we isolated the effect of our BCT to estimate its efficacy. We believe that more studies in the electronic health or mHealth arena need to take this approach either through simple isolated experiments such as this one or a fractional factorial design to test multiple potential components at once [27]. The value of this approach is that when intervention designers set out to develop complex interventions, they can combine components that are known to be efficacious. A final strength of this study is the large and diverse sample we were able to recruit via our email snowball sampling technique.

Limitations

Study results should be interpreted in light of the following limitations. First, some participants reported difficulties in completing the drawing tasks and using the simulation. We are currently redesigning the simulation to address the usability issues uncovered in this study. Second, to minimize participant burden, we left out potential moderators of the efficacy of the intervention. For example, the fact that some individuals (eg, those we excluded for the subset analysis) expressed extremely positive or negative outcome expectancies could be attributed to low health literacy [28] or numeracy [29], or it might be that those drawings accurately reflect the individuals' beliefs. To address this question, future experiments should measure these potential moderators of simulation efficacy. Third, our primary outcome of behavioral intentions to be physically active might be biased because of social desirability. Although some prior work has found evidence for this bias, the effect was small [30]. In addition, a large body of evidence has found that changes in intentions lead to changes in behavior [31]. Finally, some participants commented that they did not trust the simulation because they did not think it was personally relevant. To address this issue, in future work, we might make areas of uncertainty more explicit (eg, show the 95% CI around the simulated glucose curve or the predicted effect). Future work might also maximize the personal relevance of the simulation by integrating patient-specific data (eg, individuals' continuous glucose monitoring curve and accelerometry data).

Conclusions

Our Web-based, interactive simulation shifted outcome expectancies and increased participants' intentions to be physically active. Further work will examine the effect of the simulation on objectively measured behavior. We suggest that simulations that demonstrate the acute positive effects of behavior change might generalize to the promotion of other health behaviors and other chronic diseases.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Supplementary file 1.

[PDF File (Adobe PDF File), 47KB - diabetes_v3i1e2_app1.pdf]

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Abbreviations

AUC: area under the curve
BCT: behavior change technique
HbA$_{1c}$: hemoglobin A$_{1c}$
HCP: health care provider
mHealth: mobile health
SD: standard deviation
T2DM: type 2 diabetes mellitus

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Original Paper

Exploring the Use of Personal Technology in Type 2 Diabetes Management Among Ethnic Minority Patients: Cross-Sectional Analysis of Survey Data from the Lifestyle Intervention for the Treatment of Diabetes Study (LIFT Diabetes)

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Abstract

Background: Minority populations have higher morbidity from chronic diseases and typically experience worse health outcomes. Internet technology may afford a low-cost method of ongoing chronic disease management to promote improved health outcomes among minority populations.

Objective: The objective of our study was to assess the feasibility of capitalizing on the pervasive use of technology as a secondary means of delivering diabetic counseling though an investigation of correlates to technology use within the context of an ongoing diabetes intervention study.

Methods: The Lifestyle Intervention for the Treatment of Diabetes study (LIFT Diabetes) randomly assigned 260 overweight and obese adults with type 2 diabetes mellitus to 2 intervention arms. At baseline, we administered a survey evaluating access to and use of various technologies and analyzed the responses using descriptive statistics and logistic regression.

Results: The sample population had a mean age of 56 (SD 11) years; 67.3% (175/260) were female and 54.6% (n=142) self-identified as being from ethnic minority groups (n=125, 88.0% black; n=6, 4.3% Hispanic; and n=11, 7.7% other). Minority participants had higher baseline mean body mass index (P=.002) and hemoglobin A_{1c} levels (P=.003). Minority participants were less likely to have a home computer (106/142, 74.7% vs 110/118, 93.2%; P<.001) and less likely to have email access at home (P=.03). Ownership of a home computer was correlated to higher income (P<.001), higher educational attainment (P<.001), full-time employment (P=.01), and ownership of a smartphone (P=.001). Willingness to complete questionnaires online was correlated to higher income (P=.001), higher education (P<.001), full-time employment (P=.01), and home access to a computer, internet, and smartphone (P≤.05). Racial disparities in having a home computer persisted after controlling for demographic variables and owning a smartphone (adjusted OR 0.26, 95% CI 0.10-0.67; P=.01). Willingness to complete questionnaires online was driven by ownership of a home computer (adjusted OR 3.87, 95% CI 1.14-13.2; P=.03).

Conclusions: Adults who self-identified as being part of a minority group were more likely to report limited access to technology than were white adults. As ownership of a home computer is central to a willingness to use online tools, racial disparities in access may limit the potential of Web-based interventions to reach this population.

Trial Registration: ClinicalTrials.gov NCT01806727; https://clinicaltrials.gov/ct2/show/NCT01806727 (Archived by WebCite at http://www.webcitation.org/6xOq2b7Tv)

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Introduction

Approximately 92% of US adults own a mobile phone and 73% own a computer; therefore, it is critical to understand technology's role in effective health care delivery, particularly if the convenience of personal technology can further the goals of decreasing health care costs while promoting improved health outcomes [1,2]. Type 2 diabetes mellitus is an increasingly common chronic disease that carries substantial health care costs and places a significant personal burden on patients to sustain adequate management. The potential for a convenient technology-based intervention is, therefore, especially relevant to diabetes management, as avoidable and costly complications of neuropathy, nephropathy, and retinopathy have debilitating and irreversible impacts on patients' quality of life [3]. Recent, preliminary data suggest that using mobile phones, telecommunication, or email messaging with certified health coaches can facilitate significant weight loss, increase physical activity, and decrease hemoglobin A_{1c} (HbA_{1c}) levels [4-6]. Pludwinski et al reported that smartphone-based resources facilitated decreasing HbA_{1c} levels in ethnic minority patients of low socioeconomic status by effectively strengthening the therapeutic alliance between patient and health coach [7], findings supported by other authors [8-10]. Furthermore, several studies documented a marked increase in patients' self-efficacy, knowledge, and social support in addition to a reduction in cognitive load [7,8,11-14]. While these results are encouraging, patients' ability to access these technologies among a more diverse population must be studied to avoid the futile outcome of developing an underused technology [13,14]. In this study, we sought to assess the feasibility of capitalizing on the pervasive use of technology as a secondary means of delivering diabetic counseling though an investigation of correlates to technology use within the context of an ongoing population health study. It is unclear whether study participants have sufficient access to the technologies that would support a translational intervention. We hypothesized that this investigation of an untapped resource in diabetes care among a high-risk population might be able to uncover the potential to support a novel, low-cost solution to a significant public health challenge facing the United States.

Methods

LIFT Diabetes Study Design

Overweight and obese adults with type 2 diabetes mellitus (N=260) were recruited from Forsyth County, NC, USA to participate in a study of lifestyle modifications for effective risk factor control and the prevention of disease complications—the Lifestyle Intervention for the Treatment of Diabetes study (LIFT Diabetes). Participants were recruited between 2013 and 2015 using a variety of approaches, including mailing potentially eligible adults identified in the electronic medical records system, direct referrals (primarily from health providers), advertisements, and community health events. Details regarding recruitment have been published [15]. The participants, primarily low-income and minority patients, were randomly assigned to 1 of 2 diabetes education groups: 1 consisted of a weekly intensive group-based lifestyle intervention promoting weight loss in a community setting and the other consisted of monthly diabetes self-management education resources delivered in the clinical setting. A more detailed description of the LIFT Diabetes protocol and design can be found in Katula et al [16]. At the baseline visit, all participants completed a survey, which had been used previously in the Action for Health in Diabetes (Look AHEAD) study (which also involved a lifestyle intervention for adults with diabetes) [17]. This technology use survey posed participants multiple questions regarding their current access to specific technologies, use of specific functions, and frequency of use. Additionally, the survey evaluated how participants would prefer to receive study information and whether they would be willing to complete future questionnaires online. The study reported here is an analysis of participants' responses to this survey. The study design, methodology, and data collection protocols were approved by the Wake Forest Institutional Review Board, and written informed consent was obtained from participants. We handled all deidentified data in the statistical package Stata/IC version 14.1 (StataCorp LLC).

Statistical Analysis

We compared frequencies and means of demographic characteristics, health outcomes, and survey responses through Pearson chi-square or Fisher exact analysis and *t* tests. To understand the racial disparities within the sample, we stratified overall demographic characteristics by racial/ethnic group. Due to the small number of nonblack minorities (n=17), as well as their similarity in health and demographic trends to black participants, we grouped all minority participants together for analysis. Due to the assumption that a technology-based intervention would require participants to engage with a device at least once a week, we collapsed all survey responses indicating frequency of use into 2 groups (at least once a week vs less than once a week). Following a description of the sample means and demographics, we used logistic regression as a means of understanding the relative impact of each demographic characteristic on survey responses. To limit the number of missing values in the regressions, questions that participants were prompted to skip after answering "no" to the previous question were recoded as "no" rather than "missing." For example, if a participant did not own a mobile phone, in the subsequent question regarding smartphone ownership, their answer was coded as "no" rather than "missing." Outcome variables used were ownership of a computer and willingness to complete future study questionnaires online.

Results

Data Set and Sample

We collected demographic information, health characteristics, and survey responses from each of the 260 LIFT Diabetes participants; therefore, we included all study participants in the descriptive statistics. However, due to missing information regarding employment, smartphone ownership, and text messaging, the final regression sample for ownership of a computer consisted of 257 participants, and the regression sample for willingness to complete future surveys online consisted of 208 participants.

Descriptive Statistics

Table 1 shows the sample population's demographic and baseline health characteristics. Of the ethnic minority participants, 88.0% were black (125/142), 4.3% were Hispanic (n=6), and 7.7% were other (n=11). Although 22.3% (58/260) of the study population declined to report annual income, most of the respondents (61.4%) reported an annual income of US $49,999 or less. Minority participants were much more likely to have a lower income than white participants (*P*<.001). Education followed similar, though not significant, trends between racial/ethnic groups, with minority participants typically achieving lower educational attainment. Overall, however, most of the study population (n=207, 79.6%) achieved greater than high school education. Of the population health characteristics, we found significant racial/ethnic differences in mean age (*P*<.001), body mass index (BMI; *P*=.002), diastolic blood pressure (*P*<.001), and HbA$_{1c}$ (*P*=.003), suggesting a slightly worse baseline health profile among minority participants.

Table 2 shows technology access and use variables. Minority participants were significantly less likely to own a home computer (*P*<.001) and have email access at home (*P*=.03). To assess the participants' ability and willingness to engage in future technology-based interventions, we correlated survey responses to demographic, health, and access variables (Table 3). Those who owned a home computer were more likely to have a higher income (*P*<.001), have higher educational attainment (*P*<.001), be employed full time (*P*=.01), and own a smartphone (*P*=.001). As expected, those with higher education and income were also significantly more likely to indicate a willingness to participate in technology-based surveys (*P* ≤.001). Similarly, those who were not employed full time were less likely to indicate a willingness to complete future study questionnaires online (*P*=.01). Each of the access variables also played a significant role in participants' responses (*P* ≤.05). Of those who were not willing to complete online questionnaires, 52% (17/33) owned a home computer and 46% (15/33) had access to the internet at home.

Logistic Regression

Table 4 presents the results of the regression analysis for owning a home computer and willingness to complete questionnaires online, when adjusted for demographic characteristics (age, sex, race/ethnicity, education, employment, family size, marital status) and health status (duration of diabetes, smoking status). Minority participants had significantly lower odds of owning a home computer (adjusted OR 0.26, 95% CI 0.10-0.67; *P*=.01). Those with a high school education or General Education Development also had lower odds of owning a home computer (adjusted OR 0.25, 95% CI 0.10-0.60; *P*=.002), while those who owned a smartphone had 3.11 higher odds of owning a computer (adjusted OR 3.11, 95% CI 1.37-7.08; *P*=.01). Education also played a role in willingness to complete questionnaires online, as those with a below–high school education had significantly lower odds of responding "yes" (adjusted OR 0.45, 95% CI 0.01-0.34; *P*=.003). Additionally, those who owned a home computer were more likely to be willing to complete questionnaires online (adjusted OR 3.87, 95% CI 1.14-13.2; *P*=.03).

Table 1. Demographic and health characteristics.

Characteristics	All participants (N=260)	Minority participants (n=142)	White participants (n=118)	P value
Sex, n (%)				.002
Male	85 (32.7)	35 (24.7)	50 (42.4)	
Female	175 (67.3)	107 (75.4)	68 (57.6)	
Age (years), mean (SD)	56 (11)	53 (11)	59 (10)	<.001
Income (US $), n (%)				<.001
0-29,999	78 (30.0)	59 (41.6)	19 (16.1)	
30,000-49,999	46 (17.7)	25 (17.6)	21 (17.8)	
≥50,000	78 (30.0)	22 (15.5)	56 (47.5)	
Missing or declined to answer	58 (22.3)	36 (25.4)	22 (18.6)	
Educational attainment, n (%)				.08
Less than high school	9 (3.5)	8 (5.6)	1 (0.9)	
High school/GED[a]	44 (16.9)	26 (18.3)	18 (15.3)	
Greater than high school	207 (79.6)	108 (76.1)	99 (83.9)	
Employed, n (%)	216 (83.4)	115 (81.6)	101 (85.6)	.39
Insured, n (%)	235 (90.4)	125 (88.0)	110 (93.2)	.16
Marital status, n (%)				<.001
Never married	47 (18.1)	39 (27.5)	8 (6.8)	
Previously married	72 (27.7)	39 (27.5)	33 (28.0)	
Married or equivalent	141 (54.2)	64 (45.1)	77 (65.3)	
Family size (no. of persons), n (%)				.44
0-1	56 (21.5)	29 (20.4)	27 (22.9)	
2-4	185 (71.2)	100 (70.4)	85 (72.0)	
≥5	19 (7.3)	13 (9.2)	6 (5.1)	
Smoking status, n (%)				<.001
Current smoker	40 (15.4)	26 (18.3)	14 (11.9)	
Former smoker	86 (33.1)	32 (22.5)	54 (45.8)	
Nonsmoker	134 (51.5)	84 (59.2)	50 (42.4)	
Weight category, n (%)				.18
Overweight (BMI[b] <30 kg/m^2)	40 (15.4)	18 (12.7)	22 (18.6)	
Obese (BMI ≥30 kg/m^2)	220 (84.6)	124 (87.3)	96 (81.4)	
BMI (kg/m^2), mean (SD)	37 (8)	39 (9)	36 (7)	.002
Waist circumference (cm), mean (SD)	120 (19)	122 (22)	118 (15)	.15
Systolic blood pressure (mmHg), mean (SD)	125 (15)	127 (16)	124 (15)	.09
Diastolic blood pressure (mmHg), mean (SD)	76 (10)	78 (10)	74 (10)	<.001
Triglycerides (mg/dL), mean (SD)	147 (100)	126 (80)	173 (115)	<.001
Hemoglobin A$_{1c}$ (%), mean (SD)	7.6 (1.3)	7.8 (1.4)	7.3 (1.2)	.003
Fasting glucose (mg/dL), mean (SD)	149 (54)	148 (59)	150 (47)	.76
Diabetes duration (years), mean (SD)	8 (8)	9 (8)	8 (7)	.43
Study arm, n (%)				.21
Lifestyle weight loss	130 (50.0)	76 (53.5)	54 (45.8)	

Characteristics	All participants (N=260)	Minority participants (n=142)	White participants (n=118)	P value
Diabetes self-management	130 (50.0)	66 (46.5)	64 (54.2)	

[a]GED: General Education Development.
[b]BMI: body mass index.

Table 2. Technology use profile.

Survey questions	All participants (N=260), n (%)	Minority participants (n=142), n (%)	White participants (n=118), n (%)	P value
Own a home computer	216 (83.1)	106 (74.7)	110 (93.2)	<.001
Have email on home computer	206 (94.9)	98 (91.6)	108 (98.2)	.03
Check email on home computer at least once a week	117 (89.3)	60 (88.2)	57 (90.5)	.68
Have internet access on home computer	212 (97.7)	104 (97.2)	108 (98.2)	.68
Use the internet at home at least once a week	177 (84.7)	85 (82.5)	92 (86.8)	.39
Use the internet outside of home	185 (71.4)	95 (66.9)	90 (76.9)	.08
Use the internet outside of home at least once a week	155 (84.2)	80 (85.1)	75 (83.3)	.74
Locations of non–home internet use				
Cyber café	12 (4.6)	5 (3.5)	7 (5.9)	.36
Library	31 (11.9)	24 (16.9)	7 (5.9)	.01
Family/friend's home	48 (18.5)	23 (16.2)	25 (21.2)	.30
Work	98 (37.7)	51 (35.9)	47 (39.8)	.52
Other location	63 (24.2)	28 (19.7)	35 (29.7)	.06
Own a mobile phone	245 (94.2)	135 (95.1)	110 (93.2)	.52
Own a smartphone	161 (66.2)	86 (64.7)	75 (68.2)	.56
Can send and receive text messages on mobile phone	210 (86.8)	118 (87.4)	92 (86.0)	.75
Can send and receive emails on mobile phone	132 (54.6)	69 (51.1)	63 (58.9)	.23
Send or receive text messages at least once a week	197 (94.3)	111 (94.9)	86 (93.5)	.67
Use email on mobile phone at least once a week	117 (89.3)	60 (88.3)	57 (90.5)	.68
Use social networking	173 (66.5)	89 (62.7)	84 (71.2)	.15
Use social networking at least once a week				
Facebook	134 (79.3)	67 (47.2)	67 (56.8)	.45
Twitter	15 (10.6)	8 (5.6)	7 (5.9)	.79
Skype	13 (9.2)	3 (2.1)	10 (8.5)	.08
Other	18 (17.8)	9 (6.3)	9 (7.6)	.68
Preferred method of contact				
Home phone	74 (28.5)	42 (29.6)	32 (27.1)	.66
Mobile phone	150 (57.7)	88 (62.0)	62 (52.5)	.13
Text message	93 (35.8)	54 (38.0)	39 (33.1)	.40
Email	157 (60.4)	73 (51.4)	84 (71.2)	<.001
US mail	99 (38.1)	64 (45.1)	35 (29.7)	.01
Would complete future online study questionnaires	227 (87.3)	121 (85.2)	106 (89.8)	.27

Table 3. Survey responses by demographic and health characteristics.

Characteristics	Own a home computer (n=216)		Willing to complete questionnaires online (n=227)	
	n (%)	P trend[a]	n (%)	P trend
Age group (years)		.22		.63
<65	163 (75.5)		175 (77.1)	
≥65	53 (24.5)		52 (22.9)	
Sex		.63		.63
Female	144 (66.7)		154 (67.8)	
Male	72 (33.3)		73 (32.2)	
Income (US $)		<.001		.001
0-29,999	53 (24.5)		61 (26.9)	
30,000-49,999	40 (18.5)		43 (18.9)	
≥50,000	75 (34.7)		75 (33.0)	
Missing or declined to answer	48 (22.2)		48 (21.2)	
Educational attainment		<.001		<.001
Less than high school	5 (2.31)		4 (1.8)	
High school/GED[b]	28 (13.0)		34 (15.0)	
Greater than high school	183 (84.7)		189 (83.3)	
Employed full time	104 (48.2)	.01	108 (47.6)	.01
Weight category		.72		.97
Overweight (BMI[c] <30 kg/m^2)	34 (15.7)		35 (15.4)	
Obese (BMI ≥30 kg/m^2)	182 (84.3)		192 (84.6)	
Glycemic control (hemoglobin A$_{1c}$)		.71		.36
Good control (≤7.0%)	90 (41.7)		91 (40.1)	
Poor control (7.0%)	126 (58.3)		136 (60.0)	
Diagnosed hypertension	193 (89.4)	.51	204 (89.9)	.76
Own home computer	N/A[d]	N/A	199 (87.7)	<.001
Have internet access at home	211 (97.7)	.98	197 (98.5)	.05
Use the internet at home at least once a week	176 (84.6)	.85	169 (74.5)	<.001
Own a smartphone	144 (70.9)	.001	149 (69.0)	.01

[a]P values determined by chi-square, Fisher exact, or t test.

[b]GED: General Education Development.

[c]BMI: body mass index.

[d]N/A: not applicable.

Table 4. Fully adjusted regression results[a].

Characteristics	Own a home computer (n=257)		Willing to complete questionnaires online (n=224)	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age	1.03 (0.99-1.08)	.17	0.98 (0.93-1.04)	.56
Male	1.30 (0.51-3.29)	.58	1.52 (0.49-4.71)	.47
Minority	0.26 (0.10-0.67)	.01	1.29 (0.43-3.86)	.65
Education				
Less than high school	0.22 (0.04-1.18)	.08	0.45 (0.01-0.34)	.003
High school/GED[b]	0.25 (0.10-0.60)	.002	0.52 (0.17-1.62)	.26
Greater than high School	reference		reference	
Employed full time	2.33 (0.95-5.69)	.06	1.67 (0.59-4.77)	.34
Student	9.72 (0.93-100.9)	.06	N/A[c]	N/A
Family size (no. of persons)				
0-1	reference		N/A	N/A
2-4	1.85 (0.68-5.03)	.23	N/A	N/A
≥5	1.94 (0.42-9.05)	.40	N/A	N/A
Marital status				
Never married	reference		N/A	N/A
Previously married	0.99 (0.33-2.96)	.98	N/A	N/A
Married or equivalent	1.21 (0.38-3.83)	.75	N/A	N/A
Diabetes duration	0.98 (0.93-1.03)	.42	N/A	N/A
Current or former smoker	1.42 (0.63-3.19)	.39	N/A	N/A
Own a smartphone	3.11 (1.37-7.08)	.01	1.48 (0.52-4.17)	.46
Own a home computer	N/A	N/A	3.87 (1.14-13.2)	.03
Use social networking	N/A	N/A	1.87 (0.62-5.66)	.27
Send or receive text messages at least once a week	N/A	N/A	1.08 (0.78-1.49)	.65

[a]Model is adjusted for demographic characteristics (age, sex, race/ethnicity, education, employment, family size, marital status) and health status (diabetes duration, smoking status).

[b]GED: General Education Development.

[c]N/A: not applicable.

Discussion

Principal Findings

The objective of this study was to determine both access to and use of technology among an ethnic minority population to assess the correlates to use of information technology among adults enrolled in a diabetes study. Broadly, at proportions consistent with national averages, most of the sample owned a home computer and mobile phone and had access to email and the internet [1]. However, significant dissimilarity between racial/ethnic groups was evident in demographics, health, and technology access. The racial disparity in income was reflected in the strong correlation between income and both ownership of a home computer and willingness to complete questionnaires online. The associated racial disparity in owning a home computer persisted even after controlling for numerous demographic characteristics, suggesting that socioeconomic

status cannot fully explain the digital divide along racial lines. Subsequent analysis demonstrated that willingness to complete questionnaires online depends heavily on home computer access, which parallels a recent finding that home internet access drives patients' willingness to use technology for glycemic monitoring [18]. Together, these results indicate that access to home technology is critical to the advancement of Web-based interventions, yet a significant racial discrepancy in access limits practical, translational implementation among a minority population. Regardless of literature citing effectiveness, the potential success of a technology-based program is irrelevant without sufficient access [5,7,8]. Yet the results also indicate that access alone may not be the sole barrier to such an intervention. Approximately 50% of the study sample indicated that they had access to both a home computer and the internet yet indicated "no" when asked about completing study questionnaires online. While it is perhaps surprising that those with home access to technology would indicate an unwillingness

to participate in a technology-based intervention, these findings suggest that, while access is a critical determinant for any future intervention, purely supplying resources may not be sufficient. Whether this is an issue of familiarity with using technology or a deeper discomfort with nontraditional clinical settings, it is evident that initiating a Web-based protocol among minority patients with diabetes may fail to capture a meaningful portion of the population.

The significant relationship between educational attainment and an interest in online platforms presented here parallels previous discussions of education and telecommunication [18,19]. While higher education typically correlates to higher income, concurrent relatively low income and relatively high education seen in this study may not be unrealistic. Dray-Spira et al suggested that diabetes may impair patients' ability to maintain the standard of employment associated with higher education, or that diabetes-related disability results in significant work loss followed by termination of employment at higher levels [20]. These possibilities are bolstered by the low level of full-time employment in this study (116/260, 44.6%) and broader consideration that work disability days are significantly higher for employees with diabetes [21,22]. Therefore, significant diabetes-related work disability may have exacerbated the disparity in education status and income seen in the study population.

Although health characteristics are unlikely to influence willingness to participate in Web-based programs, it is possible that underlying health problems could influence earning capacity and thus also access to technology. However, the health technology access and health technology use correlations explored were not statistically significant (data not shown). Despite this negative finding, the health metrics described reinforce previously observed racial disparities in health outcomes [23,24]. Prior research demonstrated that these disparities cannot be adequately accounted for by childhood socioeconomic status, adult income disparities, or health behaviors, but rather by the influence of allostatic load, exposure to discrimination, and decreased social capital [24,25]. While we did not explore these social variables in this study, we did find the expected trend that minority participants with diabetes exhibited higher BMI, diastolic blood pressure, and HbA_{1c} than did white participants. Therefore, while the sample was geographically restricted, the observed health patterns are generally consistent with other research studies.

Study Limitations

This investigation was limited by its reliance on a single survey item—willingness to complete questionnaires online—as a proxy for participants' willingness to engage in health coaching or health metric tracking through Web-based technology. A more robust analysis would be facilitated by additional, specific questions focusing on the issue of telecommunication in diabetes management. Demographically, the study had relatively few black men and generally had few nonblack minority participants, which necessitated grouping these participants into a general minority classification, and this therefore may have obscured distinct minority group responses. Finally, the study was restricted to a population of patients with diabetes already under a physician's care at the time of enrollment and who were willing to be randomly assigned to a clinical trial, which may indicate higher socioeconomic position and therefore limits the generalizability of the findings to a broader minority population.

Conclusions

This study established demographic characteristics, health profiles, and access to technology within an ethnic minority population in the southeastern United States. Research on chronic disease management—specifically diabetes—and clinical practice have demonstrated the effectiveness of intensive behavioral and lifestyle interventions in reducing the risk of disease complications [26-28]. Smartphone apps, telecommunication, and other mobile technologies have been proposed as efficient and effective alternatives [4,29-31]. However, these findings have yet to be reconciled with the results presented above—that minority patients of lower socioeconomic status lack both access to and familiarity with certain computer technologies—which limits the possibility for a translational intervention. While advancing diabetes research to address health disparities will require an innovative approach, the argument for mobile technology is not well supported at this time. In addition to focusing intervention efforts in other areas, studying minority patients' perceptions of technology in the clinical setting may provide a much-needed perspective and inform the use of Web-based apps when technology becomes a viable approach. Here we highlighted the limited feasibility of introducing mobile technology to reduce health disparities among those with diabetes. However, as access to technology increases with time, future studies should investigate users' perceptions of data safety and privacy, the cost of data plans associated with mHealth tools, and barriers to using personal technology in the clinical setting, aside from resource deprivation.

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Abbreviations

BMI: body mass index
GED: General Education Development
HbA$_{1c}$: hemoglobin A$_{1c}$
LIFT Diabetes: Lifestyle Intervention for the Treatment of Diabetes study
Look AHEAD: Action for Health in Diabetes

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Original Paper

Perceptions of Persons With Type 2 Diabetes Treated in Swedish Primary Health Care: Qualitative Study on Using eHealth Services for Self-Management Support

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Abstract

Background: Digital health services are increasing rapidly worldwide. Strategies to involve patients in self-monitoring of type 2 diabetes (T2D) on a daily basis is of crucial importance, and there is a need to optimize the delivery of care such as self-management support. Digitalized solutions have the potential to modify and personalize the way in which people use primary health services, both by increasing access to information and providing other forms of support at a distance. It is a challenge to integrate core values of person-centered care into digitalized health care services.

Objective: The objective of this study was to describe perceptions of using electronic health (eHealth) services and related technologies for self-management support among people with T2D treated in Swedish primary health care.

Methods: This is a qualitative study based on interviews analyzed using qualitative content analysis conducted among people diagnosed with T2D.

Results: Findings suggest that the participants had mixed feelings regarding the use of digital health services for self-management support. They experienced potentials such as increased involvement, empowerment, and security, as well as concerns such as ambivalence and uncertainty.

Conclusions: Digital health services for self-management are easily accessible and have the potential to reach a wide population. However, targeted training to increase digital skills is required, and personalized devices must be adapted and become more person-centered to improve patients' involvement in their own care.

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Introduction

Information and communication technology (ICT) for health promotion, disease prevention, and disease management used in health care (electronic health, eHealth) is suggested to have a great potential to improve access, quality, safety and efficiency of care, and further prevention, diagnostics, treatment, and self-management among people with chronic illnesses such as type 2 diabetes (T2D) [1-3]. Until about a decade ago, the idea of allowing a digital device to play a decisive role in how T2D is controlled and monitored was unthinkable. Today, it is booming in health care with a rapid growth and supply of various applications and interactive systems aimed at improving

people's health behavior and supporting self-management in chronic illness [4].

People with T2D and their perceptions of using digital health services and related technology is the objective of this study. Digital health services or eHealth are terms that are used interchangeably in this paper. In these terms, we include using the internet for medical and health information and self-management support via, for example, diabetes websites, using patient portals, blogs, chat rooms, and forums. Furthermore, telehealth, telemedicine, telemonitoring, mobile Health (mHealth), apps, electronic health records, and other uses of digitization could be involved. These technologies are important since they are supposed to provide, improve, and support self-management and the delivery of care at a distance.

Even if developments and implementations of ICT in health care proceed quickly, opinions about the efficiency of eHealth vary among both patients and health care professionals [5-7]. This is a challenge as the use of innovative technologies in health care is not possible without the acceptance of patients and health care professionals. To support people with chronic illness to more readily accept digital health services and to gain the ability and knowledge to use ICT, we need to learn more from these groups of users [8,9]. In this paper, the focus is on people with T2D. One reason is that the prevalence of T2D is increasing with considerable morbidity and mortality, generating a heavy burden both at a personal level and at the health care system in both developed and developing countries [10,11]. In Sweden, it is estimated that 4% to 6% of the population has T2D with mean age for diagnosis of about 63 years. [12].

Self-management is a basic and integrated part of the treatment in T2D. Since it is a progressive disease, it must be complemented with oral antidiabetic agents or insulin injections over time, which could add to the burden of the disease [13-15]. To control the disease progression, people with T2D visit physicians and specialist nurses several times per year to take various tests, adjust medication, and get self-management support aimed at postponing severe complications [16]. People with T2D commonly struggle with complex self-management activities, including healthy eating, physical activity, blood sugar testing, self-monitoring, and medications [17,18]. Therefore, to manage diabetes efficiently on a daily basis over time, person-centered and tailored education and support, as well as collaboration or partnership between patients and health care professionals is recommended [13,19,20].

The various technologies used in digital health services such as the internet, mobile apps, and other kinds of interactive digital tools and devices in health care have a potential to facilitate self-management, which in turn may prevent or postpone disease complications in a chronic disease [21-25]. From an economic perspective, eHealth may lead to better cost-efficiency in the health sector [26], and it has a potential to complement or even substitute several personal contacts with health care professionals [27].

Implementation of ICT is recommended in Swedish health care. The government's vision is clear—Sweden is to be the best in the world in eHealth by 2025, and this has to be realized by using the potential of digitization and eHealth to help people achieve good and equal health and well-being, as well as develop and strengthen their own resources for increased independence and participation in society [28]. Furthermore, the use of eHealth technology is recommended for both professionals and patients, but also that the care should be person-centered [28-30]. A challenge though is to integrate goals of person-centered care (PCC) in the implementation of digitized self-management support [5]. One core value in PCC is the development of a mutual and respectful partnership between patients and health care professionals. Another is that care plans should be based on patients' narratives, where a comprehensive view of the patients and autonomy is of great importance [31]. How these core values could be integrated into eHealth-based self-management support in practice is not clearly expressed in policy documents.

Preferences for use of eHealth devices for health information are higher among younger people, while persons 70 years and older, are reported to prefer nondigital modalities for health information even if they are internet users [32]. Furthermore, among adult internet users, differences are reported where women are reported to use eHealth devices more frequently than men. There are also differences based on socioeconomic status (SOS) in favor for those with higher SOS, but no differences based on ethnicity [33]. In T2D, a main barrier has been reported to be lack of access to the internet and poor user-friendliness of Web applications. People with T2D in need of care are reported to be more engaged in long-term use of eHealth devices such as Web applications [34]. People with different diseases may also express different needs and expectations toward self-management and eHealth for self-management purposes. In a study by Huygens et al [35], participants reported that eHealth should not replace but complement personal care. They also reported feelings of anxiety and uncertainty about follow-up of deviant measurements. From Sweden, we have not found any studies regarding perceptions or expectations on use of eHealth devices for self-management support in T2D. The objective of this study was, therefore, to describe perceptions of using eHealth services and related technologies for self-management support among people with T2D treated in Swedish primary health care.

Methods

Overview

This study is part of a larger randomized intervention project aimed at designing and implementing person-centered interactive self-management support (iSMS) in primary health care in northern Sweden. The overall project has a cocreation design, and participants' perceptions are therefore of great value for designing a forthcoming intervention that is registered at ClinicalTrials.gov (NCT03165084).

Participants and Setting

The participants were treated in primary health care in a county in northern Sweden. Inclusion criteria in this study were Swedish-speaking individuals diagnosed with T2D. In total, 11 people (3 women, 8 men) aged from 50 to 78 years (median 65 years) were interviewed.

The purpose was to reach a purposeful sample with an even gender distribution, but it was difficult to recruit women in the study. The duration of T2D among the participants varied from 4 months up to about 10 years. Of these 11 participants, 7 participants lived together with a partner, while 4 were single. Each participant owned a smartphone. Initially, the aim of the study was presented by the first author at an information meeting held at the Local Diabetes Association, where 4 participants declared their interest in participating. A snowball selection was then used to include the remaining 7 participants into the study, that is, enrolled participants suggested names of other people who could be contacted for interviews.

Data Collection

The first author conducted interviews with the participants individually, either in their homes (n=8) or at the university (n=3) during 2016. All participants were contacted in person or by telephone in advance. They received information about the study, and date and place for the interview were decided. At the interview session, each interviewee was informed again and had the opportunity to ask questions or withdraw participation. The interviews performed by the first author lasted between 40 and 80 (median=60) min and were digitally recorded. During the interview, a semistructured interview guide was used, as well as an ambition to get answers that were narrative in nature. The opening question was, "If I say information technology and eHealth, what do you think of?" Examples of other questions were as follows:

- "Can you please tell me about your experiences of using digital health services in contacts with care?"
- "Have you ever used any digital technology device in your diabetes self-management? Please, tell me about those experiences."

Probing questions and prompts were used to deepen the topics and to get answers on issues not already mentioned.

Data Analysis

The interview data were transcribed verbatim by the first author and analyzed using qualitative content analysis as described by Graneheim and Lundman [36]. Qualitative content analysis is a systematic way to describe variations of content in a verbal or written communication [36,37]. The epistemological basis of qualitative content analysis is that data and interpretation are cocreations between the interviewee and the interviewer, and interpretation during the analysis phase is a cocreation of the researchers and the text [38,39]. The analysis was performed in several steps. First, all text was read through thoroughly to get a sense of the whole. This reading revealed 2 overarching domains—*Potentials* and *Concerns*—into which the text was sorted. The text in each domain was then divided into meaning units consisting of words or sentences related to each other through their content and context.

The identified meaning units were then condensed, that is, made shorter without losing the core meaning, and interpreted and labeled with codes. The codes were sorted, based on similarities and dissimilarities, into 12 subcategories within the 2 domains. The subcategories were then abstracted to 5 categories as follows:

- Potentials
  - Involvement
    - Independence
    - Responsibility
  - Empowerment
    - Knowledge
    - Participation
    - Engagement
    - Freedom
  - Security
    - Confidentiality
    - Privacy

- Concerns
  - Ambivalence
    - Insufficient support
    - Lack of digital skills
  - Uncertainty
    - Distrust of information
    - Unreliability

Following the steps of the analysis should not be seen as a linear process, rather a process of going back and forth between the steps and between original data and analyzed data. All authors also discussed the interpretations within every step of the analysis until consensus was achieved [36].

Ethical Considerations

The Regional Ethical Review Board at Umeå University approved the study (Dnr 2014-179-31M) and was conducted according to the ethical principles described in the Helsinki Declaration [40]. Before giving informed consent, the participants received oral and written information. It was emphasized that participation was voluntary and that they could withdraw from the study at any time without giving explanation; they were also assured of confidentiality. The transcripts were made anonymous by removing personal information. In addition, quotations were made anonymous with small changes in wordings that did not alter their core meaning.

Results

A total of 5 categories within the domains *Potentials* and *Concerns* were identified in the analysis. The results were divided into 2 domains, 5 categories and 12 subcategories. Each subcategory is further enlightened by quotations from the original interviews in the following text.

Potentials

Within the domain *Potentials*, which referred to the positive perceptions of using digital health services as self-management support, the categories *Involvement*, *Empowerment*, and *Security* were highlighted.

Involvement

The importance of being involved in decisions about medication and in discussions about self-management and goals—for example, blood sugar levels—were highlighted. Some had

negative perceptions from previous health care contacts when health care professionals made decisions "over their heads." The subcategories related to this category are *Independence* and *Responsibility*.

Independence

Independence included striving to handle all demands related to the disease and was expressed as being natural. However, sometimes, social demands made it difficult to remember or prioritize self-management. Using digital health services was described as a key to try harder and as something positive. Some were willing to pay for digital and technological tools that could provide insights and motivation to self-manage their chronic condition:

> *I use and have paid for an app on my smartphone, so I can monitor my weight, daily steps and of course my blood sugar. I love it.*

Responsibility

The importance of taking responsibility for oneself was highlighted. Those who had used various digital health services previously expressed that it helped them to take more action in their self-management. However, this was something they kept secret and did not always tell their diabetes nurse, since she might apprehend it as being critical of her advice. They also forced the importance of being seen as capable and responsible by the diabetes nurse, something that included that they accepted the consequences of even unhealthy choices. These participants had often got the advice from their diabetes nurses not to trust information on the internet and felt that using apps was in a gray zone, almost forbidden. Nevertheless, the participants described how it had helped them:

> *It [the app] helped me to take responsibility for a healthier behaviour; I believe I became more confident in myself since I started to use it. Much more than when I got my diabetes diagnosis.*

Empowerment

A number of areas related to eHealth were found important for the management of the participants' own health. They viewed applications and digital tools as powerful aids for understanding and becoming more aware, which enabled them to take control of their disease. Tracking their symptoms and treatments using diabetes apps and participation in online forum discussions provided them comfort. They learned of peers from online support groups by sharing what symptoms helped them take steps to adjust living with T2D, what types of treatment they used, and how this worked to strengthen them. As well-informed patients, they could more easily discuss and request different treatments with health care providers. The subcategories related to this category are *Knowledge*, *Participation*, *Engagement*, and *Freedom*.

Knowledge

Increased knowledge was highlighted as an important goal for managing T2D. The participants expressed that they preferred better collaboration between themselves and health care professionals. They saw themselves as knowledgeable, capable, and responsible for their own health and self-management. Now,

knowledge enabled them to make informed choices, which could lead to better control, something the use of apps could facilitate. Gaining knowledge at one's own pace was seen as a benefit.

> *I can get the knowledge I want about type 2 diabetes [on the internet], and make up my own goals, step by step at my own pace [using an app]...without having to discuss everything with the diabetes nurse.*

Participation

Digital health services were perceived as providing opportunities for increased participation, since they could discuss their condition with people other than health care professionals. Some gave examples of their adult children's increased participation when they lived far away. Using a mobile app that supported management of diabetes, the adult children could be updated online and follow the illness process at a distance. They could also easily get in touch with people with diabetes who they could contact through various Web-based portals for patients:

> *I especially enjoy being able to reason with others with the same problems on different patient forums. It is a kind of social networking, though I do not leave home often...*

Engagement

Digital health services and devices made the participants more engaged through an increased awareness about the disease and needs for improved self-management. It was described that they traditionally met a doctor and a nurse semiannually. Between those visits, the disease-related information was easy to "forget," and thereby they did not focus on changing habits. Due to an increased use of digital devices, they viewed personal visits at the health care center as unnecessary:

> *I feel more engaged now [using an app for self-monitoring]...I don´t always have to visit the primary health centre if I have problems, some things can be solved through eService on the primary healthcare centres website...*

Freedom

Using digital health services was expressed as increasing the participants' freedom. They gave examples of the freedom that was related to 24-hour service online. They did not have to wait until the next morning or a Monday, when the diabetes nurse was available if they had problems or had questions during the weekend:

> *Anytime during all hours I have the freedom to reflect and get feedback [from patient forums] on my thoughts. I do not have to wait until the next day when the primary healthcare centre opens as I did before.*

Security

Digital health service was experienced as offering security. Safeguard components as passwords, encryption systems such as an e-ID (BankID or Mobile BankID), and similar technical safeguards for authorization or access controls strengthened the view of technology as something positive that protected the

participants. The subcategories related to the category *Security* are *Confidentiality* and *Privacy*.

Confidentiality

The participants expressed worries and concerns about the following: that people from their community could witness them visiting the primary health care center and this could endanger their confidentiality. It could have personal consequences if information about them, known by neighbors, could get leaked to health care professionals, for example, about their families and social circumstances not known by a health care professional. In the next step, this information could get leaked to employers or maybe insurance companies. Sometimes they withheld information from health care professionals because of confidentiality concerns and also could avoid personal visits to the health care center. Web-based health care services were described as more secure, with personal log-ins, which was seen as trustworthy, and were at times perceived as better than the traditional face-to-face visits:

> *I trust that all information about me is kept confidential, even if it is online...but I do not know if I can trust that only authorised persons at the healthcare centre have access to my medical records...I mean, my neighbour works there as a secretary...*

Privacy

It was highlighted that when digitized health is discussed in the media or in popular scientific literature, the ethics, security, and privacy risks are often questioned. Despite this, the participants were not worried. Instead, they expressed that lack of privacy was a barrier to visiting health care centers in small communities. Participants mentioned breaches of their privacy and had experienced that fellow patients took mobile photos in the waiting room and put them on Facebook. Using Web-based health services, they did not have to "advertise" their problems to other patients in the waiting room, and thereby, they did not feel as vulnerable and exposed:

> *When I sit in the waiting room, I could find it problematic to meet neighbours and others. I don't want to expose myself as an ill person to them...I think I would prefer online meetings with my nurse.*

Concerns

Within the domain *Concerns*, which referred to the more negative side of the participants' perceptions of using digital health services for self-management support, the categories *Ambivalence* and *Uncertainty* were highlighted.

Ambivalence

The participants expressed ambivalence concerning using digital health services and digital devices such as apps or iSMS. Mostly, it concerned feelings of lacking confidence and not being able to manage the technology. Furthermore, they had too little training, wanted support, and therefore avoided digital devices if they could. The subcategories related to the category *Ambivalence* are *Insufficient Support* and *Lack of Digital Skills*.

Insufficient Support

Being afraid of the new technologies as well as having limited or insufficient technological support increased the risk of not getting the medical advice participants needed. They therefore preferred face-to-face meetings with health care professionals. They did not have any family members or friends who could support them, and therefore, they were afraid of having technical problems.

> *What if something goes wrong?*

Lack of Digital Skills

Participants expressed an ambivalence and reluctance toward using digital technology. The reason was expressed as having a lack of digital competence and skills. They also mentioned poor technological design as a barrier to navigate websites and apps. Participants stated that they had difficulties using their smartphones due to physical problems such as sight loss or tremor.

> *It´s too difficult to use for me, I can´t even type [on the smartphone].*

Uncertainty

Digital systems in general were questioned by participants. They felt uncertain whether they could trust information they came across on the internet, and they were afraid of problems with eHealth services due to unreliable internet connections. The subcategories related to the category *Uncertainty* are *Distrust of Information* and *Unreliability*.

Distrust of Information

Participants saw no value in using technology to manage their health. Furthermore, they did not always trust the quality and authenticity of the information on websites they found and whether these websites provided accurate and detailed information about diabetes management. It was considered unsafe to rely entirely on the Web-based information that was available since the content could be medically incorrect and potentially endanger their health.

> *I mean, how can I be 100% sure that the information online is correct? It could be fatal.*

Unreliability

Participants highlighted the unreliable and unstable connections, both on wired or wireless broadband with an internet turning on and off rapidly and slow when working. They also said that the lack of internet access through wired or wireless broadband technologies in their homes made it impossible to rely on and use the computer or smartphone for eHealth purposes. Participants expressed that even the primary health care service could not guarantee reliable computer systems:

> *What if there's a system failure due to a crash or virus, and there will be loss of data? Or an unstable connection? Can the system be really secure?*

Discussion

Principal Findings

This study has provided insight about the perceptions that people with T2D may have about using ICT and digital health services for self-management support, and the findings show that the participants are mainly positive, but they have mixed feelings regarding use of eHealth services and digital devices irrespective of whether it concerned a Web or mobile app. On one hand, they experienced potentials such as increased involvement, empowerment, and security; on the other hand, they expressed concerns such as ambivalence and uncertainty. One explanation for the variation in perceptions of using digital health services or eHealth services for self-management support could be the participants' differing capabilities such as education and computer training and experience. From literature we know that age, gender, as well as SOS situations influence people's perceptions [32-34].

Several studies report that eHealth is promising with regard to self-management support and that people with chronic conditions desire tools that effectively reduce the limitations of life caused by disease [41-43]. Alpay et al [44] concluded that by removing barriers of time and geographical distance in health care services—using digital and technological services such as video consultations and telehealth—the patients gain flexibility. They get an easier and more convenient access to health care, they may even have fewer time-demanding health care center visits, and finally, patients can receive care at a location that does not require transportation and in an environment that can be experienced as less threatening.

Regarding the category *Involvement*, our results highlight that self-monitoring may increase patients' independence. Similar results are reported by Holtz and Lauckner [45], and by Alvarado et al [46], who showed that people with diabetes could adapt easier to their condition by using their mobile phones in self-monitoring and management of diabetes. Kruis et al [47] presented that innovative eHealth self-management solutions can support or improve independence among people with chronic conditions. Ahern et al [48] concluded that the potential of patient technologies can only be accomplished by motivating patients to become more engaged and responsible for their own care. In a study by Nijland et al [42], the authors argued that interactive eHealth applications must be continuously changed and developed to promote individual self-care, through feedback and exchange of information, something that is in line with the value of independence. Interactive eHealth tools designed to provide feedback on patients' self-monitoring appear to engage patients the most, since personalized and interactive features stimulate active participation by both patients and nurses. Nijland et al [42] reported that the diabetes patients in their study felt better monitored by the feedback they received and were therefore more motivated to take a more active role in the self-management of their illness—something that also led to increased independence.

Regarding the category *Empowerment*, our results suggest that use of interactive eHealth platforms seems to have a potential to increase patient empowerment through increased knowledge,

participation, engagement, and freedom. Our findings support previous studies that report that empowerment can be improved using digitized approaches in health care [5,44,49]. Empowerment implies participation and responsibility through increased awareness and knowledge [50,51]. Self-efficacy is an important aspect of empowerment and relates to change in behavior, which is important for self-management in chronic conditions [52]. Patient empowerment and PCC are closely related complementary concepts. These do not oppose each other, and indeed patient empowerment can be achieved through PCC [53]. Both patient empowerment and PCC are emphasized by health researchers and policy makers and expressed in care policy documents nationally and internationally [7,20]. Furthermore, it has been suggested that PCC increases patient outcomes and satisfaction in chronic illnesses [54,55] and T2D [54]. Thus, using the Web for medical and health facts is an approach in health care that can support empowerment and is facilitated by a shift to PCC that can subsequently improve self-management [25,30,55,56]. Digitized access increases patient empowerment and enables them to participate more actively in making better informed choices regarding their health in interaction with health care. Technological advances for self-monitoring are changing the conditions for chronic disease management. The use of different communication tools and interactive platforms may improve patient participation in decision making and facilitate for patients to communicate easily with health care professionals [49,57]. Medical and health information on the internet, digital health that patients use as in-home monitoring, virtual consultations, and mobile apps are also available to users 24 hours a day, 7 days a week [58] to provide alternatives to them apart from the primary health care centers, and this gives a certain degree of freedom [59]. However, a benefit for health care professionals using digitalized technology in self-management support is the option to be in contact with patients more frequently than semiannually or annually, as is common today [60,61].

Regarding the category *Security*, our results shows that participants in this study experienced that use of Web-based technology was seen as something safe and reduced privacy exposures, which is confirmed by other studies [62,63]. Participants were not bothered much about security concerns; they trusted that the different technical safeguards, such as passwords or encryption systems, were safe enough. Similar results are reported by Spanakis et al [63] who stated that most patients seem to be willing to disclose information relevant to their condition to their health provider, with no particular awareness of how the patient information is transferred. The use of digital health services can also reduce the number of visits to the health care centers, something that can be experienced as stressful, time-consuming, and expensive. Fewer face-to-face visits might also imply changes in the patients' perception of self-management support as well as reconfiguring work activities for the diabetes nurse [64]. Encouraging patients to share their self-monitored data with the diabetes nurse to a higher degree may become a trade-off for fewer visits, thus having health economic implications. This is in line with a study by Eland-de Kok et al [65] who showed that adapted and person-centered support increased more than semiannual visits. This may lead to quality improvements and a higher priority

for those patients who need face-to-face visits the most. A literature review by Hardiker and Grant [66] showed that the use of different Web-based services depended on a number of factors such as the characteristics of users, the kinds of technological issues, characteristics of the digital health services social aspects of users, and the digitized services in use. This requires health care professionals to concentrate their efforts where they are needed most, by tailoring services to meet the needs of a broad range of users.

Regarding the category *Ambivalence*, our results highlight that some of the participants stressed concerns regarding, for example, lacking digital skills and knowledge about how to use digital health services, which is in line with other studies [67,68] that have also reported an existing age-related digital division. This division concerns everything from the design of the digital device and screen design to complex commands and procedures, including inadequate training and instructions that can prevent older people from interacting with digital systems. Czaja and Lee [67] reported that predictors of not using digitized technology were primarily the very old with cognitive decline associated with different aging processes such as vision impairment, and attitudes such as anxiety about computer use and the perception that technology is not useful to them, both of which are compatible with our results. Usually participants in our study were also reluctant about using digital health services and preferred face-to-face meetings with health care professionals. Similar results are reported by Currie et al [27] who conclude that digitized solutions are not the key for every patient and thus do not have the same impact as a face-to-face meeting with health care professionals, since they may create feelings of loss of proximity for some patients. The lack of proximity in digital health services is also highlighted in other studies and is a challenge to overcome. Video consultations could sometimes compensate for the lack of proximity in digitized meetings [69,70]. Technological barriers could therefore be solved and personalized to meet the needs of those who have physical barriers such as cognitive, sensory, and motor deficits.

Regarding the category *Uncertainty*, our results highlighted that participants were ambivalent about their views of the reliability and quality of Web-based digital health information. Similar findings report individuals having difficulties using the internet to find complete and proper information concerning health issues. Not relying on Web-based information in making decisions about treatment and self-management, including whether or not to seek care, may negatively influence the user's decisions [71,72]. In Sweden, 93% of the population have access to the internet at home, and outside the home, 71% connect to the internet using mobile phones or smartphones. Although access to internet is high in Sweden among the people aged 16 to 85 years, still 7% of households in Sweden do not have access to the internet. Those who have never used the internet are found mostly in the age group 75 to 85 years [73]. Even if Sweden is a country with very high internet access, we have interpreted limited access to internet connections or broadband as a factor that affects the usefulness of digital health services. This is concurrent with Currie et al [27] who reported problems for patients living in rural areas compared with those living in urban

areas concerning the use of technology for health purposes. They highlighted challenges related to slow and unreliable broadband services. Fuji et al [74], on the other hand, conclude that instead of primarily focusing on issues concerning internet infrastructure or a lack of internet access in rural areas, focus should be placed on overcoming other concerns and barriers among the users.

Our results could guide such development. The result also indicates that future digital health solutions preferably should have high demands on functionality, personalization, and an easy-to-use design to be user-friendly. Self-monitoring and measurements should also be smooth to integrate with the health care records and communication channels. Furthermore, a "universal" digital solution does not exist. One size rarely suits everyone. To improve user customization, people with T2D from various socioeconomic backgrounds, gender, and ages need to be involved in the development of future digital tools.

Strengths and Limitations

The findings in this qualitative study cast some light on the experiences of using various digital health services in self-management support among people with T2D treated in Swedish primary health care. We view our results as transferable to other groups of patients with similar lifestyle-related chronic conditions in societies similar to Sweden. However, according to Graneheim and Lundman [36], it is up to the reader's judgment as whether or not the reported findings are transferable to other contexts.

We recruited 11 people with T2D for individual interviews, using a combination of purposive and subsequent sampling [75], which made it possible to expand the group of participants. However, there is a risk of bias, since our sample may consist of participants with an interest in eHealth. Despite that, our result pointed to a variation of perceptions about the use of eHealth services and could thereby be useful.

The majority of the participants were men, and the age range was 50 to 74 years. It is possible that the outcome of this study would have been different if more women had been included and if the age range had been different, including, for example, very old patients. Nevertheless, the participants in this study are representative of people with T2D and provided rich data.

There are no rules for how large the selection of participants should be in qualitative research methodology, but the selection is generally determined by the need for information data. In this case, it was considered that it had come to the stage where further data collection would not provide more knowledge and that the collected data was sufficient for the study. The saturation point was judged as reached. The term saturation derives from grounded theory, but it is also used in other qualitative approaches [76].

The interviews were conducted by the first author alone. However, all authors listened to and discussed the interviews and then were involved in interpretations at every step of the analytical process, something we believe has strengthened the trustworthiness of the study and resulted in a consolidation of the findings.

Conclusions

The results from this study indicate that persons with T2D have diverse perceptions on using digital health technologies and eHealth services for self-management support. They are interested in digital health technologies and services for self-management support, however, ambivalence was also expressed. Our findings indicate that targeted training and support is needed to overcome barriers and that utilized devices for good reason should be personalized or carefully adapted to the specific situations at hand.

The use of digital health technologies for person-centered self-management support is challenging but can—if implemented appropriately—lead to increasing patient responsibility for their own health and strengthen patients' empowerment and self-management capabilities. Although digital health technologies of today allow for innovative approaches, there are also ethical aspects to consider when new digital health tools or solutions and eHealth services are introduced in health care. Some people may neither wish to nor be able to use digital technology for various reasons on their own, whereas others see it as an important complement to or even substitute for the traditional health care visits.

Authors' Contributions

UÖ recruited participants and performed data collection and transcription. UÖ and ÅH contributed to the main analysis and interpretation of data. UÖ drafted the first version of the manuscript. UÖ, CJO, LJ, UI, and ÅH contributed in editing the manuscript, and all authors contributed and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

eHealth: electronic health
ICT: information and communication technology
iSMS: interactive self-management support
PCC: person-centered care
SOS: socioeconomic status
T2D: type 2 diabetes

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