
JMIR Diabetes

Emerging Technologies, Medical Devices, Apps, Sensors, and Informatics to Help People with Diabetes
Volume 5 (2020), Issue 3 ISSN 2371-4379 Editors-in-Chief: Ricardo Correa, MD, EdD; Sheyu Li, MD

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Original Paper

Evaluation of a Text Messaging Intervention to Support Self-Management of Diabetes During Pregnancy Among Low-Income, Minority Women: Qualitative Study

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Abstract

Background: Given the growing burden of diabetes in underserved communities and the complexity of diabetes self-management during pregnancy, the development of interventions to support low-income pregnant women with diabetes is urgently needed.

Objective: This study aims to develop and pilot test a theory-driven curriculum of SMS text messaging for diabetes support and education during pregnancy.

Methods: This was a prospective pilot investigation of a novel SMS text messaging intervention offered to pregnant women with pregestational or gestational diabetes mellitus and publicly funded prenatal care. Prior work yielded a conceptual model of diabetes self-management barriers and support factors in this population, which was used to guide curriculum development along with health behavior theories. Participants received three supportive or educational one-way text messages per week during pregnancy. In-depth semistructured interviews were performed at study exit to solicit feedback on the program. Narrative data were analyzed using the constant comparative technique to identify themes and subthemes.

Results: Participants (N=31 enrolled and n=26 completed both interviews) consistently reported that SMS text messaging provided enhanced motivation for diabetes self-care, reduced diabetes-related social isolation, increased perceived diabetes-associated knowledge, enhanced comfort with the health care team, and reduced logistical burdens of diabetes during pregnancy. Participants requested enhanced interactive and customizable features in future intervention iterations.

Conclusions: Pregnant women with diabetes who were enrolled in this pilot study of an SMS text messaging curriculum for diabetes support described enhanced motivation, knowledge, and comfort with diabetes self-care activities as a result of the health education intervention. The next steps include enriching the interactive features of the intervention and investigating the effect of the intervention on perinatal outcomes.

(*JMIR Diabetes* 2020;5(3):e17794) doi:[10.2196/17794](https://doi.org/10.2196/17794)

KEYWORDS

gestational diabetes mellitus; type 2 diabetes mellitus; mobile health; text messaging; mobile phone; pregnancy

Introduction

Diabetes mellitus poses a significant health burden to pregnant women [1,2]. Its prevalence has rapidly risen alongside the obesity epidemic, and it disproportionately affects low-income and minority women [3,4]. Effective treatment reduces the risk of many adverse maternal and child health outcomes [5].

However, successful management of diabetes during pregnancy is challenging because of the complexity of self-management skills, advanced patient education requirements, and high-level patient engagement required for optimal glycemic control. Diabetes significantly amplifies the requirements for self-care beyond normal pregnancy; these requirements may be particularly burdensome among low-income and minority women, who face additional social and structural barriers.

Additionally, as pregnancy is a window of opportunity for health optimization [6] because of enhanced motivation and health care access, it is particularly critical to engage women with diabetes in healthy self-care during pregnancy.

Technology support interventions for individuals with chronic diseases can improve knowledge, engagement, and self-management of health conditions [1,7]. Technology expansion has made mobile health (mHealth) interventions a promising avenue for health promotion [8], especially in diabetes [9-12]. Text messages, for example, can be motivators, information sources, cues to action, reminders, and sources of support [13]. Outside of pregnancy, mHealth use is associated with improvements in glycemic control, self-care behaviors, treatment adherence, engagement, and self-efficacy [14-20]. However, existing interventions are not generalizable to pregnant women given their distinctly different clinical circumstances [21-26]. Data suggest that emerging pregnancy-related mHealth interventions may positively affect women's health attitudes and behaviors [27,28], but there is a gap in available evidence-based technologies to address the complex needs of pregnant women with diabetes, particularly for low-income women.

Thus, we initiated a multiphase project toward developing an intervention for pregnant women with diabetes. We previously developed a model of barriers and facilitators to diabetes self-management, which informed our development of a theory-driven curriculum of SMS text messaging for diabetes support and education during pregnancy. The objective was to evaluate user experiences with this intervention, including feasibility, acceptability, and areas for improvement. We hypothesized that the delivery of a comprehensive curriculum of supportive and educational text messages aimed at promoting health during pregnancy with diabetes would be feasible and positively received.

Methods

Study Overview and Inclusion

This is a pilot investigation of a novel text message-based support intervention called *Texting for Diabetes Success* (TDS). Eligible women were aged 18 years or older, were English speaking, had publicly funded prenatal care, and had type 2 diabetes mellitus or gestational diabetes mellitus (GDM). Women with both types of diabetes were included because our prior data suggested that both groups experienced similar burdens and similarly complex health management [25,26,29]. Similarly, women were eligible for inclusion regardless of treatment modality. All women were receiving care at an academic hospital-based clinic that provides prenatal care for low-income women with public insurance. Participants were required to have a mobile phone and a willingness to receive text messages. They were eligible for participation after 10 weeks of gestation, and those who entered or transferred into prenatal care past 30 weeks were excluded as they had limited time for exposure to TDS. All participants provided written informed consent.

Theoretical Foundation

There were 3 learning and health behavior theories that were used to develop this intervention: the Cognitive Load Theory, the Health Belief Model, and the Theory of Self-Efficacy. Each is discussed herein. Prior work from our group has applied Cognitive Load Theory [30,31] to frame the demands of pregnant women's diabetes burdens, yielding a model of barriers and facilitators. Cognitive load refers to a task's cognitive demand [31,32] and suggests that individuals have limited information-processing capacity, particularly with complex tasks [30,33,34]. Barriers included diabetes novelty, treatment disbelief, social instability and lack of support, limited nutrition comprehension and self-efficacy, psychological stressors, and logistical burdens of disease management [25,26,35]. Facilitators of self-care included self-efficacy, external motivation, supportive social and physical environment, and ability to self-regulate [29,36,37]. These findings formed the foundation for developing the TDS curriculum. In addition, 2 health behavior theories were applied to TDS development, as prior data suggest that effective interventions require a theoretical framework to derive the greatest benefit [8,13]. The Health Belief Model explains individuals' engagement in health behaviors [38]. The Theory of Self-Efficacy emphasizes one's belief in their ability to achieve their goals; learning and decision-making burdens of diabetes management demand self-efficacy, an issue particularly salient in pregnancy because of the short timeline for behavioral change [39,40].

Intervention Development and Structure

We worked with a multidisciplinary health professional team including obstetricians, Registered Dietitians, a Certified Diabetes Educator, an Advanced Practice Registered Nurse (Nurse Practitioner), and other clinic personnel to develop a comprehensive curriculum of >150 messages to be delivered via text message. Early versions of messages underwent cognitive testing with pregnant patients with both type 2 diabetes mellitus and GDM using *think alouds*, a commonly used approach that encourages participants to determine what specific words make them think or feel [41]. Messages were also iteratively reviewed with clinical providers.

Messages were refined based on early provider and patient feedback. Messages were then organized into a curriculum of 3 messages per week using 3 theory-based content categories: logistical support, motivation, and information and education. For example, informational messages provide content about healthy foods using the Health Belief Model, whereas the Theory of Self-Efficacy Commonly guides motivational messages. Logistical messages primarily applied Cognitive Load Theory and offered tactical support such as appointment reminders or tips for the management of diabetes. Messages were designed to contain tips, motivational statements, or reminders that address barriers and facilitators identified in preliminary data (Table 1). Each message consisted of 1 to 2 short sentences or phrases (<150 characters) written in low literacy (eighth-grade literacy level or less) level, nonslang language, and consistent with participant preferences.

Table 1. Texting for Diabetes Success example messages.

Barrier or facilitator addressed	Example text messages
Barriers	
Disease novelty^a	<p>Taking care of diabetes reduces your chance of high blood pressure and preeclampsia (toxemia).</p> <p>Pregnancy hormones make your diabetes worse. Blame the placenta, then show it who's the boss!</p>
Failure of outcome expectation^b	<p>Don't get frustrated! Stick with your diabetes plan over time to get the healthy results you want for you and your baby.</p> <p>Taking care of your diabetes during pregnancy gets you on track for life. Hard work now means a longer, healthier life</p>
Social chaos	<p>We know you have so much to do today. First thing on the list is making sure you and the baby are healthy - take care of your diabetes!</p> <p>Do you feel like you have the support you need? A healthy support system will benefit you and baby! Talk to us about resources at clinic.</p>
Nutrition comprehension and action^c	<p>Craving something crunchy and sweet? Grab a small apple and small handful of nuts. Eat healthy to control your diabetes during pregnancy.</p> <p>Try buying frozen veggies over raw ones, they can be cheaper and last longer! Vegetables can help control your blood sugar.</p>
Psychological stressors	<p>Sometimes women can experience stress from relationships in their lives. Talking about what's bothering you can be healthy for both you and baby. Tell us about it at clinic.</p> <p>Identify your emotions. Say, "I feel upset, I'm not hungry" instead of reaching for the snack.</p>
Burden of disease management^d	<p>Needles? Blood sugar checks? Ultrasounds? Too much to handle? Take it one day at a time, a healthy baby in the end will be your reward.</p> <p>You have an OB appointment at PAC tomorrow. Don't forget to come fasting and bring breakfast.</p>
Facilitators	
Diabetes self-efficacy	<p>We know you can do this! You can beat your diabetes!</p> <p>Are you feeling confident about your diabetes? Great, you've earned it!</p>
External motivation	<p>Having a hard time keeping up with your diabetes? Everything you're doing now helps your baby!</p> <p>Have kids at home? Your healthy behavior means you are a great role model.</p>
Supportive environment^e	<p>Make eating healthy a family affair! Involve the whole family with your healthy meal plan.</p> <p>Too hard to exercise near home? Try the park district or your neighborhood community center.</p>
Positive self-regulation^f	<p>Everything you do now helps you live a longer life and be there for your baby. Good job!</p> <p>Seeing target blood sugars? Good job, you're on the right track! If not, talk to us!</p>

^aRepresents the concept that diabetes and/or pregnancy are new learning concepts for the individual.

^bRepresents the concept that individuals may not believe that their actions will lead to the desired outcome.

^cRepresents the concept that nutrition recommendations may be both challenging to understand and challenging to execute.

^dRepresents the concept that having diabetes during pregnancy places a substantial burden on the patient to organize and complete logistical activities,

scheduling, monitoring, appointments, and other health-related tasks, above and beyond normal pregnancy.

^eRepresents the concept that individuals may have the support of other individuals (eg, family) or a supportive physical environment (eg, safe places to exercise).

^fRepresents an individual's ability to be responsive to feedback or data and then make subsequent changes in their health behaviors.

The overall curriculum was organized into 3 phases: a *ramp-up* at initiation, a middle period of sustained messaging, and a *wind down* at the end of pregnancy. All women received the same initial and end phases when possible; the quantity of the curriculum received in the intervening time was based on each woman's gestational age at entry. Acknowledging that women may have varying experiences with diabetes management based on their history, the ramp-up phase was intended to support the novel aspects of being pregnant with diabetes, regardless of prior experience, and provide pregnancy-specific motivation. No postpartum messages were provided. Messages were delivered via a web-based, one-way messaging system.

Participant Interviews and Analysis

After enrollment, participants completed demographic surveys that included queries on SMS text messaging access. Surveys were followed by brief interviews regarding experience with pregnancy and diabetes diagnosis, expectations for diabetes self-management requirements and burdens, and experiences with mHealth. Women then went through the remainder of the pregnancy receiving TDS.

After delivery, women underwent a 30-60 min exit interview about pregnancy struggles and support systems, experience of diabetes, and feedback about TDS. Feedback on TDS from this exit interview is the focus of this analysis. Women were asked about technical challenges, perspectives on content, positive and negative program features, favorite messages, feedback on frequency and timing of messages, and how the messages affected diabetes self-management. Women were asked about how the program supported them, if they would recommend it, and potential areas for expansion or improvement.

All interview questions were open-ended with probes as needed. Women were encouraged to speak freely and were informed that they could decline to answer any questions and that their responses would not affect their medical care. All interviews were audio recorded and conducted by trained research staff. We aimed to recruit a minimum of 30 participants to gain adequate feedback to facilitate future programmatic improvements, with the final sample size and stopping point determined based on the achievement thematic saturation [25,26,29,41].

Interviews were transcribed verbatim by a study team member. Dedoose (Dedoose, LLC), a secure qualitative data analysis

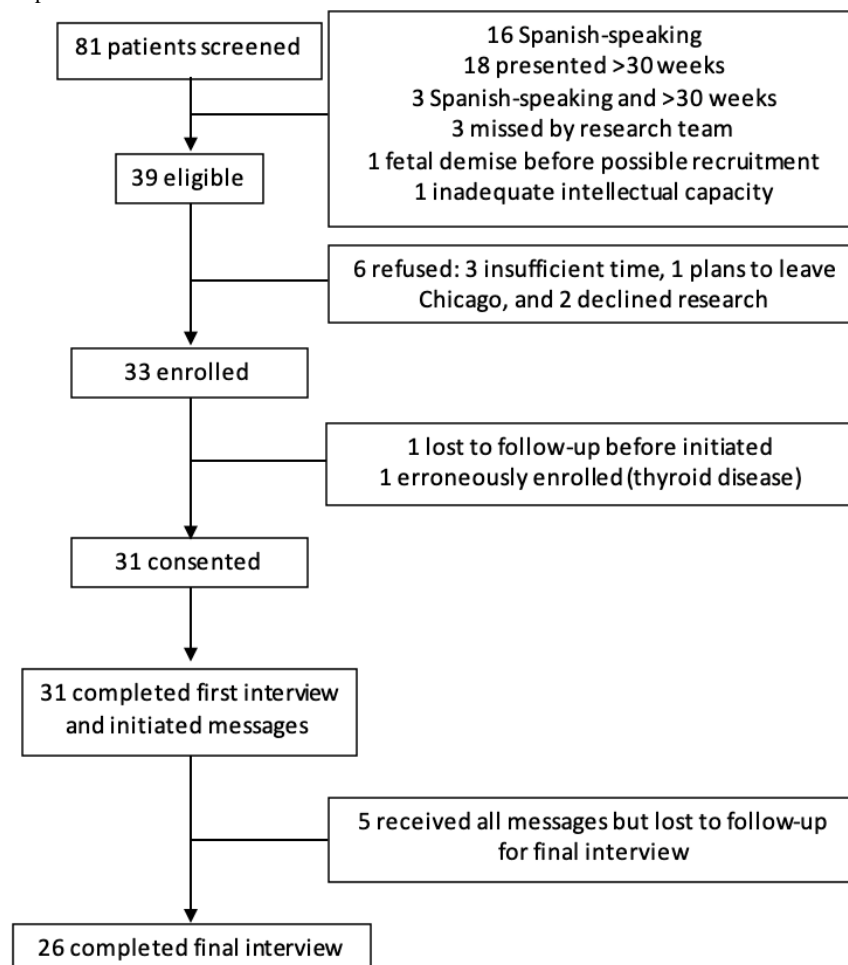
software, facilitated thematic analysis of the transcripts by 3 authors using the constant comparative method [42]. This analysis explores the themes regarding participant experience and perceived usefulness and applicability of TDS. Analysts initially chose transcript excerpts and performed open coding on the feedback themes. An initial codebook was established through exploratory analysis of all transcripts and was used by both analysts. Standardized operational code definitions were created via team discussions. Additional codes that emerged inductively during subsequent coding were added to the codebook. All codes were reassessed for effectiveness of capturing themes after initial coding; ineffective codes were removed or reclassified. Discrepancies between analysts in code applications were reviewed by the team and resolved via discussion. Interrater agreement was not calculated given the team-based iterative approach to analysis. This study was approved by the Northwestern University institutional review board.

Results

Participant Demographics and Text Messaging Access

Over an 8-month study period, 81 patients were seen in this practice and screened for eligibility, of whom 39 eligible women were approached for enrollment and 33 consented to participate. There were 6 women that declined participation because of insufficient time (n=3), plans to leave Chicago (n=1), or declining research participation (n=2). Of the 33 who consented, 1 was lost to follow-up (could not be reached) before the initiation of messaging and 1 was erroneously enrolled (did not have diabetes), leaving 31 participants who completed the first interview and received messages. Of these participants, 5 women were lost to follow-up before the final interview (could not be reached), leaving 26 participants who completed the exit interview (Figure 1). At the completion of 26 interviews, the team's review of the data determined that thematic saturation had been achieved.

Participant demographics (Table 2) were representative of the clinic population. In this cohort of largely non-Hispanic black and Hispanic women, 100% (31/31) had publicly funded prenatal care and 71.0% (22/31) were high school graduates. The majority were multiparous and had pregestational diabetes. The majority (93.5%, 29/31) had a phone plan allowing unlimited text messages, and all had smartphones.

Figure 1. Participant flow.**Table 2.** Participant demographic characteristics.

Characteristics	Values
Age (years), median (IQR)	31 (27-34)
Public insurance, n (%)	31 (100)
Race and ethnicity, n (%)	
Non-Hispanic Black	14 (45)
Hispanic	16 (52)
Asian	1 (3)
High school graduate or greater education, n (%)	22 (71)
Employment, n (%)	
Full time for pay	5 (16)
Part time for pay	7 (23)
Homemaker or student	12 (39)
Unemployed	7 (23)
Multiparous, n (%)	27 (87)
Married, n (%)	12 (39)
Pregestational diabetes, n (%)	21 (68)
Unlimited SMS text messaging plan, n (%)	29 (94)

Participant Experiences of Texting for Diabetes Success

Interviews explored participant experiences with TDS and perceived usefulness. Emergent key themes included *increased connectedness, providing new information, support with logistical burdens, improving motivation, and receiving emotional support* (Table 3).

First, the theme of *increased connectedness* included reduced social isolation and perceived closeness with the health care team. Several participants introduced the idea of feeling connected to their health care providers through TDS; by receiving 3 messages per week, participants reported an enhanced sense of follow-up and individualized attention from their health care team. Participant 10 explained:

I actually loved it...every time...I would see the message it was like okay what is it today?

Similarly, TDS prompted participants to interact with their health care team, leading to a perceived stronger connection. Additionally, text messages seemed to reduce social isolation associated with diabetes; Participant 9 noted it was helpful “knowing someone cared.”

The second theme was of *providing new information*. Many participants reported that TDS helped them by providing information to better manage their diabetes. Participant 20 reported:

Some of the information was new, but some I already knew. But it's not...hard to go over it again. Because a lot of us women that are diabetics, forget everything. You know and...me being 26 years old, we still don't know everything about diabetes. It's so much more out there, more to learn.

Similarly, Participant 25 stated:

Definitely...some of the messages encouraged me to look things online and just know a little bit more about the whole diabetes and being pregnant with it since there are so many risks with diabetes.

The third theme was *support with logistical burdens*. Participants nearly universally commented on logistical and appointment reminders as positive features. Participants perceived that TDS reduced logistical burdens associated with diabetes during

pregnancy, including remembering frequent appointments (via appointment reminders) and support for other logistical burdens (such as reminders for eating, transportation, or childcare). Appointment reminder messages may have led to fewer missed appointments for some women. For example, Participant 8 reported:

Yeah that was good because actually was forgetting and did forget one time that I had an appointment thinking it was in two weeks, and it was actually that week and [the message] came right in time letting me know that my appointment was the next day.

The fourth theme was of *improving motivation*. Participants reported that the messages provided strong motivation to push through the challenges of managing diabetes and focus on self-care for the benefit of their fetus and themselves. Participant 21 explained:

It's a way of motivation. To stay motivat[ed], you know help you understand it and give you ideas. And how to do reminders, you have [diabetes] but you can handle and take control of it.

Participants described how the messages motivated them not only toward positive behaviors but also away from negative behaviors. For example, participant 16 said:

Yeah, I mean they would stop me. Like the ones that would be like oh if you're craving this, why don't you eat an apple. And I was just like...how do they know! ...They would make me think before I did things or think like I wish I could be exercising right now.

The fifth theme was of *receiving emotional support*. As in our prior work [25], pregnant women with diabetes commonly report feeling socially isolated and emotionally stressed by the added burdens of a complicated pregnancy. Women in TDS reported that the connectivity of the program provided important emotional support to reduce stress, maintain positivity, and enhance self-efficacy. Participant 6 reported:

...you're going through a lot of hormones when you're pregnant. So it was like days I was feeling down. And I would just read the text messages and I would be like okay don't give up, everything will be better. I don't know, it was different [after receiving messages]

Table 3. Participant experiences of Texting for Diabetes Success.

Themes	Exemplary quotations
Increased connectedness	<p>“Yeah, I did and I remember one time I received a text message and I think it was one had to do with the fruit. And I ended up eating something sweet and it didn’t affect my blood sugar, but I was like oh I wish I would have gotten my message a few minutes earlier because it would have stopped me.” (Participant 33)</p> <p>“Um I didn’t really use like I didn’t really use the recipes or anything like that, but I’ll say that it was a reminder like hey you know if I’m- They’re random so I could have been going to the store or something and buying something, hey I wanna buy that, but then I get a text message and I’m like oh maybe I shouldn’t be buying that you know, maybe I should go for a healthier choice because I have gestational diabetes and I shouldn’t be eating that. So I – I guess it poses as a reminder to do better.” (Participant 14)</p>
Providing new information	<p>“Ya know, I love the text messages. The text messages, they really help me, they really help me figure out a lot of things too and more about my diabetes. More of getting activity, getting rest, stuff like that I will always get a text message in the morning” (Participant 20)</p> <p>“I guess because when you’re in the situation of being diabetic you want to hear something you know funny or you know just to give a little fix to your little life there you know, it brings up...you know to do what you have to do and you know those type of sources [resources] will help a lot yeah.” (Participant 10)</p>
Support with logistical burdens	<p>“No I think it was pretty thorough but yeah the appointment reminders were very very good. I think it helps when you’re a mom already and you have things that you have to juggle around, the appointment reminders are helpful.” (Participant 13)</p> <p>“Thanks to the text messaging, I got reminders of my appointments to help me keep track, reminding me when to go and like what kind of ideas I could um be eating to stay away from the foods that are high in carbs.” (Participant 2)</p>
Improving motivation	<p>“That’s another support that you kind of have. Someone that’s not involved in your everyday life so to me it was very encouraging, you kind of have that little push.” (Participant 25)</p> <p>“I mean I think it helped with the motivation a lot. I mean you know the days when you’re like, hey I don’t want to do this or it’s ok to have, have a couple of pieces of this instead of just none or half to go back and look and ok no you need to take care of this. This is for you, this is for you child, it’s not for anyone else.” (Participant 21)</p>
Receiving emotional support	<p>“I think everything was perfect, because like I’m telling you I would forget sometimes to check my sugars and even sometimes when I was like getting stressed, those texts and someone would send me the text messages and they would lift me up.” (Participant 23)</p> <p>“I liked the...sometimes when I, when I was like tired or you know just sitting down and I received that text that was like a little extra push you know. If you feel stressed or go out and drink water or the changes of the recipes they were kind of fun.” (Participant 26)</p>

Recommending TDS

Women were asked to highlight positive programmatic feedback, including describing whether they would participate in TDS again or recommend it to a friend. Of the 26 women who participated in the exit interview, 23 would recommend TDS to a friend, whereas 2 would not, both of whom said they would recommend future more personalized versions. Participant 10 noted:

I would [recommend TDS] especially if she’s in the same situation. I mean it’s going to be stressful, it’s going to be hard, but I would recommend just because it teach you more resources apart of the clinic.

Similarly, participants reflected on the stresses of pregnancy and how their experiences with TDS influenced their self-care and attitudes toward the intervention. In reflecting on this experience, like many other participants, Participant 20 explained the multitude of reasons why she felt positively about her participation:

Every text message that you have gave me, sent to me, it was very good. There were no text messages

that were boring. They were, they were getting to the point. They were understandable. And it was like a wakeup call. This is what you gotta do for your baby and yourself, to have a healthy baby, to have a healthy life. Ya know, I love the text messages...they really help me, they really help me figure out a lot of things too and more about my diabetes. More of getting activity, getting rest, stuff like that I will always get a text message in the morning. And be like ok this is my daily routine.

When asked about TDS drawbacks, some participants explained that they could not identify any. Participant 30 stated:

I mean it pretty much kept me aware of you know staying on track and it also alerted me to keep up with my doctor’s appointment...and it also gave helpful tips...Everything was helpful. There wasn’t anything negative stuck out to me with text messages or anything.

Participant 32 similarly summarized:

They would help you understand what to do and how to do it as far as what to eat and if you were to forget something or if you were to overeat or something how you would handle that. So it was very helpful.

Areas for Improvement

Participants were encouraged to share areas of improvement to aid future development (Table 4). There were 4 major areas for expansion that were highlighted, including *individualized/customizable messages*, *interactive features*, *more frequent messages*, and *more recipes*.

The first theme was the desire for *individualized/customizable messages*. Women desired the program to reflect their names and other personal features. Others similarly desired that the program be tailored to personal psychosocial, medical, or logistical needs. Participant 4 shared:

If it was more individualized and I knew that I was receiving these text messaging for me personally for what I was going through and dealing with the diabetes then yes, it would have helped me more. Cuz then it would have prompted me to say, to read them, cuz I would say oh man okay you know this is something...I would have read it based on I knew it was for me.

The second area that was nearly universally highlighted was the desire for *interactive features*. Some women desired a feature that allowed for conversation with their health care team. Participant 20 elaborated:

It should be like chatting...If a diabetic don't know what this is and she [texts] something, we can text her back what to do.

Other suggestions for an interactive platform were largely geared toward having user-friendly pictures, multimedia inclusion, or the ability to seek more information, suggestive of a smartphone app. For example, women desired pictures, links to resources, a library of resources, and a greater ability to access reliable content outside of the messages. Another interactive suggestion included the opportunity to share or read individualized stories of other pregnant women.

Third, women desired *more frequent messages*. Participant 14 shared:

I think it could be more, not annoying more but maybe like one more, just one in the beginning of the week and then one at the end of the week.

Participants commonly requested 4 to 5 messages per week, indicating that they were open to more frequent touch points for the motivational curriculum.

The fourth theme was the desire for *more recipes*. Women expressed that they would have appreciated more suggestions for snacks and recipes they could incorporate into their diets. Participant 3 stated:

I would like to have seen more recipe or...suggestions how to change because very often you're used to having mashed potatoes and if you want mashed potatoes it's better to have sweet potatoes or you know alternatives. That I would have liked to see more of that stuff.

Table 4. Texting for Diabetes Success areas for improvement.

Themes	Exemplary quotations
Individualized or customizable messages	<p>“Now that would have been very much helpful. If it was more individualized and I knew that I was receiving these text messaging for me personally for what I was going through and dealing with the diabetes then yes, it would have helped me more.” (Participant 4)</p> <p>“Um during the week um or you know at the end of the week or at least once a weekend that will be very helpful to maintain those weekends because you know sometimes you have on your mind okay if I do really good during the week then you cheat on over the weekend” (Participant 12)</p>
Interactive features	<p>“That’s good because when you’re pregnant its hard, it’s very hard. Especially I mean, especially because of the baby you try to eat good you know but it’s still hard, but I think it just would work. I would put a bag of chips and then something nutritional next to it like kind of but yeah I think pictures would work out yeah, especially for an app.” (Participant 23)</p> <p>“I think uh support stories would be fine to go in there you know women who have experienced it and you know overcame it or women who still have diabetes after gestational.” (Participant 30)</p>
More frequent messages	<p>“Honestly I think that you should go up to five [messages]. ‘Cause once it get towards the end of the pregnancy, you need all the support you can get. Even if it’s from a text message that comes out of the blue like “hey, it’s almost over, we’re doing good, we can get through this.” Really you don’t know how much that really helped.” (Participant 28)</p>
More recipes	<p>“The messaging program helped a lot. I would recommend like a couple recipes like once a week or once a month. Hey here’s a great snack recipe or here’s a great lunch recipe or something” (Participant 21)</p>

Discussion

Principal Findings

Diabetes during pregnancy is a major public health problem with important and long-lasting consequences for both women and their children. Innovative interventions to support pregnant women with diabetes self-management are lacking. Thus, we developed a theory-driven SMS text messaging program not only to provide psychosocial support but also to promote self-management skills and provide tactical support for pregnant women with diabetes. This intervention was feasible and well-received. Pregnant women with diabetes who were enrolled in this pilot study of an SMS text messaging curriculum for diabetes support described enhanced motivation and improved knowledge and comfort with diabetes self-care activities. Participants also had several suggestions for improvement, largely based on personalization and interactivity.

Although evidence-based mHealth interventions beyond general tracking and education provision for pregnant women are lacking, interest in such programs is high. The majority of pregnant women, including low-income and minority women, are interested in and have access to mHealth [43,44]. We found that access to this simple mHealth method—SMS text messaging—was high. Our findings mirror other reports on the growing interest in mHealth for pregnancy topics. Text4baby, for example, delivers health promotion messages to enhance general pregnancy behaviors and may positively affect health attitudes, although it is not specifically designed for women with diabetes [27,28,45,46]. GooDMomS is a web-based program that incorporates patient tracking, social networking, and weekly text messages and, in a small feasibility study, has shown promising preliminary results in assisting pregnant women with GDM manage diet and weight, although participants were largely nonminority and commercially insured women [47]. Related research has shown that culturally tailoring mHealth interventions to minority groups is vital to their success, thus underscoring the rationale for programs such as ours [48]. However, many programs still lack rigorous evidence-based or user-centered design [12], are designed for or studied among primarily nonminority women [47,49], are intended for general pregnancy support/tracking, or fail to address diabetes-specific needs [50,51]. Our findings point to the importance of addressing the myriad logistical, informational, social, psychological, and financial barriers to successful perinatal management of diabetes in the development of interventions [21-26].

Treatment of diabetes during pregnancy poses particularly complex challenges for low-income women. Multidisciplinary teams and treatment plans aim to optimize glycemic control and prevent complications via implementation of medical nutrition therapy, exercise, medication, and enhanced maternal-fetal surveillance [1,2]. Thus, perinatal care for diabetes necessitates advanced patient education and engagement along with communication, literacy, and organizational skills [25]. Such treatment requirements are particularly burdensome for women with a greater social disadvantage [21,22], who have multiple social and structural

challenges to diabetes management [21-26,52]. Thus, an mHealth intervention that reduces these burdens may be particularly impactful and needed in this community. Ultimately, given the limited ability of in-person care to improve health behaviors, the implementation of mHealth interventions such as TDS may significantly enhance the care provided by the health care team [53]. Furthermore, when designed with both patient and clinician input to offer ongoing support beyond simply tracking glucose results, motivation-focused mHealth programs may be especially successful.

The next steps include enhancing the interactive features of TDS, scaling to a *high-tech* mHealth app, and investigating the effect of TDS on maternal and perinatal outcomes. Participants provided specific feedback about expansion opportunities. They were highly motivated for curriculum delivery via smartphone-driven technology, which they felt would best support their behaviors because of familiarity with other apps, the ability of an interactive and individualized app, and the desire to interact with an app on their own terms. Smartphone technology allows participants to interact with a technology-driven intervention in a nuanced, user-driven manner; for example, *favoriting* a message to view later is only possible with a smartphone. Smartphone architecture also allows the greatest flexibility for feature expansions; for example, merging an appointment reminder system, which was highly desired by participants, with an individual's smartphone-based calendar may further enhance usability. Moreover, widespread smartphone availability, even in low-income communities, suggests that such an advancement may be widely accessible [43,54,55]. Advancement with such features may appeal to patients and enhance scalability for staff.

Strengths and Limitations

A major strength of this study is the inclusion of a diverse group of participants who provided in-depth narrative perspectives. Furthermore, the intervention was developed with a robust theoretical underpinning and provided evidence-based, expert-driven content developed to meet the needs of the population of interest. Moreover, unlike interventions that primarily track glucose values, TDS included a curriculum for motivation and support. This approach is novel and supports the importance of patient-centered perspectives when developing health interventions.

However, there are several limitations to consider. Participants were primarily English-speaking women receiving care at a single academic medical center. Thus, as is common in qualitative research, findings are not widely generalizable, although they remain valuable for future intervention improvement. Second, although participants represented the demographics of the clinic population, participants may interact with mHealth differently than nonparticipants. Similarly, a small number of participants were unable to be reached for their exit interviews, and their experiences may have differed. Participants also included women with prior diabetes experience, including women with pregestational diabetes and women with gestational diabetes who had a history of gestational diabetes in prior pregnancies. Given the sample size, it was not possible to assess differential attitudes based on when diabetes was diagnosed or

the type of diabetes diagnosis, although this topic is of critical importance for future intervention development. Future work may investigate differences in support needs and mHealth adoption based on diabetes type, prior experience with gestational diabetes, or other demographic characteristics, such as educational attainment. Finally, TDS was delivered without the ability to determine the proportion of messages received or read.

Conclusions

In summary, pregnancy is a critical time period to improve women's short- and long-term health, and improving support for women with diabetes has the potential to positively affect

the health of families [6]. Pregnant women are motivated to improve health behaviors [56-58], and thus this period has the potential to spark lifelong behavior changes [59,60]. This pilot assessment of an SMS text messaging support program for pregnant women with diabetes demonstrates that offering such support to low-income women is desirable and feasible. Future areas of work include advancing the curriculum to meet the preferences and needs of this population and to promote its sustainability and scalability. Ultimately, the refinement, testing, dissemination, and implementation of interventions such as this may fill the gaps needed to positively influence women's self-care behaviors and pregnancy outcomes.

Acknowledgments

This study was supported by the Evergreen Invitational Women's Health Grants Initiative. LY was supported by the NICHD K12 HD050121-11 at the time of the study.

Conflicts of Interest

None declared.

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Abbreviations

GDM: gestational diabetes mellitus

mHealth: mobile health

TDS: Texting for Diabetes Success

Edited by D Griauzde; submitted 13.01.20; peer-reviewed by S Crimmins, S Buchholz; comments to author 07.05.20; revised version received 01.06.20; accepted 07.06.20; published 10.08.20.

Please cite as:

Yee L, Taylor S, Young M, Williams M, Niznik C, Simon M

Evaluation of a Text Messaging Intervention to Support Self-Management of Diabetes During Pregnancy Among Low-Income, Minority Women: Qualitative Study

JMIR Diabetes 2020;5(3):e17794

URL: <http://diabetes.jmir.org/2020/3/e17794/>

doi: [10.2196/17794](https://doi.org/10.2196/17794)

PMID: [32773367](https://pubmed.ncbi.nlm.nih.gov/32773367/)

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Original Paper

User Experiences With a Type 2 Diabetes Coaching App: Qualitative Study

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Abstract

Background: Diabetes self-management apps have the potential to improve self-management in people with type 2 diabetes (T2D). Although efficacy trials provide evidence of health benefits, premature disengagement from apps is common. Therefore, it is important to understand the factors that influence engagement in real-world settings.

Objective: This study aims to explore users' real-world experiences with the *My Diabetes Coach* (MDC) self-management app.

Methods: We conducted telephone-based interviews with participants who had accessed the MDC self-management app via their smartphone for up to 12 months. Interviews focused on user characteristics; the context within which the app was used; barriers and facilitators of app use; and the design, content, and delivery of support within the app.

Results: A total of 19 adults with T2D (8/19, 42% women; mean age 60, SD 14 years) were interviewed. Of the 19 interviewees, 8 (42%) had T2D for <5 years, 42% (n=8) had T2D for 5-10 years, and 16% (n=3) had T2D for >10 years. In total, 2 themes were constructed from interview data: (1) the moderating effect of diabetes self-management styles on needs, preferences, and expectations and (2) factors influencing users' engagement with the app: one size does not fit all.

Conclusions: User characteristics, the context of use, and features of the app interact and influence engagement. Promoting engagement is vital if diabetes self-management apps are to become a useful complement to clinical care in supporting optimal self-management.

Trial Registration: Australia New Zealand Clinical Trials Registry CTRN126140012296; URL <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=366925&isReview=true>

(*JMIR Diabetes* 2020;5(3):e16692) doi:[10.2196/16692](https://doi.org/10.2196/16692)

KEYWORDS

type 2 diabetes; mobile phone; mobile apps; mHealth; smartphone; self-management

Introduction

Background

By 2045, 693 million people will be living with diabetes, the majority with type 2 diabetes (T2D) [1]. Diabetes

self-management behaviors, including blood glucose monitoring, healthy eating, being physically active and taking prescribed medications, can improve diabetes-related outcomes, reduce complications, and improve quality of life, but these behaviors can be difficult to initiate and sustain [2]. Diabetes self-management education and ongoing support are critical for

establishing and maintaining self-care routines [3]. However, the uptake of face-to-face educational programs is low because of several factors, including difficulty in attending because of medical, financial, or transport issues; lack of perceived benefits; and shame and stigma [4-7]. Furthermore, the provision of ongoing support is difficult because of resource constraints and issues of reach and scalability [5]. An increasingly common strategy to address these challenges has been to use smartphone apps as a means to deliver diabetes education and self-management support to complement clinical care.

The evidence for the efficacy and acceptability of diabetes self-management apps is increasingly robust [8-11]. However, research trials typically focus on overall efficacy, not individual differences in user experiences, and cannot shed light on factors that influence engagement [12-14]. This is a gap that needs to be addressed if apps that demonstrate efficacy in controlled trial settings are to be translated into effective real-world interventions [15,16].

The lower engagement, or lack of thereof, with diabetes self-management apps is often attributed to a mismatch between what people with T2D want and the functions provided by apps, loss of motivation, and the difficulty integrating app use into everyday life [17-22]. Research suggests that multiple factors, including treatment, attitudes to self-management, and existing knowledge, influence the needs and preferences of people with T2D [22]. For example, people with newly diagnosed diabetes favor apps that educate them about diabetes, whereas those with more experience of living with and managing diabetes express frustration with basic education materials and are keen to see more *cutting edge* news and links for further reading [23-25]. Those who have been living with diabetes for longer engage with technology to refine care routines, whereas those less experienced use diabetes self-management tools to establish routines, for example by troubleshooting out-of-range blood glucose readings [20,26]. Finally, those with more experience are less willing to explore new options, including apps, especially if the benefits are uncertain, and the effort is substantial [27]. Unfortunately, participants in these studies were asked either to give feedback on apps they had not used before or to use unfamiliar devices. These limitations precluded an in-depth examination of user experiences over time and in the context of participants' everyday lives.

Objectives

Therefore, this study aimed to investigate users' experiences of a diabetes self-management app (*My Diabetes Coach* [MDC]) accessed via personal devices and used in the context of everyday life over a prolonged period and to understand the interplay between users' characteristics, needs, and preferences and engagement with a diabetes self-management app.

Methods

Design and Ethics

This qualitative study was a substudy of a randomized controlled trial testing the efficacy of a T2D self-management app MDC. The trial was conducted from 2014 to 2018 (Australia New Zealand Clinical Trials Registry ID ACTRN12614001229662) [28,29]. The University of Melbourne's human research ethics committee approved this study (HREC number: 1442433). In-depth, semistructured interviews were conducted to evaluate the MDC app in terms of users' experiences. We used a qualitative approach to explore subjective perspectives constructed from the experience of people with T2D using a self-management app in the context of their everyday lives [30]. This report is consistent with the consolidated criteria for reporting qualitative research checklist ([Multimedia Appendix 1](#)) [31].

Intervention Description

The MDC app was designed to provide education, support, and feedback on diabetes self-care using weekly sessions or *appointments* with an embodied conversational agent *Laura* ([Figure 1](#)). Laura had human-like characteristics and mimicked human conversation using interactive voice recognition (IVR) and a database of prerecorded conversational elements. Laura conversed with users either via spoken voice or text, using sophisticated script logic. The app's script logic was personalized by incorporating information and targets provided by users' health care professionals (eg, blood glucose monitoring targets). Users were able to respond to Laura by speaking, inputting text, or touching an option on the screen. The program was designed to enable responses made in a preceding session to dictate the direction of the next session with the user, enabling a high degree of personalization.

The first *appointment* with Laura was scheduled to suit the user and thereafter occurred at the same time every week, with some flexibility, enabling users to complete their appointment up to 48 hours after the planned time. Users could choose a particular module from those available but were required to complete the module over a series of sessions before moving to a new one. Available modules included blood glucose monitoring, nutrition, physical activity, medication taking, and foot care. The app applied several gamification elements, including goal setting, monitoring of progress, feedback, and quizzes [32].

Throughout the trial, users had access to a program coordinator to assist them with technical difficulties. They were also given an Accu-Chek Advantage blood glucose monitoring device with Bluetooth capabilities (Roche Diabetes Care), enabling the automated upload of glucose data to the MDC app. Finally, the app had inbuilt links to a website with diabetes resources and a user guide for the app.

Figure 1. Embodied conversational agent Laura.



Study Participants and Recruitment

Invitations to participate in the MDC trial were sent by mail to adults with T2D (in New South Wales, Queensland, Victoria, and Western Australia) registered with the National Diabetes Services Scheme (NDSS). Participants were eligible if they were adults aged 18 years or older, diagnosed with T2D, registered with the NDSS for <10 years, had access to a smartphone (with an operating system of at least iOS 8.0 for Apple devices or OS 4.2 for Android), and fluent in the English language. The exclusion criteria were as follows: women who were pregnant or planning to become pregnant; individuals reporting severe comorbid conditions that would prevent participation in the trial; and individuals on nonstable doses of diabetes-related medications.

Interview participants for the qualitative study were recruited from the intervention arm of the MDC trial, all of whom had accessed the MDC app for up to 12 months. Purposive sampling was used to achieve variation in user characteristics, including age, gender, education, occupation location, duration of T2D, and use of the app (operationalized as the number of completed chats).

Data Collection

Participants were sent a plain language statement describing the study and were required to provide written consent. Participant characteristics were collected at baseline via a self-report questionnaire, including demographic and clinical details and current health app use.

An interview guide was developed to include questions about the user's self-reported diabetes expertise, how they managed

their diabetes, when and how they engaged with the app, and their experiences using it. In-depth semistructured interviews were conducted through telephone (by SB) and recorded using SmartInteraction Suite, a cloud architecture voice recording solution (CTI Group). SB has several years of experience in diabetes-related research, including conducting telephone interviews. She worked as a research assistant on the MDC project and was involved with program development, participant recruitment, and data collection. Many of the participants had previously interacted with her. At the beginning of each interview, SB summarized the research and reasons for her interest in it.

The first 2 interviews were analyzed, and changes were made to the interview guide to capture additional information on the context of use and feedback on the timing and delivery of sessions. Data included researcher observations and postinterview notes. Data collection continued until saturation was achieved (19 interviews), as indicated by the recurrence of themes and no new themes emerging. Recordings were stored in a secure cloud-based location and transcribed verbatim by an accredited transcription service with privacy certification. During each interview, SB kept notes of points of interest and used these as prompts. Immediately after each interview, SB prepared a written summary of the interview and relevant observations. These were used to communicate interim findings to the wider research team. When appropriate, additional questions were added to the interview guide, allowing for further exploration of issues raised by participants that were relevant to the research aims. These notes were also used to guide meaningful interpretation of data during data analysis.

Data Analysis

Descriptive statistics were computed for demographic and clinical characteristics and current app use using SPSS version 25 (IBM Corp). Data are presented as mean (SD) or number (percentage). Raw interview data were imported into NVivo 11 (QSR International) for coding and analysis. We followed 6 steps for the thematic analysis with the development of themes guided by a priori objectives identified in the aims: (1) data familiarization, (2) identifying initial codes and developing a coding framework, (3) identifying potential themes, (4) matching themes to the supporting data, (5) defining and naming themes, and (6) extracting relevant themes and producing a description of findings [30,33]. SB and GW coded the data. A constructionist approach, focusing on social conditions (user

profiles and context of use) and structural conditions (app features and delivery of content), was used to interpret the data.

Results

Overview

A total of 19 adults with T2D were interviewed (mean age 60 years, SD 14 years; 42% women). Additional participant characteristics are detailed in Table 1. Interview participants were older, more educated, had a lower baseline hemoglobin A_{1c}, and used the app twice as much as those in the intervention arm of the MDC trial. The mean duration of the interviews was 51 min (range 29-79 min).

Table 1. Participants' demographic and clinical characteristics and current app use.

Characteristics	MDC ^a trial (intervention arm) sample (n=93)	MDC interview participants (n=19)
Gender (female), n (%)	44 (47)	8 (42)
Age (years), mean (SD)	55 (10)	60 (8)
Education (highest level), n (%)		
Year 10	10 (11)	5 (26)
Year 12 or apprentice	42 (45)	2 (11)
Graduate/postgraduate	41 (44)	12 (63)
Employment status, n (%)		
Paid employment	59 (64)	7 (37)
Retired	22 (23)	11 (58)
Unemployed or other	12 (13)	1 (5)
Diabetes duration (years), n (%)		
<5	43 (46)	8 (42)
>5 to 10	29 (31)	8 (42)
>10 to 20	7 (8)	3 (16)
Unknown	14 (15)	0 (0)
Hemoglobin A _{1c} (%), mean (SD)	7.3 (1.5)	6.8 (0.9)
Hemoglobin A _{1c} (mmol/mol), mean (SD)	56 (44)	51 (20)
General app use, n (%)		
Multiple times per day	69 (74)	14 (74)
Once a day	23 (25)	4 (21)
Less than once a day	1 (1)	1 (5)
Interactions with the MDC app (number), mean (SD)	18 (15)	36 (17)

^aMDC: My Diabetes Coach.

Themes

A total of 2 high-level themes were constructed from the data: (1) the moderating effect of diabetes self-management styles

on needs, preferences, and expectations and (2) factors influencing users' engagement with the app: one size does not fit all. These comprised several subthemes, as described in the following sections (summarized in Textbox 1).

Textbox 1. Interview themes and subthemes.

Moderating effect of diabetes self-management styles on needs, preferences, and expectations

- Self-directed versus externally directed self-management styles
- Group differences in app preferences

Factors influencing users' engagement with the app: one size does not fit all

- Interaction mode preferences
- Minimizing disruption to everyday life
- Initiating engagement

Theme 1: Moderating Effect of Diabetes Self-Management Styles on Needs, Preferences, and Expectations

This theme describes variations in self-management styles and how these influenced app preferences.

Self-Directed Versus Externally Directed Self-Management Styles

When asked to describe how they managed their diabetes and their diabetes knowledge before using the MDC app, participants expressed very different levels of autonomy, motivation, and efficacy. Of the 19 participants, 11 described themselves as having always had an independent, self-directed self-management style. For example, they were intrinsically motivated to seek diabetes-related information when they were first diagnosed, saying:

I'm a bit of a researcher because it's about my own health.

They also expressed confidence in their diabetes knowledge and self-care ability, describing themselves as experts in their own care and comparing themselves with “other people [with] diabetes [who] don't have as much knowledge.” A common shared characteristic was that they used their smartphones for “just about everything” and reported previously using health apps to help them achieve their health goals.

In contrast, the remaining 8 participants expressed a more externally directed style and did not engage in independent information seeking. Instead, they preferred to rely on their health professionals and diabetes organizations for diabetes-related information. They expressed less confidence in their diabetes knowledge, describing it as limited to “only what the doctor has told me.” As they did not seek diabetes information at diagnosis, they referred to being “very lost in the beginning, [because] nobody tells you anything.” Although most participants used computers and tablets, they were not as comfortable with smartphones, only using them for phone calls and text messaging: “the mobile, it's just for [an] emergency.” Consequently, these participants were less likely to report using other health apps.

When asked to describe their experiences with the MDC app, there were clear differences between participants expressing a self-directed versus externally directed self-management style in terms of their needs, preferences, and expectations.

Group Differences in App Preferences

The self-directed participants described how support via an app should ideally account for their existing diabetes expertise and be presented to enable them to have the final say in their care:

If I can summarize what I look for, it's not so much “tell me what the answers and solutions are, but give me the information, give me the options, I'm making this decision.” I'm not looking for hand holding.

Consequently, facilitating decision making by enabling easy tracking of multiple sources of health-related data was a key consideration. For example:

Track the things that I want to track, daily readings, weight, blood pressure, record medication [and] blood test results and probably 15 other things that are important to me. If you can't record something, you can't control something.

The purpose of tracking was to refine established routines and identify how specific actions, for example, taking certain supplements such as *Chromium Picolinate 400 mg*, related to *actual changes*, such as lowering blood glucose levels from 7.1 to 6.5. The other purpose of tracking was to facilitate changes to self-management, for example:

When I'm making a change in my own practices: to closely monitor things when I'm increasing my exercise.

Curated, in-depth information was another vital feature for this group: “my motivation in using an app is [only] to get information.” They were interested in exploring a wide range of topics:

I'm interested in the technology of diabetes care, I'm interested in stuff all over the place, like reading about the impact of sugar on muscle.

It was important that the information was reliable, like *Cochrane Reviews* and *curated*, that is, organized in a way that enabled them to distinguish *basic information* from *in-depth discussion*.

Conversely, what was most helpful for participants with a more externally directed self-management style was not having to search out and evaluate diabetes information:

The information is provided, you don't have to go searching for it, and that's what's convenient.

Without this easy access, one participant described how they “wouldn't have looked [it] up... because lazy people don't do

that.” There were other instances where these participants described needing additional motivational support. For example, one person said they “get lazy,” and another said:

I'm one of these people - I go really good at something for a while, and then I get a bit slack and then I stop doing stuff.

This may explain why this group appreciated attempts at gamification and making learning fun, describing novel features of the app, such as IVR and the relational agent, as being “exciting,” “more interactive,” “cool and unique,” and increasing their “interest.” However, those who described a more autonomous self-management style were less receptive of attempts at increasing engagement such as gamification (eg, quizzes), which for them did not “add or detract from the experience” and were dismissed as examples of “the same information presented in a different way.”

Perhaps because of their experience using other health apps, the group expressing more self-directed self-management styles had higher expectations of the MDC app and were less tolerant of technical issues:

It has to be reliable because that's my expectation now of apps and other things and I can always find an alternative these days.

They expected flexibility in navigating through the MDC app in a way that suited them. For example, “a little less linearly,” with “a higher degree of user control in terms of being able to investigate down particular information paths and then back out of them.” They wanted the choice to be able to skip a particular topic if it was not “relevant” or “to go back over information” later through increased “searchability” if they found a topic particularly interesting.

On the other hand, participants from the other group did not have much experience with using apps and, therefore, were more forgiving of technical issues, for example, “just teething problems because it was so new.” However, because this group tended to limit their smartphone use to phone calls, they expected to be able to use the MDC app on their tablet device:

I'm one of these people that think a mobile phone is a mobile phone, and if I want to do anything else I go to the iPad.

Theme 2: Factors Influencing Users' Engagement With the App: One Size Does Not Fit All

This theme describes how participants engaged with the app, specifically the context, mode, frequency, and duration of interactions and the factors influencing these choices.

Interaction Mode Preferences: “I Could Read Quicker, So I Chose to Not Listen”

Participants could choose one of the multiple ways to interact with the MDC app. First, they could use the built-in IVR technology to listen to what the embodied conversational agent Laura said and respond using the microphone. Second, they could listen to what Laura said but respond by touching one of the options on the screen. Third, they could choose to ignore or

mute Laura’s voice, read the text on the screen, and respond by touching an option on the screen.

The novelty of being able to interact with Laura using IVR was described by some as “exciting” and “more interactive.” However, most users, regardless of their self-management style, soon discontinued their use of IVR, choosing instead to read the text and respond by touching one of the options on the screen. The primary reasons were that IVR did not offer any obvious advantages and had some drawbacks. For example, using IVR as a mode of receiving and responding to messages within a session took much longer than reading the text and tapping in a reply:

There was nothing wrong with the pace of her speech, it was just that I could read quicker, so I chose to not listen to her.

Technical difficulties were also a hindrance:

She didn't understand me [laughs]. I found that frustrating.

The context of use also influenced the choices of users. For example, many described the IVR function as inconvenient because of their surroundings, for example, “I was always doing it in the bedroom in the morning when my husband was still in bed asleep” or “I didn't use it, because most of the time I was on the train.” Some participants also described talking to the phone as unnatural: “I think it just looked silly, to be talking to your phone.”

Giving the user a choice to opt out of using IVR and use other interaction modes was critical. As one participant put it:

If I had to have talked to her, I think I would have pulled out!

Minimizing Disruption to Everyday Life: “It Wasn't a Problem to Find a Half an Hour”

The MDC app required participants to complete a session with Laura once a week at a time that suited them. A weekly appointment suited most, as “any more would become a chore” or “just too much.” The discipline of a regular weekly appointment was viewed favorably because it increased commitment:

If I did it my own way, I wouldn't have done it. I think an appointment time kept me accountable.

Another positive attribute was that they mimicked offline appointments, encouraging automaticity:

It was like an appointment with a doctor or going out for dinner with friends. You knew that at 6:30 Friday, you had to sit down and talk to Laura.

Another participant said:

Even my grandchildren would say to me, oh grandma, it's Thursday, and you've got to speak to Laura. I structured things outside of those times because I knew that time was taken. I did things around that time because it was to me a standard appointment.

Those in paid employment appreciated being able to choose a time that suited them:

I'm glad I could choose a time that suited me.

They also valued the flexibility of being able to complete chats within a certain time frame:

[If I missed my time] that was easy to get around, because you had 24 hours to actually go in and have the chat with Laura.

On the other hand, those who were retired had a set time every week and made the chat part of their schedule, with little to no variation from 1 week to the next “I'm retired now [laughs], so what else do I do?” or “I'm a creature of habit, and I like things to be ordered and I like the regularity, [so] I put it in the calendar.”

For those with busy schedules, the fact that the MDC intervention was divided into 15 to 30 minute chats, over several months, was a benefit and compared favorably with face-to-face diabetes self-management education and support programs:

It wasn't a problem to find a half an hour. When you've got to go off to some of these diabetes [education things] it's four-and-a-half hours! You try and find four-and-a-half hours when you work a 16-hour day, it just doesn't work.

Initiating Engagement: “You Need to Get [the App] in Front of People When They're in the First Days”

Participants unanimously emphasized the importance of access to an app supporting self-management immediately after the diagnosis of T2D as a means to come to terms with their diagnosis:

You need to get that in front of people when they're in the first days, [and thinking] “Whoa, what just happened to me?!”

Participants suggested that having an “introduction to the basic stuff, in a fairly accessible manner,” resulted in “the greatest benefit” and “greatest impact and usefulness.”

Many participants described diabetes education as nonexistent or insufficient:

Other than being prescribed medication, there was really nothing to support [self-management]

Others who had access described diabetes education as being “blunt, didactic stuff, do this, do that, do this,” with no attempt to account for their personal circumstances.

Insufficient time spent with the health care team was described as another barrier to receiving comprehensive information and understanding it:

I think for most people, they're getting information [from the app] they wouldn't otherwise have heard, unless their diabetes educators are very, very thorough, and you're visiting them once a week, and we don't do that. They [educators] don't have the time for that. Your GPs don't have the time to go through that information with you.

In some cases, the lack of education had the effect of delaying attempts at initiating lifestyle changes and self-management behaviors:

So, I was able to reject [my diabetes] and lived in a bit of denial. It took me quite a while to find and assemble a team of people that I felt could help me.

Participants consistently expressed the view that MDC would be “useful for someone who was newly diagnosed” to “help them transition”:

They need to be pointed in the right direction, because it will take them a while to find it if they're not pointed in that direction.

Many also acknowledged the potential role of health care professionals in facilitating access to and adoption of apps following diagnosis:

I would see a real benefit in ensuring that people like GPs, diabetic educators are made very aware of the app and that they actively engage patients on diagnosis with the app.

Another said:

The GP should be going, well here's your blood test results, download this app and learn what's happening and why it's happening.

Discussion

Principal Findings

This qualitative study investigated users' experiences of a T2D self-management app accessed via their own smartphones over a 9-month period in the context of their everyday lives. We identified 2 main themes: (1) the moderating effect of diabetes self-management styles on needs, preferences, and expectations and (2) factors influencing users' engagement with the app—one size does not fit all. We found that the needs, preferences, and expectations of diabetes self-management apps differed based on participants' self-management styles. The broad implication is that, in addition to previously identified characteristics, such as age, gender, and socioeconomic status, self-management styles also influence engagement and need to be investigated further [16,34,35].

Participants expressing self-directed rather than externally directed self-management styles were more likely to be proactive in seeking diabetes-related information and using other health apps [36,37]. A possible explanation for this finding may be found in the literature on *health consciousness*, defined as the extent to which an individual takes ownership of their own health condition [38]. Our data are consistent with previous evidence suggesting that individuals who are more health conscious may also be more self-directed in their information-seeking behaviors and more proactive in managing their health [39].

Our findings corroborate previous research on the benefits of personalization and tailoring while providing preliminary evidence on *how* app preferences can be personalized based on a specific user characteristic—diabetes self-management style [21,26,36,40]. For example, participants expressing more self-directed styles value tools that assist them in making independent, informed decisions about their own care. This suggests that to engage these users, messaging within an app

needs to be presented as volitional choices rather than explicit directives and needs to acknowledge the user as an expert in their own care [41]. Additional features that are likely to improve engagement by this group include in-depth, current, accurate information on a range of topics related to diabetes care; the ability to track, link, and interpret multiple sources of diabetes-related data; and a high level of flexibility in navigating the app.

Our study also corroborates previous research that shows that people who present a more externally directed self-management style may need additional encouragement to sustain engagement. Previous research suggests that changing attitudes to and motivations for diabetes self-management may be especially important for this group [3,42]. As diabetes is a self-managed condition, successful models of care, especially for those who are not intrinsically motivated, must focus on strategies that promote and maintain autonomy [43]. Strategies to improve engagement in this group could include gamification elements such as quizzes and features that promote accountability, such as goal setting and mechanisms that re-engage users, such as regular feedback [24,32,44,45]. It may also be useful to consider giving these users more customization choices, for example, the device they prefer, because many users were more comfortable with a desktop computer or tablet than with a smartphone.

Almost invariably, the participants did not use IVR because it did not provide any additional benefit. Our findings add to existing research that suggests that features, such as IVR, although novel and interesting initially, can deter or distract from the main objective of using an app over time, especially if they do not improve usability and require additional effort [46]. The implication is that novel features should be used with caution because they can be expensive to implement and may not have the expected benefit. At the very least, users need to choose to turn off features based on personal preferences. Optimizing functionality is key because ease of use and efficiency trump novelty when apps are used in the context of ongoing, real-world self-management of a chronic condition [27,44,47].

Many participants described receiving little to no diabetes education and support following diagnosis, and in some cases, this delayed engagement in self-management [48]. Making time for and having access to adequate face-to-face education and support are often challenging for people with newly diagnosed T2D [4,6,7]. Our data support previous research demonstrating that providing diabetes education and self-management support via an app could be a feasible and acceptable complement to clinical care [8-10,14]. Equally important is the suggestion that this support may be more successful in engaging people when accessed immediately following diagnosis [37,49,50].

Our findings suggest that the proposed contact frequency and duration (ie, weekly sessions of 15-30 min) was acceptable (even for those with busy schedules) and enhanced engagement, potentially through increasing accountability and automaticity [51]. Enabling users to choose a regular time fitting into their schedule and some flexibility in altering that time to fit with competing demands encouraged engagement. However, it was

clear that some limits on how the app was used were considered beneficial, even necessary, as many described how complete freedom could result in disengagement. Appointment reminders were useful, but only to those with a busy schedule because those who described themselves as less busy (eg, retired) preferred set appointment times and considered them to be part of an established routine, for which they did not need a reminder.

Finally, our data suggest that although diabetes self-management apps may be helpful in initiating and maintaining self-management behaviors, people with T2D are more likely to engage with an app when it is endorsed by their health care professional. There is some evidence to suggest that although health care professionals think apps may be useful, sourcing evidence-based, high-quality apps from the thousands available on the app stores remains a challenge [50,52,53]. Thus, initiatives are needed to provide health care professionals with reliable resources that enable them to choose quickly from a curated selection of evidence-based diabetes self-management apps while matching them with the individual's needs.

Strengths and Limitations

A key strength of this study is that it was conducted in the context of a randomized controlled trial of the MDC app. In contrast with many previous trials of self-management apps, participants used the app *in the wild*, that is, in the context of their everyday lives via their own familiar devices, addressing some of the limitations of previous trials. Participants also had access to the app for up to 9 months, making it possible to explore their real-world use and changes over time. This was a significant strength relative to most previous research where participants only used an app once or for a short period (usually less than four weeks). The purposive interview sampling strategy was successful in recruiting participants with a range of experience, facilitating examination of the interplay between user characteristics, app preferences, and engagement. One exception is that expert app users and those expressing a more autonomous self-management style were overrepresented, perhaps because these characteristics made them more likely to want to participate in the interview study. In addition, interview participants used the app twice as much as those in the intervention arm of the MDC trial, suggesting that we were less successful at recruiting less engaged users. We recommend that future research focuses on identifying the experiences and needs of users who are less autonomous and less experienced with technology because they are likely to have different diabetes education and support needs. Finally, our sample did not include younger adults with T2D, a burgeoning cohort with clear unmet needs [54]. Further research is needed to explore the experiences of such a sample.

Conclusions

Our study is one of the first to investigate the use of a diabetes self-management app in the wild. Our findings suggest several ways in which user experiences can be engineered to improve engagement with T2D self-management education and support via an app, such as personalizing app features to user characteristics, recommending a potential optimal time to intervene, developing resources to assist health professionals make evidence-based recommendations for diabetes apps, and

recommend potential frequency and scheduling of the intervention. Further research investigating interactions between user characteristics, including self-management autonomy and engagement, is warranted to determine specific strategies to improve engagement with T2D self-management apps if diabetes self-management apps are to become a useful complement to clinical care.

Acknowledgments

The MDC randomized controlled trial was conducted with funding from a National Health and Medical Research Council partnership grant (ID1057411), with additional financial and in-kind support provided by Diabetes Australia, Diabetes Queensland, Diabetes Victoria, Diabetes Western Australia, and Roche Diabetes Care. The development of the MDC app was the result of a collaboration between the University of Melbourne, Bupa Australia, the Bupa Foundation, and Clevertar. SB is a graduate researcher supported by a postgraduate scholarship from the National Health and Medical Research Council, Australia, and Diabetes Australia. JS is supported by core funding from the Australian Centre for Behavioural Research in Diabetes derived from the collaboration between Diabetes Victoria and Deakin University. The authors would like to thank all the study participants for volunteering their time, insights, and experiences.

Authors' Contributions

BO conceived the MDC study and developed the MDC research program, together with DB, JS, and the MDC Research Group (Emily D Williams, Michaela A Riddell, Paul A Scuffham, and Anthony Russell). SB, JS, and BO developed the interview schedule. SB conducted the interviews. SB and GW analyzed and interpreted the data with input from JS and BO. SB prepared the first draft of the manuscript. All authors reviewed and edited the manuscript for critical content and approved the final version.

Conflicts of Interest

BO and DB received some royalty payments for the development of the scripts for the MDC platform.

Multimedia Appendix 1

COREQ Checklist.

[[PDF File \(Adobe PDF File\), 497 KB - diabetes_v5i3e16692_app1.pdf](#)]

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Abbreviations

IVR: interactive voice recognition
MDC: My Diabetes Coach
NDSS: National Diabetes Services Scheme
T2D: type 2 diabetes

Edited by C Richardson; submitted 31.10.19; peer-reviewed by J Finderup, J Santos; comments to author 05.02.20; revised version received 08.03.20; accepted 05.05.20; published 17.07.20.

Please cite as:

Baptista S, Wadley G, Bird D, Oldenburg B, Speight J, The My Diabetes Coach Research Group

User Experiences With a Type 2 Diabetes Coaching App: Qualitative Study

JMIR Diabetes 2020;5(3):e16692

URL: <http://diabetes.jmir.org/2020/3/e16692/>

doi: [10.2196/16692](https://doi.org/10.2196/16692)

PMID: [32706649](https://pubmed.ncbi.nlm.nih.gov/32706649/)

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Original Paper

The Diabits App for Smartphone-Assisted Predictive Monitoring of Glycemia in Patients With Diabetes: Retrospective Observational Study

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Abstract

Background: Diabetes mellitus, which causes dysregulation of blood glucose in humans, is a major public health challenge. Patients with diabetes must monitor their glycemic levels to keep them in a healthy range. This task is made easier by using continuous glucose monitoring (CGM) devices and relaying their output to smartphone apps, thus providing users with real-time information on their glycemic fluctuations and possibly predicting future trends.

Objective: This study aims to discuss various challenges of predictive monitoring of glycemia and examines the accuracy and blood glucose control effects of Diabits, a smartphone app that helps patients with diabetes monitor and manage their blood glucose levels in real time.

Methods: Using data from CGM devices and user input, Diabits applies machine learning techniques to create personalized patient models and predict blood glucose fluctuations up to 60 min in advance. These predictions give patients an opportunity to take pre-emptive action to maintain their blood glucose values within the reference range. In this retrospective observational cohort study, the predictive accuracy of Diabits and the correlation between daily use of the app and blood glucose control metrics were examined based on real app users' data. Moreover, the accuracy of predictions on the 2018 Ohio T1DM (type 1 diabetes mellitus) data set was calculated and compared against other published results.

Results: On the basis of more than 6.8 million data points, 30-min Diabits predictions evaluated using Parkes Error Grid were found to be 86.89% (5,963,930/6,864,130) clinically accurate (zone A) and 99.56% (6,833,625/6,864,130) clinically acceptable (zones A and B), whereas 60-min predictions were 70.56% (4,843,605/6,864,130) clinically accurate and 97.49% (6,692,165/6,864,130) clinically acceptable. By analyzing daily use statistics and CGM data for the 280 most long-standing users of Diabits, it was established that under free-living conditions, many common blood glucose control metrics improved with increased frequency of app use. For instance, the average blood glucose for the days these users did not interact with the app was 154.0 (SD 47.2) mg/dL, with 67.52% of the time spent in the healthy 70 to 180 mg/dL range. For days with 10 or more Diabits sessions, the average blood glucose decreased to 141.6 (SD 42.0) mg/dL ($P < .001$), whereas the time in euglycemic range increased to 74.28% ($P < .001$). On the Ohio T1DM data set of 6 patients with type 1 diabetes, 30-min predictions of the base Diabits model had an average root mean square error of 18.68 (SD 2.19) mg/dL, which is an improvement over the published state-of-the-art results for this data set.

Conclusions: Diabits accurately predicts future glycemic fluctuations, potentially making it easier for patients with diabetes to maintain their blood glucose in the reference range. Furthermore, an improvement in glucose control was observed on days with more frequent Diabits use.

(*JMIR Diabetes* 2020;5(3):e18660) doi:[10.2196/18660](https://doi.org/10.2196/18660)

KEYWORDS

blood glucose predictions; type 1 diabetes; artificial intelligence; machine learning; digital health; mobile phone

Introduction

Background

Diabetes mellitus is one of the biggest public health challenges of our days. Globally, the number of adults living with the disease has risen from 108 to 422 million between 1980 and 2014, constituting about 8.5% of the worldwide adult population [1]. The complications of diabetes caused by increased blood glucose levels (hyperglycemia) include both macrovascular (ischemic heart disease, cerebrovascular disease, peripheral vascular disease leading to lower extremity amputations) and microvascular (eg, diabetic retinopathy and nephropathy) diseases [2].

In healthy adults, the pancreas maintains blood glucose levels between approximately 70 mg/dL and 180 mg/dL [3] (mostly at the lower end of this range, except for short postprandial increases) by balancing the levels of insulin and glucagon in the bloodstream.

Owing to impaired pancreatic function and/or reduced insulin sensitivity, patients with diabetes face the challenge of maintaining their blood glucose levels within the reference range via exogenous insulin administration, medications, and lifestyle modifications (eg, changes in diet, exercise, sleep patterns). These patients, especially those with type 1 diabetes (whose pancreas produces no insulin at all), must constantly monitor their glycemic state and use exogenous insulin to keep their blood glucose from increasing beyond the healthy range into hyperglycemia, while avoiding out-of-range low (hypoglycemic) values, which can potentially lead to seizures, coma, and even death [4].

The task of blood glucose monitoring, traditionally performed using capillary blood sampling, has been made easier in recent years with the introduction of continuous glucose monitoring (CGM) devices [5], which measure glucose levels at a set frequency, typically every 5 min, via interstitial fluid. Currently, CGM devices are capable of providing an accurate picture of recent and current blood glucose levels and alerting the users of hypo- or hyperglycemic events. Some of the existing devices have incorporated simple autoregression algorithms to predict impending blood glucose fluctuations (usually no more than 15-20 min ahead of time) and issue a notification if a hypo- or hyperglycemic event is expected. However, we believe that the functionality of CGM devices can be significantly extended with additional tools to improve their utility and, consequently, the quality of life of their users.

Current Research on Blood Glucose Predictions

There are two common reasons for making blood glucose predictions. The first is to be able to manage blood glucose levels automatically via a closed-loop feedback system for a continuous insulin pump [6,7]. The second, which is the way in which predictions are used in Diabits, the diabetes management app whose predictive approach and accuracy are reviewed in this publication, is to give the results back to the patient so that their insulin and food intake and other behaviors can be corrected to avoid possible hypo- or hyperglycemia.

Owing to the potential benefits of anticipating blood glucose changes ahead of time, there have been many studies (eg, [8-41]) dedicated to developing models capable of short-term (usually in the range of 15-120 min into the future) glycemic predictions. These studies generally fall into 2 categories: (1) physiological approaches [8-12], wherein researchers try to model the metabolic processes within the patient's body using general knowledge of human physiology, and (2) data-driven models [13-41], which mostly rely on statistical and machine learning techniques applied to the existing CGM data and other available information (eg, meals, exogenous insulin, sleep, and physical activity) to derive standard patterns of blood glucose behavior, which are then used to predict future glycemic events.

The challenge of using physiological predictive models lies in the fact that to be accurate, these models require a more detailed description of the current state of the patient's body than can normally be achieved, and even in the presence of such data (eg, in a clinical setting), the performance of physiological models is limited because of the inherent complexity of the human glucose-insulin dynamics, which makes identification of model parameters a difficult task. Therefore, data-driven models (or hybrid models that combine statistical methods with physiological insights) are more viable in practice for short-term blood glucose predictions, as evidenced by most studies cited above.

The data-driven models reported in the literature use a variety of traditional signal processing [14-23] and machine learning [24-41] methods for making blood glucose predictions. These models normally use recent CGM measurements as the primary predictive input.

Among the methods that are not based on machine learning techniques are those using autoregressive methods [14-18], Kalman filters [19-21], and impulse response techniques [22,23] to extrapolate the existing CGM behavior into the near future. Machine learning methods include neural networks [24-36], support vector machines (SVMs) [37,38], decision trees [39,40], grammatical evolution [41], and other approaches. These methods use supervised learning techniques in which the models of blood glucose behavior created on the basis of past measurements are used to anticipate future changes.

Evaluation of Prediction Accuracy

The accuracy of short-term blood glucose predictions reported in different studies cannot be easily compared, partly because there exists a great variety of metrics that are used by researchers to evaluate predictive performance, such as the root mean square error (RMSE), mean absolute relative difference [42], prediction time lag and the J index [43], and different methods [44-47] based on using error grids developed for blood glucose meter evaluation, such as the Clarke Error Grid [48] and the Parkes (Consensus) Error Grid [49,50]. More importantly, even with the same metric, glycemic prediction models can exhibit noticeable variation in accuracy when applied to different sets of data owing to the nature of data (in silico or in vivo), the amount of data available for each patient, physiological differences between patients, behavioral changes for each patient, and data quality issues. This variance can be partially reduced by using larger data sets, but for many researchers, only

limited data are available owing to the fact that blood glucose readings, similar to all medical data, are usually not shared freely because of patient privacy concerns. Although there have been recent attempts to facilitate blood glucose research by creating established sets of CGM data available to scientists, such as the Ohio T1DM (type 1 diabetes mellitus) data set [51], most studies published to date use private data sets for evaluation, which makes it difficult to objectively evaluate the quality of their results.

Furthermore, the prediction accuracy of different studies may be significantly affected by varied availability of non-CGM data, particularly information related to meal and insulin events. If predictions are only made for periods when no such events occur (which can only be done if the researcher has the data indicating their occurrence), or if these events are taken into account by the predictive model, the accuracy is likely to be much higher than in case of making a prediction for an interval during which unknown events affecting the patient's blood glucose may have taken place.

Feedback Delays and Implications for Predictions

It is important to point out that CGM devices do not measure the actual blood glucose levels but measure the concentration of glucose in interstitial fluid, which tends to follow blood glucose with a patient- and condition-dependent time lag, usually in the range of 5 to 20 min [52-55]. Although the postprocessing of measured CGM data may partially account for this delay, to avoid out-of-range blood glucose excursions, the predictions need to be made in advance in order for the user (or an automatically controlled insulin pump if the predicted values are used by an artificial pancreas algorithm) to be able to make a correction, while the true blood glucose concentration is still within its reference range.

There are several other sources of delays when using predictions for blood glucose control. Frequently, predictions themselves may be lagging compared with the future interstitial glucose levels because of the nature of the predictive algorithm. Next, CGM devices only perform measurements using discrete time intervals (usually between 3 and 15 min, with 5 min being the most common in practice). Therefore, the last measured point may not be quite up to date at the moment the user sees the prediction. Additional delays are introduced by the CGM filtering algorithms [53]. In addition, the corrective action by

the user may not have an immediate effect on blood glucose (eg, even for rapid-acting insulin delivered subcutaneously, the action is delayed by about 5-10 min [56]).

Owing to all these delays, in order for the predictions to be maximally effective in preventing out-of-range blood glucose excursions, it is preferable to anticipate glycemic changes for at least 30 min in advance, especially in cases of hyperglycemic events caused by the delayed action of insulin. For hypoglycemia prediction, shorter time horizons may be acceptable [23], although a longer accurate prediction would still give the user more time to take preventive measures.

Goals

The aim of this paper is to describe how the challenges that exist in blood glucose predictions are addressed in the Diabits smartphone app and to evaluate the accuracy of its predictions and the potential clinical effects of the app using data from the app's users and other existing data sets.

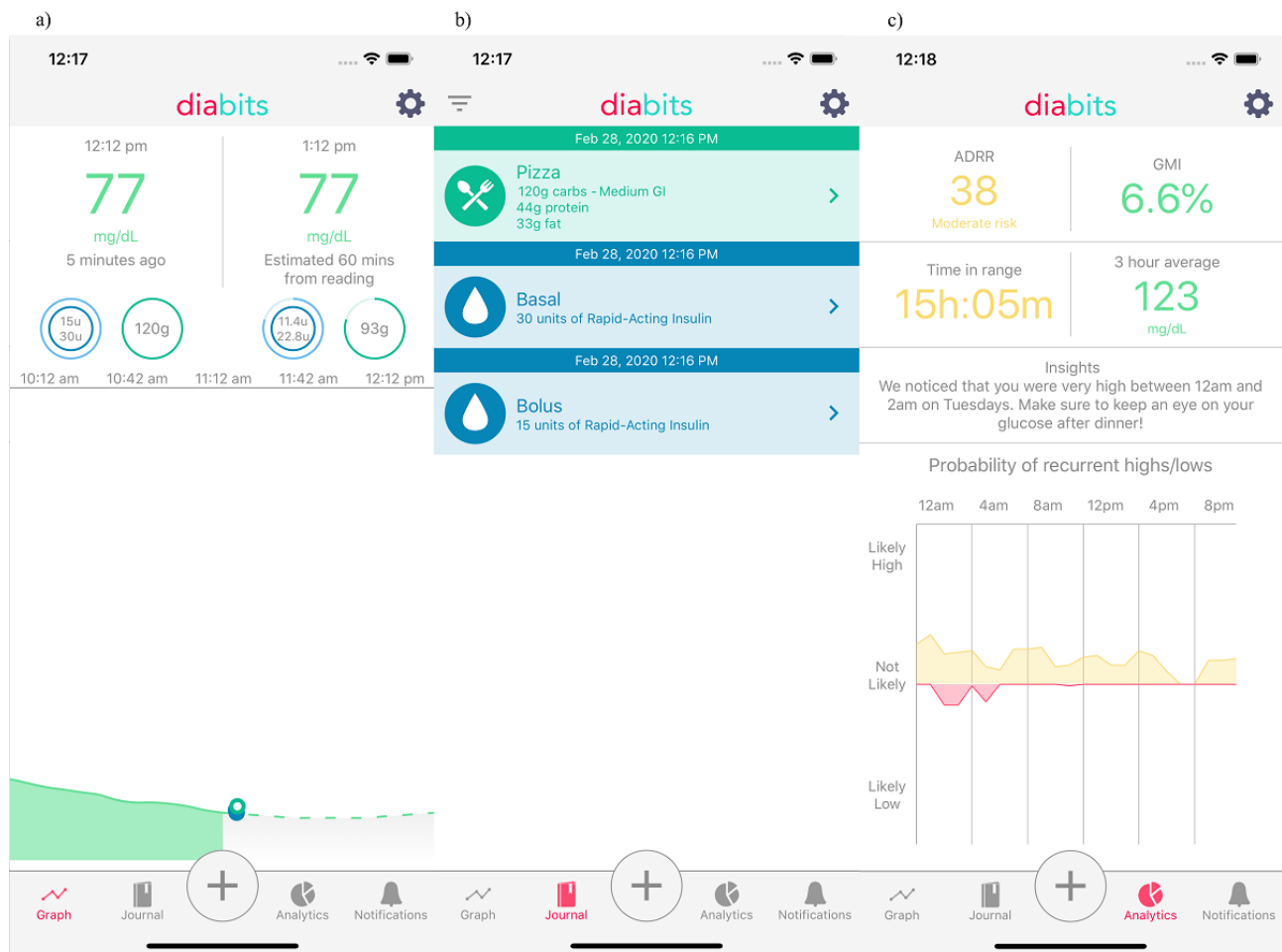
Methods

General Description of Diabits

Diabits is a smartphone app that is available both for iOS and Android phones, which reads current blood glucose data either from the app associated with a Dexcom CGM device (via Dexcom Share) or from Nightscout, a cloud-based data aggregator project that can collect, if configured by the user, current data from a Dexcom or Medtronic CGM, and then presents these data in real time to the user, along with predictions of blood glucose behavior for the next 60 min and statistical information and charts based on the patient's past blood glucose data.

The main parts of the user interface of the app are shown in Figure 1. Graph panel (a) is the main screen of the app, displaying the recent CGM data, predicted future blood glucose values, and estimated values of insulin and carbohydrates *on board*, that is, available for future use by the body. The meal and insulin information, entered manually by each user of the app based on their best knowledge, is displayed in the Journal panel (b). The Analytics panel (c) shows several statistics based on the recent history of the patient's blood glucose. Some of the graphic parts of the design may have experienced minor changes throughout the study.

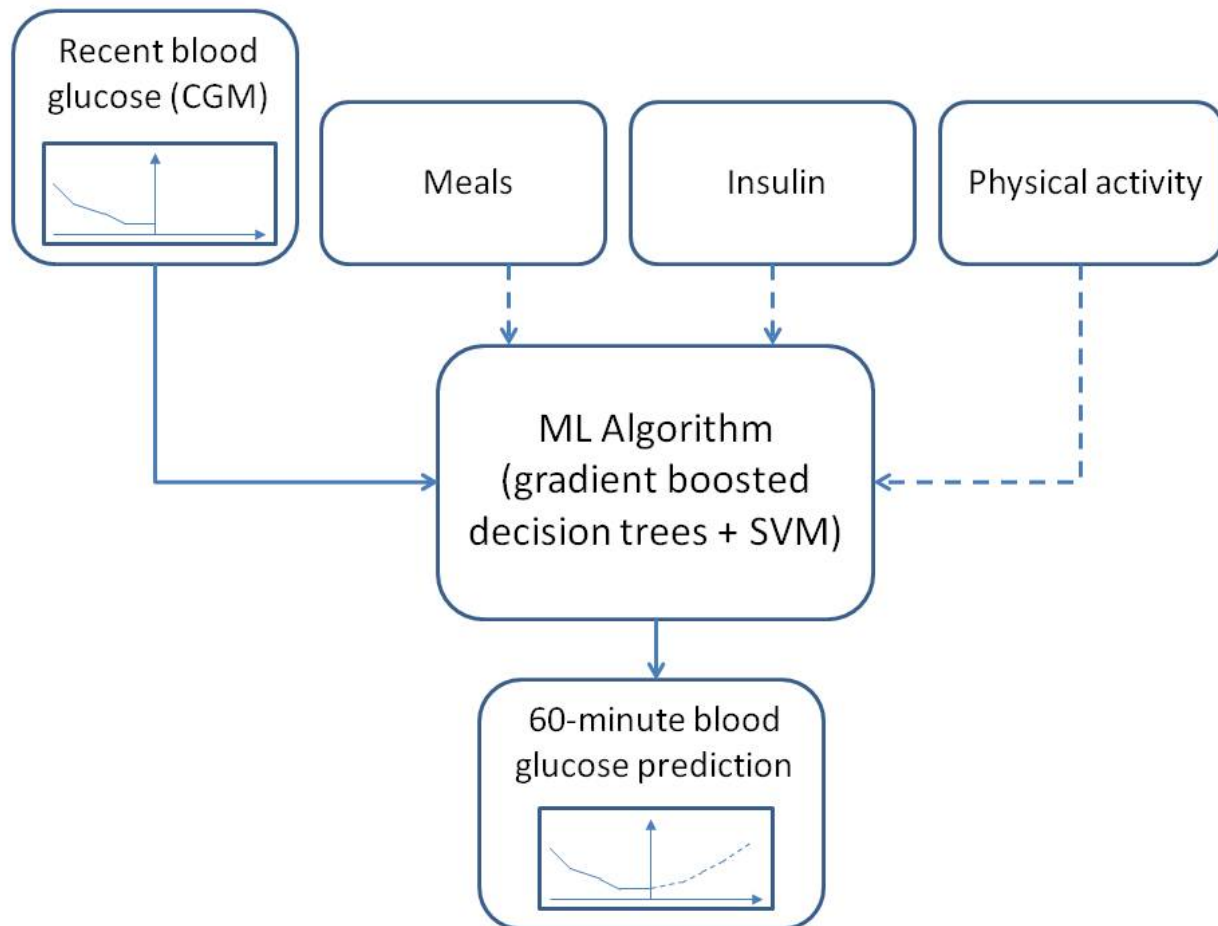
Figure 1. The interface of Diabits, including (a) the Graph panel, showing recent CGM values and the predictions for the next hour; (b) the Journal panel, where the users can enter relevant event information (food, insulin, etc), and see the past history of CGM data and events; (c) the Analytics panel, showing various glycemic statistics and insights that may help the users control their blood glucose levels. CGM: continuous glucose monitoring.



The predictive models of Diabits were originally created on the basis of the results of a clinical study conducted in collaboration with the endocrinology unit of BC Children's Hospital (located in Vancouver, Canada) between April and October 2017 [57]. During this study, CGM data and heart rate and physical activity information of 9 young patients with type 1 diabetes were collected over a period of 2 months with the goal of creating an accurate model for short-term blood glucose predictions. The predictive models that were developed during this study were subsequently refined [58] using data from a larger pool (approximately 1200 people) of free-living users of the app with approximately 1.6 million data points.

The app gives users an option to manually record, according to their knowledge, food consumption (carbohydrate, protein, and fat content and the glycemic index), insulin intake (the number of units and the type of insulin), physical exercise (intensity and duration), and other events that may affect their blood glucose. This information is added to the CGM data as model inputs to increase the prediction accuracy. The predictive models of Diabits rely significantly on CGM inputs, as most users do not provide enough food and insulin information required to make a model that is primarily based on physiological principles. However, all available physiological inputs are taken into account when making a prediction. A schematic diagram of the Diabits prediction approach is shown in Figure 2.

Figure 2. A block diagram of the Diabits predictive module. Solid connections between blocks indicate mandatory data, whereas dashed connections show optional inputs. The dashed line in the bottom block shows the 60-min prediction that was generated by the machine learning algorithm. CGM: continuous glucose monitoring; ML: machine learning; SVM: support vector machine.



Details of Machine Learning Approach Used in Diabits

Glucose predictions are made via a supervised machine learning framework, with personalized models trained using each patient's past data.

Glucose values are calculated for 4 time points: 15, 30, 45, and 60 min ahead, with a separate model trained for each point. When plotting the data for users, the in-between points are filled using cubic interpolation. Although it is possible to train models for any number of minutes divisible by the CGM time step (eg, for 5, 10, 15 min, if the CGM time step is 5 min), it is not necessary in practice because the actual blood glucose behavior of patients with insulin-dependent diabetes typically lacks a noticeable high-frequency component [59] (even though unfiltered CGM values may exhibit such fluctuations because of random measurement errors).

To create inputs for the model, in addition to CGM data, recent food and insulin records, if available, are used to estimate the amount of carbohydrates and insulin currently present in the body (this information is also displayed for the user to see) and their rates of utilization. The calculations are performed using physiological models similar to those reported in the literature, (eg, [12,60]). As these physiological models have a number of parameters that are specific to each patient, these calculations can only be performed once a sufficient number of previous

points with food and insulin data have been collected so that personalized parameters can be estimated from these. Until that point (for newer app users and those who rarely provide such data to the app), a simpler estimation approach for the current amount of carbohydrates and insulin remaining is used based on the food and insulin information reported by the patient, each patient's insulin-to-carbohydrate ratio and correction factor provided to the app at sign-up, and the changes in blood glucose levels since each food and/or insulin event.

Other data points, such as those related to the time of the day, day of the week, and recent physical activity data, are also added as separate model inputs to increase the accuracy of predictions.

The resulting inputs are used for training a model that combines gradient boosted decision trees and SVM regression. Gradient boosted decision trees [61] is an ensemble machine learning technique that works by consecutively training new trees on the differences between the ground truth labels and the combined prediction of all preceding trees. SVM regression [62] operates similar to linear regression, but with a maximum margin (hinge) loss and a kernel mapping that allows to model nonlinear systems. Diabits uses standard implementations of both of these algorithms from open-source Python packages.

The exact mechanism by which these two methods are implemented and combined are not addressed in this paper but

may be disclosed in future publications. Generally, the decision tree model is used to evaluate which of the several possible physiological states the patient is currently in, and then an SVM model trained exclusively on the data pertaining to this particular state (as determined by the training algorithm) generates the prediction.

For each Diabits user, the initial personalized (based solely on this user's data) model is built once 2000 CGM points (about a week of continuous data) are available. Thereafter, the model is retrained every 2 weeks to take advantage of the most recent data.

Prediction Adjustments in Diabits

One of the issues that needs to be addressed when predictive models are trained on past patient behavior is that in the absence of detailed nutritional and insulin information for free-living patients, training points may reflect unrecorded prior corrections that the patients have made by either ingesting carbohydrates or using insulin. This is particularly problematic when blood glucose is near the edges of the target range (eg, just above 70 mg/dL or just below 180 mg/dL for the standard reference range of glucose values). A model trained on such data will likely predict similar corrections happening in the future, which may result in the patient actually foregoing necessary corrections owing to the fact that blood glucose is predicted to normalize on its own.

To mitigate this effect, in situations where such errors are likely to occur (ie, in situations with an impending hypo- or hyperglycemic event that the user is likely to have avoided in the past training data by taking food or insulin), Diabits uses an additional algorithm to correct its predictions to generate the most likely trajectory of blood glucose in the absence of future external interventions. The user can then decide, based on their own judgment, if any interventions are necessary. This adjustment is only used when blood glucose is trending toward the outside of the target range, there has been no recent change in the direction of the trend indicating a possible unreported meal or insulin event, and no meal or insulin events have been reported in the last 40 min. The final prediction is generated as a weighted average of the main model's prediction and a prediction that applies linear regression to the recent CGM data and therefore is guaranteed to continue the current trend.

Note that this Diabits adjustment, which typically increases the calculated prediction error (because we are no longer trying to predict what will actually happen, but instead what will happen if no action is taken) but, in our opinion, makes the predictions more practically useful, was not used to ensure a fair comparison in part III of the results of this paper, namely when comparing the prediction accuracy of our model with published research on the Ohio T1DM data set. The results for the actual in-app predictions and glycemic control versus frequency of app use (part I and part II), however, are based on a model that does include this adjustment.

Study Format and Ethical Compliance

All parts of this research are based on retrospective observational cohort studies. The first part (*Accuracy of Past In-App Predictions for Free-Living Users*) and the second part

(*Glycemic Control vs Frequency of App Use*) analyzed the past data of free-living Diabits users. The researchers, in accordance with the Diabits' privacy policy, had no access to personally identifiable information of the users, relying instead on anonymized randomly generated universally unique identifier strings [63], and had no contact with any of the participants. Thus, we believe that the participants did not fall under the definition of human subjects [64]; hence, no institutional review board review was necessary. Informed consent was received from every Diabits user upon sign-up that their anonymized data could be used for research purposes.

In the third part of the study (*Accuracy of Predictions on the 2018 Ohio T1DM Data Set*), a publicly available anonymized 2018 Ohio T1DM data set [51] was used. The data user agreement for this data set allows the use of its data for research purposes.

Part I: Accuracy of Past In-App Predictions for Free-Living Users

The goal of this part of the study was to examine a large set of past Diabits predictions made for the actual users of the app and to determine the clinical safety of these predictions using Clarke and Parkes Error Grid analysis. All of Diabits users with type 1 diabetes (as reported by the patients themselves during sign-up) were ranked by the number of blood glucose data points they shared with the app in 2019, and the 500 patients with the most points were chosen for analysis. The sex and age of each specific subject was not known to the researchers; however, in general, there are many Diabits users in all age categories, from newborn to those older than 70 years, and of different sexes (approximately evenly split between males and females). All of the CGM devices used by the study participants were among those compatible with the app (*General Description of Diabits*). The investigators did not have any further information regarding specific device models for each participant.

The distribution between the Clarke and Parkes Error Grid zones of actual 15-, 30-, 45-, and 60-min predictions made by the app in real time, as compared with the ground-truth data from future CGM points, was calculated using all of the points for these 500 patients where the prediction was made and all of the ground-truth labels were available (6,864,130 total points). The results were examined to determine whether the predictions provided could potentially have led to adverse patient outcomes.

Part II: Glycemic Control Versus Frequency of App Use

The goal of this part of the study was to determine whether there is a correlation between how often the users look at the blood glucose graph of Diabits during each day and their blood glucose control. A total of 280 Diabits users who had at least 180 days of CGM data recorded by the app in 2018 to 2019 were included. The patients came from the same pool as in the first part of the study (in fact, many are the same patients); however, their data from 2 calendar years (2018 and 2019) were used for analysis.

The blood glucose control metrics that were calculated included the average blood glucose and its SD, time in euglycemic range (TIR) [65], glucose management indicator (GMI) [66], and high BGI (HBGI) and low BGI (LBGI) blood glucose risk indices [67].

All of the metrics were analyzed as functions of the frequency of daily use, which was defined as the number of times a Diabits user looked at the graph containing CGM values and future blood glucose predictions during 1 calendar day. Diabits records each user's CGM data as long as the app is running on the smartphone even if the user is not actively looking at the results, so days with zero sessions were included.

The hypothesis of the study was that all of the blood glucose control metrics would improve with more frequent use of the app. All of the users' days were categorized into 4 different groups, namely those with 0 sessions, 1 to 5 sessions, 6 to 10 sessions, and more than 10 sessions. P values, calculated using a one-sided t test, are reported for the difference of each metric from that in the group with zero daily sessions (no active use of the app; P_0) and in the closest group with fewer sessions (P_{fewer}). A value $\alpha=0.01$ was used for the alpha level of significance in all cases, using the Bonferroni correction [68] for multiple comparisons.

Part III: Accuracy of Predictions on the 2018 Ohio T1DM Data Set

To facilitate the comparison of the predictive accuracy of Diabits with existing research, the base Diabits prediction framework was applied without any data set-specific adjustments to the data from the Ohio T1DM data set [51] that was used in 2018 Blood Glucose Level Prediction (BGLP) challenge at the third International Workshop on Knowledge Discovery in Healthcare Data.

Using the training portion of the data in the 2018 Ohio T1DM data set, personalized Diabits models were created for each of

the 6 patients in the data set. Next, 30-min predictions were generated for all points in the test portion of the data except for the first hour, and the prediction error (RMSE) was calculated and compared against the published results of the challenge [18,30-33,35,40,41].

The CGM data were used as is (no averaging or smoothing to eliminate random errors), and only past and present data (CGM glucose levels, basal and bolus insulin, meal, and exercise information) were used for each point to make predictions. In other words, the data were used in the same manner it is normally used in Diabits, with the training data used to train each patient's personalized prediction models and the test data to generate predictions and calculate their accuracy.

Results

Part I: Accuracy of Past In-App Predictions for Free-Living Users

Actual 30-min Diabits predictions under free-living conditions for the 500 most active patients in 2019 (approximately 6.8 million points) made using personalized models based on the gradient boosted decision trees and the SVM regression algorithm discussed above and evaluated using Parkes Error Grid were found to be 86.89% (5,963,930/6,864,130) clinically accurate (zone A) and 99.56% (6,833,625/6,864,130) clinically acceptable (zones A and B). For the 60-min predictions, the results were 70.56% (4,843,605/6,864,130) clinically accurate and 97.49% (6,692,165/6,864,130) clinically acceptable (Table 1). A sample distribution of predicted values plotted against actual values for both Clarke and Parkes Error Grids is shown in Figure 3.

Figure 3. A sample scatter graph of blood glucose values predicted 30 min in advance by the Diabits model versus measured CGM values, plotted against Clarke (left) and Parkes (right) Error Grids.

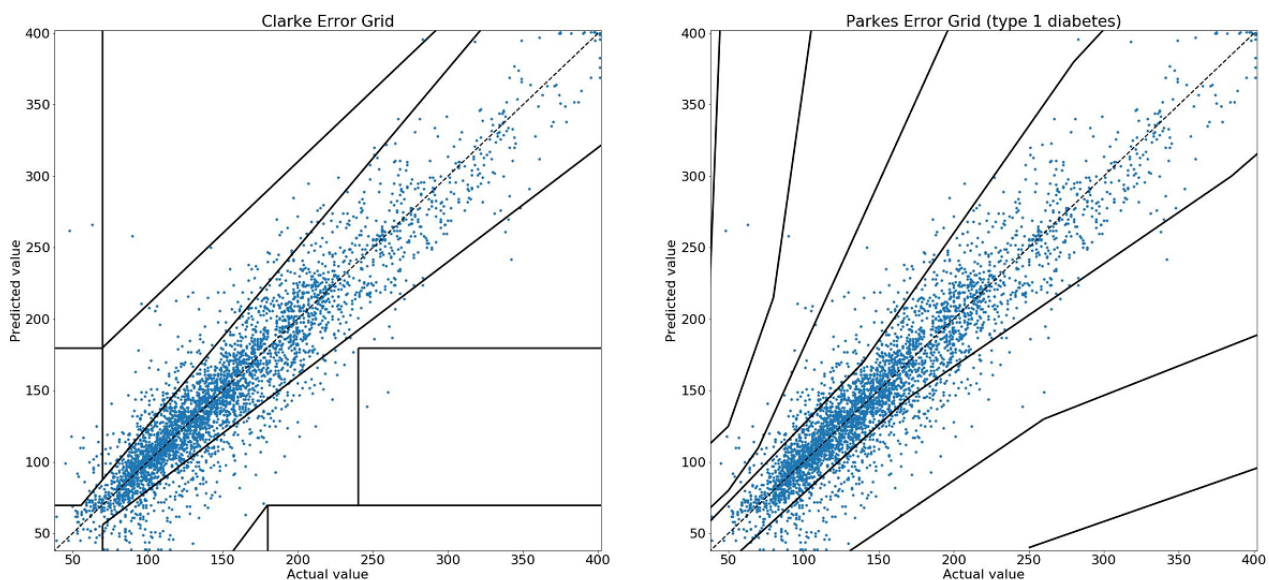


Table 1. Results of error grid analysis of the prediction accuracy of Diabits based on 6,864,130 actual predictions made for 500 most active app users in 2019.

Minutes and error grid type	A, n (%) ^a	B, n (%) ^a	C, n (%) ^a	D, n (%) ^a	E, n (%) ^a
15					
Clarke	6,565,030 (95.64)	278,954 (4.07)	135 (0.00)	19,981 (0.29)	30 (0.00)
Parkes	6,613,321 (96.34)	246,767 (3.60)	3968 (0.06)	71 (0.00)	3 (0.00)
30					
Clarke	5,835,511 (85.01)	964,979 (14.06)	3276 (0.05)	59,834 (0.87)	530 (0.01)
Parkes	5,963,930 (86.89)	869,695 (12.67)	29,587 (0.43)	915 (0.01)	3 (0.00)
45					
Clarke	5,174,795 (75.39)	1,559,461 (22.72)	21,510 (0.31)	103,629 (1.51)	4735 (0.07)
Parkes	5,359,782 (78.08)	1,414,438 (20.61)	85,974 (1.25)	3931 (0.06)	5 (0.00)
60					
Clarke	4,626,623 (67.40)	2,024,709 (29.50)	55,195 (0.80)	144,512 (2.11)	13,091 (0.19)
Parkes	4,843,605 (70.56)	1,848,560 (26.93)	162,537 (2.37)	9416 (0.14)	12 (0.00)

^aThe numbers show the percentage of prediction points in each zone of the Clarke and the Parkes Error Grid. For both grids, the zones are defined as clinically accurate (A), clinically acceptable (B), and clinically inaccurate (C-E) [48-50].

Part II: Glycemic Control Versus Frequency of App Use

To evaluate the correlation between the daily frequency of Diabits use and the quality of blood glucose control, several commonly used blood glucose control metrics were calculated for 280 users who had at least 180 days of CGM data recorded by the app in 2018 to 2019 (86,973 days combined for all users) as a function of daily number of sessions (ie, the times the user opened the app to look at the blood glucose graph) with Diabits (Table 2).

As can be seen from Table 2, all of the metrics except LBG1 were better for days with more frequent Diabits use (in almost all cases, $P/2 < \alpha/36 = .00027$, the latter value being the significance level calculated using the Bonferroni correction formula for multiple comparisons, thus indicating a statistically significant positive correlation). In the case of LBG1, there was a very slight statistically significant increase in hypoglycemic risk when using the app more frequently (as could be expected owing to tighter glucose control); however, all of the values were well within the minimal risk region of $LBGI < 1.1$ [69].

Table 2. Various metrics of blood glucose control as a function of frequency of daily Diabits use.

Daily sessions ^a	0	1-5	6-10	>10
Average blood glucose (mg/dL)	154.0	150.7; $P_0 < .001$; $P_{\text{fewer}} < .001$	145.6; $P_0 < .001$; $P_{\text{fewer}} < .001$	141.6; $P_0 < .001$; $P_{\text{fewer}} < .001$
Standard deviation (mg/dL)	47.6	45.3; $P_0 < .001$; $P_{\text{fewer}} < .001$	42.1; $P_0 < .001$; $P_{\text{fewer}} < .001$	41.5; $P_0 < .001$; $P_{\text{fewer}} = .07$
Time in euglycemic range, as % of all data	67.52	69.39%; $P_0 < .001$; $P_{\text{fewer}} < .001$	73.05%; $P_0 < .001$; $P_{\text{fewer}} < .001$	74.28%; $P_0 < .001$; $P_{\text{fewer}} = .004$
GMI ^c (%)	6.99	6.91%; $P_0 < .001$; $P_{\text{fewer}} < .001$	6.79%; $P_0 < .001$; $P_{\text{fewer}} < .001$	6.70%; $P_0 < .001$; $P_{\text{fewer}} < .001$
HBGI ^d (<4.5: low risk; 4.5-9.0: moderate risk; >9.0: high risk) [67]	4.63	4.20; $P_0 < .001$; $P_{\text{fewer}} < .001$	3.62; $P_0 < .001$; $P_{\text{fewer}} < .001$	3.13; $P_0 < .001$; $P_{\text{fewer}} < .001$
LBGI ^e (<1.1: minimal risk; 1.1-2.5: low risk; 2.5-5.0: moderate risk; >5.0: high risk) [69]	0.42	0.45; $P_0 < .001$; $P_{\text{fewer}} < .001$	0.46; $P_0 = .007$; $P_{\text{fewer}} = .32$	0.59; $P_0 < .001$; $P_{\text{fewer}} < .001$

^aDaily sessions refers to the number of times a Diabits user looks at the CGM values and predictions during 1 calendar day. Diabits records each user's CGM data as long as the application is running on the smartphone even if the user is not actively looking at the results, so days with 0 sessions are included.

^bAll P values $< .001$ are reported as $P < .001$. P_0 and P_{fewer} are defined in the methods section of this paper.

^cGMI: glucose management indicator.

^dHBGI: high blood glucose risk index.

^eLBGI: low blood glucose risk index.

Part III: Accuracy of Predictions on the 2018 Ohio T1DM Data Set

The calculated RMSE values for Diabits predictions on the test portion of the 2018 Ohio T1DM data set [51] are presented in

Table 3. Root mean square error (mg/dL) of 30-min prediction accuracy of the base Diabits model for 6 patients in the 2018 Ohio type 1 diabetes mellitus data set compared with the best of the published results of 2018 Blood Glucose Level Prediction Challenge [51] on the same data.

Predictive model (RMSE ^a , mg/dL)	Patient number						Mean (SD) ^b
	559	563	570	575	588	591	
Diabits base model	<i>17.94</i> ^c	18.29	<i>15.44</i>	22.22	17.53	20.64	18.68 (2.19)
Martinsson, 2019 (LSTM RNN ^d) [35]	18.77	<i>17.96</i>	15.96	<i>21.68</i>	18.54	<i>20.29</i>	18.87 (1.79)
Chen, 2018 (DRNN ^e) [31]	18.78	18.12	15.46	22.83	17.73	21.34	19.04 (2.42)
Bertachi, 2018 (feed-forward NN ^f) [33]	18.83	19.43	15.88	22.86	17.84	21.12	19.33 (2.24)
Xie, 2018 (SVM ^g) [18]	18.19	19.12	15.67	24.61	<i>17.49</i>	22.12	19.53 (2.99)
Xie, 2018 (ARX linear regression) [18]	18.36	19.02	16.03	23.90	18.25	21.99	19.59 (2.60)
Martinsson, 2018 (LSTM RNN) [30]	19.50	19.00	16.50	24.20	19.20	22.00	20.07 (2.44)
Midroni, 2018 (XGBoost) [40]	19.81	18.42	18.14	24.17	19.24	22.49	20.38 (2.21)
Contreras, 2018 (Grammatical evolution) [41]	20.98	19.36	19.55	24.49	20.45	22.28	21.19 (1.77)
Zhu, 2018 (WaveNet convolutional NN) [32]	21.72	20.17	18.03	24.80	21.42	24.22	21.73 (2.30)

^aRMSE: root mean square error.

^bThe mean column is calculated by averaging the 6 previous columns (mean root mean square error over all patients).

^cThe best result for each patient is highlighted in italics.

^dRNN: recurrent neural network.

^eDRNN: dilated recurrent neural network.

^fNN: neural network.

^gSVM: support vector machine.

Discussion

Principal Findings

This paper has studied the predictive accuracy of Diabits, a smartphone app that performs blood glucose monitoring based on CGM data, presents a statistical analysis of past data, and generates short-term (up to 60 min) predictions of future glucose behavior. In addition, the correlation between daily use of Diabits and blood glucose control metrics of its users was examined.

A large number of actual predictions made by Diabits for its users were evaluated using the Clarke and Parkes Error Grid, and the resulting values were found to be in the clinically acceptable range 97.49% of the time (6,692,165/6,864,130) for 60-min predictions and 99.56% of the time (6,833,625/6,864,130) for 30-min predictions on the Parkes Grid (with similar results for the Clarke Grid), which showed that the vast majority of predictions were accurate enough to not adversely affect the patients.

By analyzing the results of actual app use, it was statistically established that more frequent daily use of Diabits was correlated with improvement in many blood glucose control metrics, including average blood glucose and its SD, TIR, GMI, and HBGI. This is consistent with the goal of the app to help

Table 3.

Of note, the mean prediction error of the Diabits base model (18.68 mg/dL) is lower than that of all other published results.

patients better manage their blood glucose and pre-emptively avoid hyper- or hypoglycemia.

Finally, the accuracy of Diabits was directly compared with that of existing research using predictions on the 2018 Ohio T1DM data set, with the resulting RMSE being lower than that in the studies published by other researchers [18,30-33,35,40,41].

All of these results show the viability of Diabits as an effective tool for blood glucose control in CGM users. They also support the quality of the model underlying Diabits to make informative blood glucose predictions based on personalized machine learning models.

Strengths, Limitations, and Possible Future Developments

In part I, the accuracy of the actual glycemic predictions of Diabits was calculated using more than 6.8 million data points. This provided a solid statistical basis for the calculations and ensured the validity of the results.

The combination of gradient boosting decision trees and SVM regression in the Diabits models may have provided an additional ensembling [70] benefit that enhanced the prediction accuracy. In addition, we believe that one of the reasons why Diabits personalized models based on these techniques work

particularly well for most patients compared with, for example, neural network models, is the somewhat limited amount of training data available for each patient, which favors the traditional machine learning techniques. However, the downside is that the current personalized approach fails to take advantage of the global pool of data available through the app. One possible future research direction is to use combined data from a large number of patients to train a deep neural network model (which may achieve better accuracy with a large amount of data), and then fine-tune this model for each patient.

In part II, the discovered correlation between the daily use of Diabits and the improvement in blood glucose control metrics

was based on more than 86,000 days of app use, once again giving the results statistical significance. However, the observational nature of the study and the lack of knowledge of which, if any, corrections were made by the users based on the app output does not allow us to establish causality or estimate the level of importance of each feature of Diabits, which may be a topic of future research.

In part III, the predictions of Diabits on the 2018 Ohio T1DM data set showed an improved average RMSE for 30-min predictions over other published approaches, demonstrating Diabits' high predictive accuracy when compared with other leading models on the same data set.

Acknowledgments

The authors acknowledge the help of Cindy Marling and Razvan Bunescu from Ohio University for providing the Ohio T1DM data set.

Conflicts of Interest

All authors are current employees of Bio Conscious Technologies, Inc (BCT), the developer of the Diabits app. The study was performed as part of their work at BCT.

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Abbreviations

BCT: Bio Conscious Technologies, Inc
BGLP: Blood Glucose Level Prediction
CGM: continuous glucose monitoring
GMI: glucose management indicator
HBGI: high blood glucose risk index
LBGI: low blood glucose risk index
RMSE: root mean square error
SVM: support vector machine
T1DM: type 1 diabetes mellitus
TIR: time in euglycemic range

Edited by K Mizokami-Stout; submitted 10.03.20; peer-reviewed by C Toffanin, S Mougiakakou, R Mpofu, C Basch; comments to author 26.04.20; revised version received 19.06.20; accepted 30.07.20; published 22.09.20.

Please cite as:

Kriventsov S, Lindsey A, Hayeri A

The Diabits App for Smartphone-Assisted Predictive Monitoring of Glycemia in Patients With Diabetes: Retrospective Observational Study

JMIR Diabetes 2020;5(3):e18660

URL: <http://diabetes.jmir.org/2020/3/e18660/>

doi: [10.2196/18660](https://doi.org/10.2196/18660)

PMID: [32960180](https://pubmed.ncbi.nlm.nih.gov/32960180/)

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Original Paper

Web-Based and mHealth Technologies to Support Self-Management in People Living With Type 2 Diabetes: Validation of the Diabetes Self-Management and Technology Questionnaire (DSMT-Q)

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Abstract

Background: A growing number of web-based and mobile health (mHealth) technologies have been developed to support type 2 diabetes self-management. Little is known about individuals' experiences with these technologies and how they support self-management. Appropriate tools are needed to understand how web-based and mHealth interventions may impact self-management.

Objective: This study aimed to develop an instrument, the Diabetes Self-Management and Technology Questionnaire (DSMT-Q), to assess self-management among people living with type 2 diabetes who use web-based and mHealth technologies.

Methods: A total of 36 candidate questionnaire items, drafted previously, were refined using cognitive debriefing interviews (n=8), expert consultation, and public patient involvement feedback. Item reduction steps were performed on survey data (n=250), and tests of validity and reliability were subsequently performed.

Results: Following amendments, patients and experts found 21 items relevant and acceptable for inclusion in the instrument. Survey participants included 104 (41.6%) women and 146 (58.4%) men. Two subscales with high construct validity, internal consistency, and test-retest reliability were identified: "Understanding individual health and making informed decisions" and "Confidence to reach and sustain goals."

Conclusions: Analyses confirmed good psychometric properties in the DSMT-Q scales. This tool will facilitate the measurement of self-management in people living with type 2 diabetes who use web-based or mHealth technologies.

(*JMIR Diabetes* 2020;5(3):e18208) doi:[10.2196/18208](https://doi.org/10.2196/18208)

KEYWORDS

mHealth; self-care; type 2 diabetes; self-monitoring; questionnaire

Introduction

In 2018, just over 3.8 million people in the United Kingdom were diagnosed with diabetes [1], an increase of 2.4 million since 1996 [2]. A total of 90% of those diagnosed with diabetes are thought to have type 2 diabetes (diabetes mellitus), with a further 1 million estimated to be unaware they have the

condition [2]. Complications that may need to be managed include gastroparesis, painful diabetic neuropathy, autonomic neuropathy, foot problems, kidney disease, erectile dysfunction, and eye disease [3]. Complications arising from this long-term condition can be avoided mainly through supporting patients to manage their condition through, for example, through achieving glycemic control, through education and/or through

lifestyle changes. Nevertheless, they are estimated to cost the National Health Service over GBP £7 billion (US \$8.7 billion) per year in direct costs [4].

People living with type 2 diabetes need to be supported to manage their condition, improve well-being, and prevent diabetes-related complications from arising. Key management priorities for UK health services include patient education, dietary advice, blood glucose management, and drug treatment [3]. While some areas of routine care (for example, therapy changes) may need to be implemented during face-to-face interactions, digital health care can also be adopted outside these interactions (for example, when promoting adherence and providing peer support) [5]. Some evidence indicates that web-based and mHealth technologies can be used successfully to enable patients to access information, individualize management, track progress and reach personalized goals and, facilitate communication with health professionals or peers [6]. The use of technology has led to improvements in physical activity, diet, problem-solving, and blood glucose control [7-12]; however, some evidence suggests that there may be aspects of self-care that are best-supported face-to-face [13]. In the long term, it may be that self-management technologies (for example, a mobile app targeting blood glucose control), are most effective when they are used interactively with a professional health care team [14].

Despite the availability of many mHealth self-management technologies, minimal evidence exists around their effectiveness, particularly concerning longer-term outcomes [15]. Evaluations of mobile apps aimed at encouraging behavior change predominantly focus on content evaluation and few measure effectiveness [16]. This gap is particularly evident for diabetes-related apps where content or usability is typically evaluated using self-developed checklists or through user feedback [16]. Many instruments used to measure the effectiveness of diabetes-related web-based or mHealth interventions have poor psychometric properties, do not meet guidelines promoted by regulatory bodies (for example, by not including the patient during development [17,18]) and may lack sensitivity to the effects of web-based and mHealth technologies as they were developed before their existence [8].

Assessing the effectiveness of technologies supporting self-management requires suitable instruments that (1) are appropriate for use with people living with type 2 diabetes, (2) includes user perspectives throughout development, and (3) is sensitive to the impact of web-based and mHealth technologies. A truly useful instrument would also be suitable for use in a comparator group not receiving the intervention. This study, therefore, aimed to develop a new measure, the Diabetes Self-Management and Technology Questionnaire (DSMT-Q), to assess self-management among people living with type 2 diabetes using web-based or mHealth technologies.

The content of the DSMT-Q was informed by a previous study that undertook in-depth qualitative interviews (n=15) with people living with type 2 diabetes in order to explore experiences of using web-based and mHealth technologies to manage their health [19]. The analysis identified seven themes as important to participants when using technology to support

self-management. These themes were termed: information, understanding individual health and personal data, reaching and sustaining goals, minimizing disruption to daily life, reassurance, communicating with health care professionals, and coordinated care (see Kelly et al [19] for further details). Draft questionnaire items were constructed to reflect the seven themes, forming an item pool of 36 candidate items for the new questionnaire. The 36 questionnaire items were arranged in two parts. The first 22 items asked about the management of type 2 diabetes and the use of web-based or mHealth technology, while a further 14 items asked about the extent to which a specific technology helped to manage aspects of diabetes. This paper reports the item refinement and psychometric validation of the candidate items.

Methods

Design and Ethics

A mixed methods study, Phase 1 aimed to refine the 36 candidate DSMT-Q items drafted previously using cognitive debrief interviews, expert consultation, and public patient involvement (PPI) feedback. Phase 2 carried out a psychometric validation of the remaining candidate items using appropriate quantitative methods. Ethical approval for this research was granted by the Medical Sciences Inter Divisional Research Ethics Committee of the University of Oxford (reference R59651/RE001).

Phase 1: Patient, Expert, and Public Item Refinement

Cognitive Interviews of People Living With Type 2 Diabetes

Thirty-six candidate items were pretested for ease of completion and understanding among people living with diabetes to ensure that items superficially made sense [20], and provided further support for content validity through ensuring that each theme identified in the qualitative interviews [19] was represented through the item content [21]. Participants were probed about their understanding of the proposed items and each item's relevance to self-managing health and the use of technology [21,22]. In cases where items were ambiguous or repetitive, they were amended or removed.

Study Participants and Procedure

Participants were aged 18 or over with a (self-reported) clinical diagnosis of type 2 diabetes and experience of using one or more diabetes-related web-based or mHealth technology. Participants who had previously taken part in an in-depth interview [19] to inform items and who consented to be contacted were emailed a participant information sheet. On agreeing to take part, participants could ask any questions about the research, asked to complete an online consent form, and given a link to the draft online survey containing the candidate items. Participants were given a GBP £20 (US \$24.92) voucher for their participation.

Interviews

Interviews were recorded and carried out over the telephone using a verbal probing method of cognitive interviewing to allow respondents an opportunity to give uninterrupted answers,

which was then followed by a focused interview [23]. During the focused interview, participants were reminded of their answers to each item, and to gain a deeper understanding of their responses, the reasoning behind their answers was explored [24].

Analysis

Participant comments were summarized and collated in an Excel document (Microsoft) according to each instruction and questionnaire item, allowing within-case (how the item fits within the questionnaire as a whole) and between-case (interpretation and consistency of items across the sample) analysis. Interpretation difficulties or inconsistencies were discussed among authors, amended where appropriate, and retested.

Expert Consultation

An expert panel consisting of three survey development and patient-reported outcome experts, one survey expert and user engagement manager for a national diabetes program, two diabetes experts specializing in digital health, one professor of diabetic medicine, and one consultant physician in diabetes were invited to review the candidate DSMT-Q items via email. Consulting experts sought to evaluate items from both health professionals and survey developers' perspectives. Comments and feedback were received via email, and items amended where appropriate after discussion among the authors.

PPI

PPI representatives who were members of a volunteer list held by the Nuffield Department of Primary Care Health Sciences Coordinator of Patient & Public Involvement were emailed an invite to take part in questionnaire feedback. Representatives were required to have type 2 diabetes, but as questions were designed to be answerable to both those who use technology to manage their health and those who do not, they were not required to have experience using technology to manage their health. Feedback was given over the telephone after representatives had been allowed to review the online survey.

Phase 2: Psychometric Validation

Two web-based surveys were formatted using Qualtrics' survey software. Survey 1 included the refined DSMT-Q (21 items), the Diabetes Self-Efficacy Scale (DSES) [25], two questions on the use of technology and additional demographic questions.

The first question in Survey 1 asked the respondent if they had experience using web-based or mHealth technologies to manage their diabetes. They were shown an appropriate preamble to the DSMT-Q items: 'Think about the management of your type 2 diabetes over the *past four weeks*' or 'Think about the management of your type 2 diabetes, including your use of web-based or mobile technology, over the *past four weeks*.' All item stems remained the same regardless of the questionnaire preamble, and all responses were collated for item analysis.

The DSES is an eight-item scale to assess self-efficacy among people living with diabetes. The Diabetes Self-Efficacy Scale was developed for a randomized trial assessing community-based peer-led diabetes self-management [25]. Items were based on earlier chronic-disease self-efficacy scales [26].

The internal consistency of items is high ($\alpha=.85$), and the scale demonstrates good test-retest reliability (intraclass correlation coefficient [ICC]=0.80) [25].

Survey 2 aimed to assess the test-retest reliability of the DSMT-Q. The DSMT-Q, together with a transition item (whether the respondent's health has changed in the last two weeks), was therefore administered 2 weeks after Survey 1 had been completed.

Procedure

Study Participants and Recruitment

Participants were aged 18 or over with a (self-reported) clinical diagnosis of type 2 diabetes. Participants were recruited through a professional survey recruitment company. Eligible participants were provided with a participant information sheet and asked to confirm their consent to take part. Participants who confirmed they might be contacted again regarding the study while completing Survey 1 were sent an email 2 weeks later asking them to complete Survey 2.

We aimed to recruit 250 participants to complete Survey 1. Estimates suggest that meaningful psychometric tests require at least three times as many respondents as items [27], making this a conservative (large) sample size.

Analysis

Descriptive statistics were used to present demographic data. DSMT-Q items were subjected to several initial data checks to confirm their suitability for inclusion in further analysis. Decision rules for item removal included items with high floor and ceiling effects (>40% of respondents selecting one of the extreme response options) [28,29] and items demonstrating a large number of weak correlations (<0.2) with other items. Exploratory factor analysis (EFA) was performed to group items into conceptually sound sub-scales. Suitability of using EFA on the dataset was assessed through performing the Bartlett Test of Sphericity ($P<.05$) [30] and calculating the Kaiser-Meyer-Olkin (KMO) statistic which has a recommended value of above 0.6 [31]. Factors with Eigenvalues >1 were rotated using an oblique, Direct Oblimin, rotation so that axes were not restricted to right angles, hence allowing correlation between the factors [32,33]. While both the Structure and Pattern matrices were used in interpreting output, and the Structure matrix offered primary guidance for interpretation [34].

Once domain structures were finalized, sub-scales floor and ceiling effects (>20% of responses scoring 0 or 100) were examined, and population characteristics were explored to identify potential covariate factors impacting the final scales. Convergent validity was examined using Pearson correlation coefficients (r) to compare relationships between the DSMT-Q sub-scales and the DSES [33,35]. The DSES was hypothesized to have moderate correlations with DSMT-Q scores. Internal consistency, an indication of a scale's reliability, was evaluated using the Cronbach alpha statistic (>0.7) [36]. External reliability was assessed using the test-retest procedure with the use of the ICC statistic to assess the stability of the scores [37].

Results

Phase 1

Patient Interviews

Eight participants took part in two rounds of cognitive interviews. In the first round, participants (n=4) considered most questionnaire content to be relevant to the management of type 2 diabetes; however, considerable changes needed to be made to the arrangement of the items. Participants found it challenging to respond to the second set of mHealth specific items as they did not typically use one specific technology (for example, one mobile app) in isolation. Furthermore, many questionnaire items did not apply to every technology used, and it was, therefore, difficult for them to determine how they should respond. The second part of the questionnaire was removed, resulting in 12 items being deleted and 2 items, covering topics not already present in the first part, being restructured and included. Two further items, which asked about health care services, were deleted from part one due to participant feedback stating they were unrelated to the personal management of their type 2 diabetes. Twenty-two items were therefore retained.

Five items were amended following participant feedback. Two were amended to improve comprehension and clarity, one was amended to make it more suitable to the response options, one was changed to be more specific and capture the intended meaning better, and one item was changed to prevent duplication with a previous item.

In the second round of cognitive interviews, following participant (n=4) feedback, four items were deleted as they were considered to duplicate existing content. Five items were amended to improve clarity, and one item was revised to apply

to a broader population. Two items were considered too broad and were made into four items to improve accuracy. This process resulted in 20 items for expert consultation.

Expert Consultation

Twenty items were circulated to the expert group. Following feedback, two items were amended to improve language for low literacy groups. One item was amended to be more inclusive to a broader range of people. Six items were amended to improve clarity, and one item was split into two items to try and find the best way to capture reassurance, resulting in 21 items.

Public Patient Involvement (PPI)

PPI representatives (n=4) gave feedback on the 21-item questionnaire. All items were understood by representatives; however, some showed a preference for the further granularity of items. For example, one representative expressed a wish to have separate questions for how easily they can monitor their blood glucose levels, diet, and exercise. This change was omitted due to the likelihood of high frequencies of not applicable or missing data.

Phase 2

Characteristics

Survey 1 participants included 104 (41.6%) women and 146 (58.4%) men. The average age was 55.9 years old (SD 16.4, range 69 years). The modal time since diagnosis of type 2 diabetes was between one and five years ago (n=90, 36%). Most participants (n=232, 92.8%) described themselves as White British. Further sample characteristics can be viewed in [Table 1](#).

Table 1. Participant characteristics.

Characteristic	Value
Sex, n (%)	
Male: Female	146 (58.4): 104 (41.6)
Age (years)	
Mean (SD, range)	55.9 (16.4, 19-88 years)
Time since diagnosis, n (%)	
<12 months	27 (10.8)
1-5 years	90 (36.0)
6-10 years	56 (22.4)
>10 years	77 (30.8)
Ethnic group, n (%)	
White British	232 (92.8)
White (other)	5 (2.0)
Black African	4 (1.6)
Asian	4 (1.6)
Mixed race	3 (1.2)
Other	2 (0.8)

Item Reduction and Scale Development

Six items were removed due to ceiling effects of greater than 40%. The KMO value for the remaining 15 items exceeded the recommended value of 0.6 (KMO= 0.90), and the Bartlett Test of Sphericity reached statistical significance ($P<.01$), indicating there was a correlation between the items. Three factors were initially extracted, explaining 69.1% of the variance. One factor consisted of two items and had a poor Cronbach alpha level of

0.40. These two items were removed, and a second-factor rotation extracted two factors, explaining 63.6% of the variance. See Table 2 for the factor structure and loadings. Factor 1, entitled *Understanding individual health and making informed decisions*, consisted of seven items and had a Cronbach alpha level of 0.90. The second factor, entitled *Confidence to reach and sustain goals*, consisted of six items and had a Cronbach alpha level of 0.88.

Table 2. DSMT-Q factors and item loadings on the Structure matrix.

Item	Factor loading ^a	
	1	2
I can easily monitor important information about my diabetes (for example, my blood glucose levels, diet, or exercise).	0.813	0.645
I am able to make sense of any information that I monitor (for example, my blood glucose levels, diet, or exercise).	0.812	0.639
I feel informed when making decisions about the management of my diabetes.	0.804	0.553
I am aware of the potential outcomes of any actions I take when managing my diabetes (for example, when taking medications or choosing foods to eat).	0.804	0.479
I have access to relevant information about my diabetes.	0.796	0.443
I can usually identify the reasons behind any changes to my blood glucose levels.	0.757	0.441
I understand how my body reacts to exercise.	0.728	0.612
I feel reassured that I am managing my diabetes well.	0.546	0.865
I think my diabetes is under control.	0.509	0.856
I can achieve any personal goals I set when managing my diabetes.	0.491	0.807
I am motivated to carry out routines to manage my diabetes (for example, take medication, exercise).	0.584	0.775
I know when to take action to maintain my desired blood glucose levels.	0.705	0.726
I feel motivated to play an active role in my diabetes management.	0.564	0.627

^aRotation Method: Oblimin with Kaiser Normalization.

Scale Distributions and Validation

Each scale was transformed to a 0-100 metric, where 0 indicated low levels of self-management, and 100 indicated high levels of self-management of type 2 diabetes. Scale scores were calculated by summing the final response values in each sub-scale and dividing the summed score by the maximum scale score. The raw scale score was then transformed into a 0-100

metric by multiplying the raw score by 100. Scale distribution statistics are reported in Table 3. Neither scale exhibited floor or ceiling effects, which was considered to be >20% of responses, achieving the minimum or maximum score. Minimal respondents achieved scores of 0, while 10.8% (n=27) of Factor 1 scores and 10.4% (n=26) of Factor 2 scores achieved the maximum score of 100.

Table 3. Scale score descriptive statistics (N=250).

Scale	Minimum	Maximum	Mean (SD)	Skewness	Kurtosis	ICC ^a , n=113	P value
Factor 1: Understanding Individual Health and making informed decisions	0	100	75.3 (18.1)	-0.89	1.19	0.89	<.001
Factor 2: Confidence to reach and sustain goals	0	100	75.4 (17.7)	-0.95	1.43	0.86	<.001
DSES ^b	0	10	7.7 (1.9)	-1.01	1.00	N/A ^c	N/A

^aAbsolute agreement.

^bDiabetes Self-Efficacy Scale.

^cN/A: not applicable.

Relationships between each DSMT-Q scale and a range of potential covariate factors were examined. No significant differences were found for either sex (Factor 1: $t_{248}=-0.54$,

$P=.59$ and Factor 2: $t_{248}=-0.35$, $P=.72$) or age (n=248, Factor 1: $r=-0.11$, $P=.10$ and Factor 2: $r=-0.06$, $P=.31$) among either sub-scale scores. Nonparametric tests to examine sex

(Mann-Whitney *U* test of significance; Factor 1, $P=.59$, Factor 2=0.71) and age ($n=248$; Factor 1: $\rho=-1.37$, $P=.03$, Factor 2: $\rho=-0.09$, $P=.15$) also demonstrated no significant differences. No significant differences were observed for time since diagnosis for using parametric (analysis of variance; Factor 1: $F_{2,46}=2.14$, $P=.10$, Factor 2: $F_{2,46}=1.891$, $P=.13$) or nonparametric tests (Kruskal-Wallis *k* independent samples; Factor 1: $P=.13$, Factor 2: $P=.15$).

Relationships between the DMST-Q scales and the DSES scale were examined to assess convergent validity. Correlations were high (Factor 1, $r=0.67$, $P<.001$ and Factor 2, $r=0.75$, $P<.001$), indicating the scales were tapping into similar but different concepts.

As predicted, those who did use technology to support self-management scored more highly on both new DMST-Q scales. For Factor 1, those using technology to support self-management ($n=92$) had a mean score of 78.81 (SD 16.64), while those who did not use technology ($n=158$) scored 72.60 (SD 18.42, $t_{248}=3.09$, $P=.002$). For Factor 2, those using technology to support self-management ($n=92$) had a mean score of 80.21 (SD 14.61), while those who did not use technology ($n=158$) scored 72.52 (SD 18.73, $t_{248}=3.38$, $P<.001$).

Factor 1 and 2 also demonstrated good test-retest reliability with ICC values, for those who had indicated their health had remained the same compared to two weeks ago ($n=113$), equal to 0.78 ($P<.001$) and 0.74 ($P<.001$), respectively.

Discussion

Principal Findings

This paper reports the development of a new instrument, the DSMT-Q, to assess self-management in people living with type 2 diabetes using web-based and mHealth technologies to manage their health. Phase 1 used patient and expert feedback to reduce and refine 36 candidate items to 21 items. Phase 2 further refined items using EFA and confirmed the presence of two sub-scales. The first sub-scale contained seven items and was entitled “Understanding individual health and making informed decisions.” Understanding individual health to make informed decisions was found to be extremely important in the preliminary qualitative work to support this research [19]. It is further supported by other diabetes research that links logging, visualizing, and understanding individual health to acquire new knowledge and make changes to behavior [38]. Similar conclusions can also be found in other condition groups, including COPD, where mHealth applications have also been used to support self-management [39].

The second subscale contained six items and was entitled “Confidence to reach and sustain goals.” Although the preliminary qualitative work carried out to inform this instrument supports the grouping of these items, it is also supported through early research, which links the potential of

web-based interventions to patient empowerment [40]. Gaining confidence and taking ownership to reach personal goals through monitoring physical activity on a mobile app has also been demonstrated among patients in the primary care setting [41].

Statistical analyses confirmed the DSMT-Q subscales were highly related to the DSES scale scores and therefore providing evidence of similar, yet distinct constructs. As expected, no significant differences were found for sex or age. Respondents who indicated that they did use technology to manage their health scored more highly on both scales indicating that the items can differentiate between technology and nontechnology users. Internal and external reliability was demonstrated for both scales.

The methods used in this study enabled input from both people living with type 2 diabetes and experts during the refinement of the new instrument. Incorporating the patient throughout the stages of instrument development is essential to ensure the user’s perspective is accurately reflected [18,42], and the inclusion of experts helped to ensure that the instrument would be of use in a range of applied settings.

Questionnaire items were also designed to be used in a comparator, nonintervention group to maximize utility of the measure. Although the items are based on themes identified as relevant to the use of web-based and mHealth technologies, they are also applicable and worded appropriately for those who are not using technology to manage their health. As such, this instrument may be used in a variety of contexts where a comparator group receives standard care or other technology or non-technology-based resources. In contrast with other technology-specific instruments that include references to a specific device or website [43], the wording of the items allows for the responder to use multiple resources, for example, mobile apps plus wearable devices.

Limitations

There are a few limitations to this study regarding the participant sample. First, Black, Asian, and minority ethnic groups were underrepresented within the sample. Second, it should be noted that the use of survey panels to recruit participants for surveys is in its relative infancy in the patient-reported outcome setting; however, it is a method that has been incorporated into other research settings, such as health economics [44]. With regard to measurement properties, further longitudinal research is required to demonstrate the instrument’s sensitivity to change.

Conclusions

This paper reports two phases of the development of a new instrument—the DSMT-Q. Analyses confirmed good psychometric properties in the DSMT-Q scales. This tool is fully compliant with relevant regulatory bodies, such as the FDA and EMA, and will facilitate the measurement of self-management in people living with type 2 diabetes using web-based or mHealth technologies.

Acknowledgments

LK contributed to the study design, carried out the survey, and had a lead role in the analysis. CJ and DM contributed to the study design and analysis. All authors contributed to and approved the final manuscript.

The authors would like to thank Diabetes UK and Diabetes Support Forum UK, who helped with recruitment for the Phase 1 interviews. The authors would also like to thank the participants who volunteered their time to take part in the study. The authors would like to thank all the expert reviewers who volunteered their time.

This research was funded by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care Oxford at Oxford Health NHS Foundation Trust. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care. Research costs were funded internally within the Health Service Research Unit, Nuffield Department of Population Health, University of Oxford.

Conflicts of Interest

None declared.

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Abbreviations

CBG: continuous blood glucose

DSES: Diabetes Self-Efficacy Scale

DSMT-Q: Diabetes Self-Management and Technology Questionnaire

EFA: exploratory factor analysis

HbA_{1c}: glycated hemoglobin

ICC: intraclass correlation coefficient

KMO: Kaiser–Meyer–Olkin

NHS: National Health Service

Edited by D Griauzde; submitted 11.02.20; peer-reviewed by J Zhou, K Anderson; comments to author 21.03.20; revised version received 15.05.20; accepted 22.05.20; published 09.07.20.

Please cite as:

Kelly L, Jenkinson C, Morley D

Web-Based and mHealth Technologies to Support Self-Management in People Living With Type 2 Diabetes: Validation of the Diabetes Self-Management and Technology Questionnaire (DSMT-Q)

JMIR Diabetes 2020;5(3):e18208

URL: <https://diabetes.jmir.org/2020/3/e18208>

doi: [10.2196/18208](https://doi.org/10.2196/18208)

PMID: [32673214](https://pubmed.ncbi.nlm.nih.gov/32673214/)

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Original Paper

Changes in Patient-Reported Outcome Measures With a Technology-Supported Behavioral Lifestyle Intervention Among Patients With Type 2 Diabetes: Pilot Randomized Controlled Clinical Trial

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Abstract

Background: In the United States, more than one-third of the adult population is obese, and approximately 25.2% of those aged ≥ 65 years have type 2 diabetes (T2D), which is the seventh leading cause of death. It is important to measure patient-reported outcomes and monitor progress or challenges over time when managing T2D to understand patients' perception of health and quantify the impact of disease processes or intervention effects. The evaluation of patient-reported outcome measures (PROMs) is especially important among patients with multiple chronic conditions in which clinical measures do not provide a complete picture of health.

Objective: This study examined the feasibility of collecting Patient-Reported Outcome Measurement Information System (PROMIS) measures, and preliminarily evaluated changes in PROMIS scores and compared the scores with standard scores of the general US population. The parent study is a pilot randomized controlled clinical trial testing three different modes (mobile health [mHealth], paper diary, and control) of self-monitoring in a behavioral lifestyle intervention among overweight or obese patients with T2D.

Methods: Patients with comorbid overweight or obesity and a diagnosis of T2D for at least 6 months were recruited from a diabetes education program. Participants were randomized to the following three groups: mHealth, paper diary, and control (standard of care) groups. Paper diary and mHealth experimental groups received additional behavioral lifestyle intervention education sessions, as well as tools to self-monitor weight, physical activity, diet, and blood glucose. All participants completed PROMIS-57 and PROMIS-Global Health (GH) version 1.0 questionnaires during visits at baseline, 3 months, and 6 months. The PROMIS-57 includes the following seven domains: anxiety, depression, fatigue, pain interference, physical function, satisfaction with participation in social roles, and sleep disturbance. The PROMIS-GH is composed of the following two domains: global mental health and global physical health.

Results: A total of 26 patients (mHealth, 11; paper diary, 9; control, 6) were included in our analysis. The study sample was predominantly African American (68%) and female (57%), with a mean age of 54.7 years and a mean BMI of 37.5 kg/m². All patients completed the PROMIS-57 and PROMIS-GH questionnaires, and we compared the mean scores of the three groups to investigate potential differences. No relevant differences were noted across the groups. However, positive trends were noted in both intervention (mHealth and paper diary) groups in the middle (month 3) and end (month 6) of the study.

Conclusions: Our pilot study provides evidence for the feasibility of using PROMIS questionnaires to record important components of T2D-related symptoms among overweight or obese individuals. The results from our study support the use of PROMIS questionnaires to provide clinicians and researchers with a benchmark for assessing the overall need for symptom management and determining the success or challenges of an intervention.

Trial Registration: ClinicalTrials.gov NCT02858648; <https://clinicaltrials.gov/ct2/show/NCT02858648>

(*JMIR Diabetes* 2020;5(3):e19268) doi:[10.2196/19268](https://doi.org/10.2196/19268)

KEYWORDS

Patient-Reported Outcome Measurement Information System; patient-reported outcomes; patient-reported outcome measures; type 2 diabetes; self-management; self-monitoring; behavioral lifestyle interventions

Introduction

In the United States, more than one-third of the adult population is obese [1], and the prevalence of obesity among adults in Texas is currently 33.0% (up from 21.7% in 2000). Texas is ranked 14th for obesity in the United States [2]. Obesity-related conditions, such as type 2 diabetes (T2D), heart disease, stroke, and certain types of cancer, are some of the leading causes of preventable premature death [3]. Obesity affects some groups more than others, and Hispanic people and non-Hispanic black people were reported to have the highest age-adjusted prevalence of obesity at 47.0% and 46.8%, respectively [3]. T2D is the seventh leading cause of death in the United States, and the percentage of adults with diabetes shows an increase with age, reaching a high of 25.2% among those aged ≥ 65 years [4]. Compared with non-Hispanic white people, the age-adjusted prevalence of diagnosed and undiagnosed diabetes was reported to be higher among Hispanic and non-Hispanic black people [4]. The management of diabetes is complex, and people living with diabetes need to make many choices related to their treatment and management, including self-monitoring their diet and activity.

Mobile health (mHealth), defined as the delivery of health care services and information using mobile technologies, is being increasingly utilized in diabetes management [5,6]. The technologies include smartphones, wearable devices, smart and connected devices, and apps. Several studies and systematic reviews have strongly supported the effectiveness of mobile apps and smart devices for diabetes management in recent years [5-8]. The authors have highlighted the positive clinical outcomes of these interventions, including reduction of hemoglobin A_{1c}, when compared with standard care, and other diabetes and cardiometabolic variables such as blood glucose levels, blood pressure, serum lipid levels, and body weight.

Although clinical outcomes are important in the management of T2D, it is also important to integrate patient-reported outcome measures (PROMs) to improve overall care among people with T2D. The Patient-Reported Outcome Measurement Information System (PROMIS) initiative from the National Institutes of Health was developed to improve and standardize measurements of patient-reported outcomes [9]. PROMIS is a set of person-centered measure scores that screen; evaluate interventions; and monitor physical, mental, and social health and well-being in general populations and among individuals with chronic conditions to understand their perceptions of health and ultimately what information is most meaningful to them [9]. This is especially important among patients with chronic conditions in which clinical performance measures do not provide a complete picture of health [10]. It can also provide clinicians and researchers with a benchmark for assessing the

overall need for treatment and management, and determining the success or challenges of an intervention or treatment [9]. There is growing evidence of the validity of PROMIS tools, and they are in widespread use but have undergone limited validation in vulnerable populations with multiple comorbid conditions, including overweight or obese adults with T2D.

This study is a secondary analysis examining the feasibility of collecting PROMIS data and a preliminary evaluation of changes in PROMIS questionnaires, as part of a pilot randomized controlled clinical trial testing three different modes (mHealth, paper diary, and control) of self-monitoring of behavioral lifestyle interventions among overweight or obese patients with T2D [11]. We compared the mean scores and SDs for the three study groups to the data of a US reference population. The presence of a common set of outcome metrics would greatly improve the ability to compare outcomes across institutions and populations and inform the provision of effective care [9].

This study aimed to examine the feasibility of collecting PROMIS measures and to preliminarily evaluate the changes in PROMIS-57 and PROMIS Global Health (GH) questionnaires in a pilot randomized controlled clinical trial testing three different modes (mHealth, paper diary, and control) of self-monitoring of behavioral lifestyle interventions among overweight or obese adults with T2D from a parent study [11].

Methods

Recruitment

Participants were recruited from a certified American Diabetes Association diabetes education program in Harris County, Texas. The primary clientele of the selected location is uninsured or underinsured individuals from the surrounding area. Flyers were distributed by diabetes educators to patients attending diabetes education classes, and interested participants could contact the study team for additional details and enrollment.

Participants were screened for eligibility based on the following criteria: (1) diagnosis of T2D for at least 6 months (confirmed in the electronic health records); (2) overweight or obesity (BMI ≥ 25 kg/m²); (3) age 21 to 75 years; (4) ability to read and write in English; and (5) completion or near completion of the basic diabetes self-management education offered at the recruitment site. The exclusion criteria were as follows: (1) history of severe psychiatric disorders (eg, bipolar disorder and schizophrenia); (2) inability to perform regular activity; (3) current pregnancy or planning for pregnancy or nursing in the next 6 months; (4) planning for a vacation in the next 6 months; (5) previous participation in an intensive behavioral lifestyle intervention; and (6) substance abuse in the past year.

This paper describes the secondary data analysis of a three-group pilot randomized controlled clinical trial, which compared the efficacy of behavioral lifestyle interventions using either mHealth or paper diary self-monitoring tools among underserved populations with comorbid T2D and overweight or obesity [11]. The pilot study's primary and secondary outcome measures were glycemic control and weight, respectively. All three groups completed usual diabetes care and education; the mHealth and paper diary experimental groups additionally completed 11 group sessions as part of the behavioral lifestyle intervention over 6 months and self-monitored their diet, physical activity, weight, and blood glucose levels [11].

In addition to other measures, participants in all three groups completed PROMIS-57 and PROMIS-GH version 1.0 questionnaires at baseline, 3 months, and 6 months to evaluate the impact of behavioral lifestyle interventions on PROMs in this study.

There is substantial clinically valid evidence that PROMIS was successful in developing measures that are effective across a range of chronic conditions (chronic heart failure, chronic obstructive pulmonary disease, rheumatoid arthritis, cancer, back pain, and major depression) and predominately in white non-Hispanic people [12]. The PROMIS-57 is intended for use across a variety of conditions and assesses the following seven domains: physical function, anxiety, depression, fatigue, sleep disturbance, pain interference, and satisfaction with participation in social roles and activities [13]. There is also a single item in all PROMIS questionnaires measuring pain intensity, which has 11 response options ranging in value from 0 to 10. For the pain intensity domain, higher values reflect greater pain [13]. The seven domains are composed of eight items, with response options ranging on a 5-point Likert scale (always, often, sometimes, rarely, and never). For the physical function and satisfaction with participation in social roles domains, higher scores reflect better functioning. In contrast, for the anxiety, depression, fatigue, pain interference, and sleep disturbance domains, higher scores reflect poorer functioning. PROMIS-GH refers to a person's general evaluation of health and produces the following two scores: global physical health (GPH) and global mental health (GMH). The GPH assesses physical health (ie, physical functioning, pain intensity, and fatigue), whereas the GMH assesses overall quality of life, mental health, satisfaction with social activities, relationships, and emotional problems. Higher scores for GMH and GPH reflect better functioning [13].

Statistical Analysis

Statistical Package for the Social Sciences (SPSS) version 25 (IBM Corp) was used for all statistical analyses. Significance was set at $\alpha=.05$ [14]. For all variables, frequency distributions were generated. For nominal and ordinal variables, percentages and modes were evaluated. For interval and ratio variables, means and standard deviations were calculated if the variables were normally distributed. When response sets for participants were incomplete, missing responses were imputed using regression substitution if 80% or more of the responses were present. After imputations, raw score totals and T-scores were generated for complete response sets [13]. The Mann-Whitney *U* test was used when comparing two groups for an ordinal dependent variable (mHealth group and paper diary group). The Kruskal-Wallis test was used when comparing three groups (mHealth, paper diary, and control) for an ordinal dependent variable. To compare the T-scores of the mHealth group to those of the paper diary group for the seven domains from the PROMIS-57 and the two domains from the PROMIS-GH, Mann-Whitney *U* analyses were performed. To examine if the T-scores for the seven domains from the PROMIS-57 and the two domains from the PROMIS-GH varied as a function of the group at each time point, Kruskal-Wallis tests were performed.

Results

Sample Description

A total of 26 patients (11 in the mHealth group, 9 in the paper diary group, and 6 in the control group) were included in our analysis. The study sample consisted of predominantly African American (68%) and female (57%) participants, with a mean age of 54.7 years and a mean BMI of 37.5 kg/m². A detailed description of the sample can be found in the parent study [11].

Table 1 presents the descriptive statistics for PROMIS-57 and PROMIS-GH. The feasibility of collecting PROMIS-57 and PROMIS-GH data in a pilot randomized controlled clinical trial is high, and all of the 26 patients completed the baseline and 3- and 6-month assessments on PROMIS tools.

The analysis compared group scores at baseline, 3 months, and 6 months. Evaluation of the results from the Mann-Whitney *U* test and Kruskal-Wallis test indicated that there were no relevant differences in PROMIS scores among the three groups at any time point. However, interpretation of the results from the Mann-Whitney *U* test indicated a trend for the PROMIS-GH domain GMH at 3 months ($U=-1.8$, $P=.06$), that is, GMH showed a trend of lower scores in the mHealth group (mean 42.3, SD 4.5) than in the paper diary group (mean 45.9, SD 5.2) at 3 months; however, this was not significant ($P=.06$).

Table 1. Descriptive statistics on PROMIS-57 and PROMIS Global Health.

Questionnaire domain and time point ^a	mHealth ^b (n=11), mean (SD) score	Paper diary (n=9), mean (SD) score	Control (n=6), mean (SD) score
PROMIS^c-57			
Physical Function^d			
Baseline	40.6 (7.5)	39.1 (6.3)	41.5 (5.2)
Three months	41.4 (8.4)	44.1 (7.9)	42.5 (8.9)
Six months	40.2 (8.2)	47.1 (10.1)	45.1 (11.9)
Satisfaction with social roles^d			
Baseline	46.6 (9.2)	42.4 (10.5)	46.5 (4.3)
Three months	49.0 (10.3)	53.4 (11.9)	42.5 (7.5)
Six months	45.6 (11.4)	46.6 (14.8)	52.0 (13.1)
Anxiety^e			
Baseline	53.4 (10.2)	56.1 (11.6)	52.0 (10.5)
Three months	54.8 (8.1)	55.0 (9.9)	51.6 (6.7)
Six months	51.7 (11.7)	50.4 (14.2)	48.1 (8.5)
Depression^e			
Baseline	48.9 (9.9)	53.2 (10.5)	45.0 (10.2)
Three months	49.0 (9.8)	49.8 (11.6)	50.4 (3.0)
Six months	46.6 (12.9)	49.9 (12.7)	44.0 (7.4)
Fatigue^e			
Baseline	53.5 (10.1)	55.4 (12.6)	52.9 (5.5)
Three months	54.0 (7.7)	53.1 (11.1)	53.5 (7.8)
Six months	53.9 (7.7)	47.8 (13.1)	52.8 (2.9)
Sleep disturbance^e			
Baseline	56.4 (5.4)	53.0 (10.0)	59.4 (3.1)
Three months	56.6 (3.2)	56.1 (5.7)	59.3 (1.7)
Six months	56.6 (5.6)	59.5 (4.1)	56.8 (4.4)
Pain interference^e			
Baseline	61.0 (9.1)	57.0 (10.3)	59.5 (5.5)
Three months	61.7 (5.2)	56.3 (11.8)	57.6 (11.5)
Six months	58.2 (9.8)	55.1 (12.5)	57.2 (3.5)
Pain intensity^e			
Baseline	5.7 (2.4)	4.7 (2.4)	4.5 (4.2)
Three months	5.5 (2.8)	4.2 (3.1)	5.3 (4.4)
Six months	4.8 (2.5)	3.6 (3.5)	5.6 (2.3)
PROMIS-GH^f			
Global Physical Health^d			
Baseline	37.8 (4.2)	39.3 (5.1)	39.4 (4.2)
Three months	38.7 (4.0)	39.8 (5.0)	41.4 (7.0)
Six months	38.2 (4.8)	41.1 (5.4)	42.5 (5.9)
Global Mental Health^d			

Questionnaire domain and time point ^a	mHealth ^b (n=11), mean (SD) score	Paper diary (n=9), mean (SD) score	Control (n=6), mean (SD) score
Baseline	40.8 (4.4)	42.3 (4.5)	45.8 (2.6)
Three months	42.3 (4.5)	45.9 (5.2)	45.5 (6.2)
Six months	42.3 (5.1)	42.8 (6.0)	44.4 (4.0)

^aFor all domains listed, the mean (SD) score for the US reference population is 50 (10).

^bmHealth: mobile health.

^cPROMIS: Patient Reported Outcome Measurements Information System.

^dHigher scores indicate better functioning.

^eHigher scores indicate worse functioning.

^fPROMIS-GH: Patient Reported Outcome Measurements Information System Global Health.

Thereafter, we compared the mean scores and SDs for the three groups (ie, mHealth, paper diary, and control) to the data of the US reference population. The mean score and SD for the US reference population for each of the seven domains of the PROMIS-57 and two domains of the PROMIS-GH were 50 and 10, respectively. For each domain, a higher score indicates that more of the concept has been measured. For the three groups in our study, the mean scores for physical function (PROMIS-57) and for PROMIS-GH were lower than the scores in the US reference population (mean score of 50), indicating poorer functioning (Table 1). Specifically, for physical function, the mean scores ranged from 39.1 to 47.1; for GMH, the mean scores ranged from 37.8 to 42.5; and for GPH, the mean scores ranged from 40.8 to 45.9. In addition, for the three groups in our study, the mean scores for anxiety, pain interference, and sleep disturbance were higher than the scores in the US reference population (mean score of 50), indicating poorer functioning. Specifically, for anxiety, the mean scores ranged from 48.1 to 56.1; for pain interference, the mean scores ranged from 55.1 to 61.7; and for sleep disturbance, the mean scores ranged from 53.0 to 59.5. Furthermore, the baseline scores of anxiety (mean 53.4), depression (mean 48.9), pain interference (mean 61.0), and pain intensity (mean 5.7) improved at the end of the study in the mHealth intervention group.

Discussion

Principal Findings

Our pilot study provides evidence for the feasibility of using the PROMIS questionnaires to measure patient-reported outcomes among overweight or obese individuals diagnosed with T2D. The mean T-scores across time for each group (ie, raw view) indicated that those in the mHealth and paper diary groups reported symptom improvement at months 3 and 6 from baseline. It is important to note that individuals with T2D in the study had greater symptom burden and poorer physical functioning at baseline than the general US population. The PROMIS *P* values were $>.05$; however, positive trends were noted in both intervention groups (mHealth and paper diary) in the middle (month 3) and end (month 6) of the study. Our results found that the mean scores of our participants for most domains were poorer than those of the US reference population. This suggests that overweight or obese individuals diagnosed with T2D have higher symptom burden and poorer functioning compared with healthy individuals. The results from our study

support the use of the PROMIS questionnaires to provide clinicians and researchers with a benchmark for assessing the overall need for disease management and determining the success or challenges of an intervention.

Similar results have been reported in a cross-sectional study among patients diagnosed with T2D, where patients reported higher levels of pain and fatigue that were closely related to sleep disturbance [15]. Another cross-sectional study reported that patients who were very active in their self-care related to T2D had lower depression, better social outcomes, and better physical function [16]. To address the missing items from our study, we looked at the study conducted by Paz et al [17] that estimated the readability of the PROMIS questionnaires to assess their comprehensibility in a sample of African American and Latino older adults (aged ≥ 65 years). The authors reported that the participants had challenges in readability, comprehension, and interpretation of PROMIS items. The authors further reported that the study participants had limited educational attainment and socioeconomic status (similar to our study) and may experience cognitive decline from aging, chronic diseases, and possible polypharmacy, which could have contributed to our findings of missing items.

Strengths and Limitations

The PROMIS instruments chosen for the study offer an opportunity to explore a variety of health concerns in patients with T2D, which may not have time for discussion during a standard clinic visit. The participation retention rate of 92% at 6 months supports the idea that participants are interested in and accepting of self-monitoring behavioral lifestyle interventions.

Our pilot study has several limitations. It is important to note that the study population included individuals who were overweight or obese and had T2D, predominantly included African American people, and mostly included individuals lacking health insurance and having a lower socioeconomic status. At baseline, they had lower PROMIS scores than the mean score of the general US population (mean 50, SD 10), and their scores stayed low throughout the study. The participants were those seeking care at a diabetes education center and thus may not be representative of the general population. In addition, the pilot study was not designed to detect statistical significance, as the study was a feasibility study.

Conclusions

Our pilot study provides evidence for the feasibility of using the PROMIS questionnaires to measure patient-reported outcomes among overweight or obese individuals diagnosed with T2D. It is important to note that individuals with T2D in this study started out with greater symptom burden and poorer physical functioning at baseline compared with the general US population. The results from our study support the use of PROMIS questionnaires to provide clinicians and researchers with a benchmark for assessing the overall need for treatment and determining the success or challenges of the intervention. The *P* values of the PROMIS-57 and PROMIS-GH were $>.05$

(not significant); however, positive trends were noted in both intervention groups (mHealth and paper diary) in the middle (month 3) and end (month 6) of the study.

Future studies should consider using PROMIS computerized assessment testing that may be associated with higher completion rates and may reduce respondent burden by limiting the number of questions (fixed length) that participants need to answer. Future directions include (1) development and validation of a T2D-specific PROM that combines persons with similar clinical characteristics and risks for complications to identify treatment needs and (2) integration of these patient-reported outcome tools into routine patient care and research studies.

Acknowledgments

This study was supported by the RL5 Mentored Research Career Development Award through San Antonio Claude D. Pepper Older Americans Independence Center (P30AG044271). The parent study was funded by the Dean's Research Award and PARTNERS Awards at UT Health Cizik School of Nursing.

Conflicts of Interest

None declared.

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Abbreviations

GH: global health

GMH: global mental health

GPH: global physical health

mHealth: mobile health

PROM: patient-reported outcome measure

PROMIS: Patient-Reported Outcome Measurement Information System

T2D: type 2 diabetes

Edited by G Eysenbach; submitted 10.04.20; peer-reviewed by JH Cho, J Rich; comments to author 04.05.20; revised version received 31.05.20; accepted 21.06.20; published 24.07.20.

Please cite as:

Jiwani R, Wang J, Berndt A, Ramaswamy P, Mathew Joseph N, Du Y, Ko J, Espinoza S

Changes in Patient-Reported Outcome Measures With a Technology-Supported Behavioral Lifestyle Intervention Among Patients With Type 2 Diabetes: Pilot Randomized Controlled Clinical Trial

JMIR Diabetes 2020;5(3):e19268

URL: <http://diabetes.jmir.org/2020/3/e19268/>

doi: [10.2196/19268](https://doi.org/10.2196/19268)

PMID: [32706652](https://pubmed.ncbi.nlm.nih.gov/32706652/)

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Original Paper

Intervention Enhancement Strategies Among Adults With Type 2 Diabetes in a Very Low–Carbohydrate Web-Based Program: Evaluating the Impact With a Randomized Trial

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Abstract

Background: Adults with type 2 diabetes may experience health benefits, including glycemic control and weight loss, from following a very low–carbohydrate, ketogenic (VLC) diet. However, it is unclear which ancillary strategies may enhance these effects.

Objective: This pilot study aims to estimate the effect sizes of 3 intervention enhancement strategies (text messages, gifts, and breath vs urine ketone self-monitoring) that may improve outcomes of a 12-month web-based *ad libitum* VLC diet and lifestyle intervention for adults with type 2 diabetes. The primary intervention also included other components to improve adherence and well-being, including positive affect and mindfulness as well as coaching.

Methods: Overweight or obese adults (n=44; BMI 25–45 kg/m²) with type 2 diabetes (glycated hemoglobin [HbA_{1c}] ≥6.5%), who had been prescribed either no glucose-lowering medications or metformin alone, participated in a 12-month web-based intervention. Using a 2×2×2 randomized factorial design, we compared 3 enhancement strategies: (1) near-daily text messages about the intervention's recommended behaviors (texts n=22 vs no texts n=22), (2) mailed gifts of diet-relevant foods and cookbooks (6 rounds of mailed gifts n=21 vs no gifts n=23), and (3) urine- or breath-based ketone self-monitoring (urine n=21 vs breath n=23). We assessed HbA_{1c} and weight at baseline and at 4, 8, and 12 months. We evaluated whether each strategy exerted a differential impact on HbA_{1c} and weight at 12 months against an a priori threshold of Cohen *d* of 0.5 or greater.

Results: We retained 73% (32/44) of the participants at 12 months. The intervention, across all conditions, led to improvements in glucose control and reductions in body weight at the 12-month follow-up. In intent-to-treat (ITT) analyses, the mean HbA_{1c} reduction was 1.0% (SD 1.6) and the mean weight reduction was 5.3% (SD 6.0), whereas among study completers, these reductions were 1.2% (SD 1.7) and 6.3% (SD 6.4), respectively, all with a *P* value of less than .001. In ITT analyses, no enhancement strategy met the effect size threshold. Considering only study completers, 2 strategies showed a differential effect size of at least a *d* value of 0.5 or greater.

Conclusions: Text messages, gifts of food and cookbooks, and urine-based ketone self-monitoring may potentially enhance the glycemic or weight loss benefits of a web-based VLC diet and lifestyle intervention for individuals with type 2 diabetes. Future

research could investigate other enhancement strategies to help create even more effective solutions for the treatment of type 2 diabetes.

Trial Registration: ClinicalTrials.gov NCT02676648; <http://clinicaltrials.gov/ct2/show/NCT02676648>

(*JMIR Diabetes* 2020;5(3):e15835) doi:[10.2196/15835](https://doi.org/10.2196/15835)

KEYWORDS

type 2 diabetes; diet, ketogenic; text messages; self-management

Introduction

Type 2 diabetes is a costly [1] and deadly illness [2] affecting more than 30 million Americans. Our previous research suggests that a web-based *ad libitum* very low-carbohydrate, ketogenic diet (VLC) and lifestyle intervention that includes training in positive emotions and mindful eating can help overweight adults with type 2 diabetes improve their blood glucose control and lose weight [3,4]. This, in turn, may reduce the future risk of health complications [5]. Although other approaches, such as very low-calorie diets, may also increase glycemic control and reduce the need for antidiabetic and antihypertensive drugs [6], recent recommendations from the American Diabetes Association [7] and other reviews of research and clinical evidence [8,9] support the use of very low-carbohydrate diet interventions.

In this study, we evaluated 3 potentially helpful enhancements to the VLC diet and lifestyle web-based intervention: (1) text messages, (2) food and book gifts, and (3) type of dietary adherence self-monitoring using different measures of ketones (urine vs breath). Although potentially beneficial, these enhancements may also increase participant burden or increase intervention costs. Thus, the primary goal of this pilot study was to determine which methods may be effective for enhancing behavior change in future trials. All participants received access to a comprehensive web-based intervention that included positive emotion and mindful eating training in addition to dietary guidelines [4]. We then varied, in a 2×2×2 full factorial design, whether participants received each of the 3 extra intervention enhancements or not.

First, we varied whether or not participants received text messages targeting improved intervention adherence. Message-based interventions have been shown to improve a wide variety of health behaviors, possibly because of their ability to remind participants of intervention-relevant behaviors or to address barriers to adherence [10,11]. Messages based on this particular diet and lifestyle intervention have not been previously tested. However, messages might also increase intervention costs and complexity and/or burden participants. Thus, this strategy should be tested before being included in future interventions.

Second, we tested the impact of mailing gifts of diet-relevant foods and cookbooks (6 rounds of mailed gifts vs none). Although providing meal replacements has generally been found to be helpful for weight loss [12,13], to our knowledge, it is novel to provide gifts of intervention-related foods and cookbooks. Previous research has hypothesized that mailed gifts increase positive affect, which, in turn, may increase intervention

adherence [14]. However, this approach likewise adds expense, approximately US \$150 per participant in our design, and thus should be carefully evaluated for inclusion in future interventions.

Third, we assessed the impact of urine versus breath ketone self-monitoring. Self-monitoring may increase behavioral adherence to dietary interventions by providing external feedback for the targeted behaviors [15,16]. Such self-monitoring behavior improves diabetes self-management [17], and greater dietary self-monitoring is generally related to greater weight loss and dietary adherence [18]. People adhering to a VLC diet should produce ketones detectable in the breath or urine [19]. Hence, we sought to help participants self-monitor their ketones and thus dietary adherence in a less burdensome way than tracking their diet directly because dietary self-monitoring can be burdensome and long-term daily adherence can degrade in the long term [20]. We were especially interested in testing this enhancement strategy because of the price difference between the 2 ketone measurement approaches: when we conducted this trial, the urine test strips cost approximately US \$25 for 100 strips, and the breath meter costs approximately US \$150. We sought to determine whether the more expensive method of monitoring dietary adherence was actually more beneficial for participants.

Our study design was informed by the multiphase optimization strategy, which encourages intervention optimization through full factorial designs, allowing us to efficiently identify promising enhancement strategies for more definitive future testing. By using a full factorial as opposed to a three-arm study, this design requires fewer participants to rule in or out potentially promising intervention strategies [21]. The overriding goal of this trial was to help inform decisions about which enhancement strategies may be the most promising and should be combined into a treatment package to be tested in a full-scale follow-up trial [22].

Methods

Procedure

The institutional review board (IRB) at the University of Michigan, which also served as the IRB of record for study investigators at the University of California, San Francisco, approved the study materials (HUM00102827). We registered this study with clinicaltrials.gov (NCT02676648). We recruited participants between February 2016 and November 2016 and completed data collection by October 2017. We placed advertisements or notices of the research on the web (including Reddit, Facebook, Craigslist, University of Michigan's web-based portal for clinical trials, LinkedIn, Pandora radio,

and ResearchMatch) and sent invitation letters to potentially eligible participants identified from health plan records at Michigan Medicine. We directed interested participants to the study website, where they completed a web-based self-report screening survey (Qualtrics) and where we displayed the logos of both schools involved. Those who were eligible for further screening based on their survey responses were asked to provide web-based electronic consent to undergo a second web-based survey (Qualtrics); self-administered glycated hemoglobin (HbA_{1c}) test from DTI Laboratories, Inc; and 3 days of dietary tracking on MyFitnessPal. We also mailed these individuals a body weight scale that connects to its own cellular network (BodyTrace). Finally, those who met all entry criteria (below) were invited to participate in the trial.

Participants were eligible to participate if they were aged 21-70 years, had a current HbA_{1c} of 6.5% or higher (measured with the at-home test), had a BMI of 25 to 45 kg/m² (based on self-reported height and measured weight per electronic communication from the mailed scale), had access to the internet for personal use, were willing to check their email at least once

a week, were comfortable reading and writing in English, had no potentially serious comorbidities such as liver or kidney failure, were planning on living in the United States for the duration of the trial, were not vegetarian or vegan, and were not on medications known to cause weight gain such as second-generation antipsychotics. Given that this study was conducted remotely, to mitigate the risk of hypoglycemia, we excluded participants who reported taking any glucose-lowering medication other than metformin.

Experimental Design

This 2×2×2 full factorial experiment examined the impact of 3 experimental, two-level factors. We randomized the participants to 1 of 8 unique experimental conditions (Table 1).

Once all baseline measurements had been completed, the study staff randomized the participants to one of the abovementioned 8 conditions using a computer program to reveal the next assignment. The order was created using block randomization procedures, with blocks randomly allocated to size 8 or 16 and with the seed number of 714119960524911 from the Sealed Envelope website, we create a blocked randomization list [23].

Table 1. All tested combinations of the 3 intervention enhancement strategies.

Combinations	Experimental factors		
	Texting	Gifts	Ketone measurement
1	Texts	Gifts	Urine
2	Texts	Gifts	Breath
3	Texts	No gifts	Urine
4	Texts	No gifts	Breath
5	No texts	Gifts	Urine
6	No texts	Gifts	Breath
7	No texts	No gifts	Urine
8	No texts	No gifts	Breath

Standard Intervention

We encouraged all participants to eat an *ad libitum* (noncalorie-restricted) VLC diet, as in our previous research [3,4], which focused on reducing carbohydrate intake to between 20 and 35 nonfiber grams a day and including calories derived from meats, cheeses, dairy products, eggs, fats, nuts, seeds, and low-carbohydrate vegetables and fruits. If participants experienced muscle cramps, we suggested that they consider taking over-the-counter magnesium supplements as needed.

We also provided participants with strategies to increase day-to-day positive emotions, mindfulness, and mindful eating [24-28]; a coach (the first author), who answered the participants' questions via email or phone [29]; encouragement to be physically active [30] and get sufficient sleep [31]; information about web-based VLC support groups; and suggestions to track their diet using a free web-based and mobile app, MyFitnessPal [32], daily in the first month, and starting in the second month, for 3 consecutive days every 4 weeks. We did not test basic aspects of the intervention, such as weekly emails and access to an email-based coach, via a full factorial

trial design in this study. This is because such a trial design is best suited to testing potential components that may be costly or burdensome to participants.

The intervention lasted 12 months. During the first 4 months, we emailed the participants weekly. These 16 emails contained links that connected them to (1) a short survey to assess intervention-related adherence and health concerns; (2) a short, embedded video to teach assigned topics; (3) downloadable handouts to accompany the videos; and (4) links to external resources pertaining to that week's information. As some participants may prefer not to watch videos, we also provided video transcripts in a downloadable PDF format. Participants could watch and read the lessons whenever they wished. Lessons varied in length but, on average, required approximately 10 to 30 min to complete, including watching the video and reading the handouts. For the remaining 8 months of the program, we emailed participants links to the coursework every other week.

Three Experimental Enhancement Strategies

Once we assigned participants to 1 of 2 levels of each factor, we sent them assignment-specific materials throughout the 12-month intervention.

Text Messages

To encourage the adoption, engagement, and maintenance of the intervention, we randomized half of the participants to receive an average of 5 (SD 0.2) text messages per week (5 sent for 50 weeks, 6 sent for 2 of the weeks, sent each day between 9 AM and 5 PM). These were drawn from a pool of 262 unique messages that included motivational and educational reminders about the intervention's lessons or goals, advice about the VLC diet (recipes, web-based resources, and quotes from others who had tried the diet), advice about physical activity (with an emphasis on finding activities they enjoyed), advice about sleep (such as suggestions about sleep hygiene behaviors), and advice about psychological skills (around positive emotions, mindfulness, and mindful eating). The other half of the participants received no text messages.

Food and Book Gifts

We randomly assigned half of the participants to receive a mailed assortment of unusual and hard-to-find foods relating to the VLC diet and popular lay-press cookbooks or books specifically tailored for or about the diet. At baseline, we mailed these participants an assortment of foods for the VLC diet: 1 pound each of almond flour, coconut flour, and chia seeds as well as 1 ounce of liquid sucralose. They also received popular lay-press cookbooks or books specifically tailored for or about the diet at different times throughout the 12-month program (at baseline: *Keto Living 3 Cookbook: Lose Weight with 101 All New Delicious and Low Carb Ketogenic Recipes* [33]; at 3 months: *Bacon & Butter; the Ultimate Ketogenic Diet Cookbook* [34]; at 5 months: *The Wicked Good Ketogenic Diet Cookbook: Easy, Whole Food Keto Recipes for Any Budget* [35]; at 7 months: *Good Calories, Bad Calories: Fats, Carbs, and the Controversial Science of Diet and Health* [36]; at 9 months: *The KetoDiet Cookbook: More Than 150 Delicious Low-Carb, High-Fat Recipes for Maximum Weight Loss and Improved Health* [37]; and at 11 months: *Quick & Easy Ketogenic Cooking: Meal Plans and Time Saving Paleo Recipes to Inspire Health and Shed Weight* [38]). If participants in this group told study staff that they had difficulty with VLC adherence, we mailed them supplemental books and/or food products. This occurred with 2 participants. One participant was mailed several types of commercially available VLC breads. Another, whose computer was temporarily not functional, was mailed a physical copy of *The Ketogenic Diet: A Scientifically Proven Approach to Fast, Healthy Weight Loss* [39]. Participants in the nongifts group were not sent anything extra.

Urine Strips Versus Breath Meter for Ketone Self-Monitoring

We randomly assigned participants to self-monitor their dietary adherence biomarkers using either a urine- or breath-based meter. The urinary ketone test kits (KetoStix, Abbott; included 100 strips) provide feedback about urinary ketone acetoacetate. The breath meter (Breath Ketone Analyzer, Ketonix) measures

the exhaled ketone acetone. We asked participants to use these at least once weekly for the first few months of the intervention.

Assessments

We measured outcomes at baseline and at 4, 8, and 12 months after baseline. As an incentive for continued participation, we paid participants US \$25 for completing their outcome measurements at 4 months, US \$25 at 8 months, and US \$50 at 12 months. At each period, we measured glycemic control and body weight (described below), and using web-based surveys at Qualtrics, we assessed the perceived helpfulness of the enhancement strategies (rated from 1 [*not helpful*] to 7 [*very helpful*]) and overall program satisfaction (rated from 1 [*not at satisfied*] to 7 [*very satisfied*]). For this particular study design, it was impossible for the participants or coach to be masked to the allocation status.

Glycemic Control

We assessed glycemic control by measuring HbA_{1c} using the self-administered, mailed AccuBase HbA_{1c} test (DTI Laboratories). This Food and Drug Administration–approved whole blood test uses a capillary tube blood collection method for reliable home-based data collection and high-performance liquid chromatography laboratory testing.

Body Weight

We measured body weight by mailing participants a scale that connects to its own cellular network. This method corresponds well to same-day in-person measurement by research staff [40] and has a back-end interface to allow easy download of participant data. As it connects via its own cellular phone network, participants do not have to set up any passwords, simplifying ease of use. We encouraged participants to weigh themselves weekly but only requested it at baseline and at 4, 8, and 12 months postbaseline. To ensure that we measured the participants' weight and not someone else's in their household who was using the scale casually, for these critical measurements, we asked them to step twice on the scale within 5 min. We averaged the 2 measurements to estimate their weight.

Analytic Plan

For completers-only analyses, we excluded participants who did not complete the 12-month assessment. For intent-to-treat (ITT) analyses (all participants included), we imputed missing 12-month values using the last observation carried forward method, one option for handling missing data in clinical trials [41]. We first collapsed across all groups and examined pre-post 12-month changes in HbA_{1c} and percent weight change using within-subjects *t* tests. We then examined the effect sizes of the 2 levels of each enhancement strategy compared with one another using Cohen *d* (using a pooled SD of the 2 levels of each strategy). Our primary goal was to screen each strategy for a medium effect size represented by an a priori Cohen *d* threshold of 0.5 [42]. Moreover, because all participants were assigned to an active intervention and our sample size was small, we understood that we may not reach statistically significant differences between the levels of the enhancement strategies. However, we focused on effect size differences, as

nonsignificant between-level effect sizes can still help advise which enhancement strategies may be worth including in future trials. At 12 months, we also examined participants' impressions of the strategies and whether the strategies altered their overall satisfaction with the program (comparing the groups with *t* tests).

Results

We screened a total of 464 potential participants. We excluded potential participants if they used hypoglycemic medications other than metformin ($n=96$), reported a recent HbA_{1c} below

6.5% ($n=31$), had a measured HbA_{1c} below 6.5% ($n=52$), self-reported BMI above 45 kg/m² ($n=40$), or did not provide usable contact information in the original survey ($n=101$; Figure 1).

Ultimately, we enrolled and randomized 44 participants, who were, on average, aged 52 years, had diagnosed type 2 diabetes for about 5 years, and started with an HbA_{1c} of 8.4% (Table 2). Approximately half of the participants were randomized to each level of the 3 experimental components (Figure 1). All participants lived in the United States, and half of the participants lived in Michigan.

Figure 1. Study participant flowchart. HbA_{1c}: glycated hemoglobin.

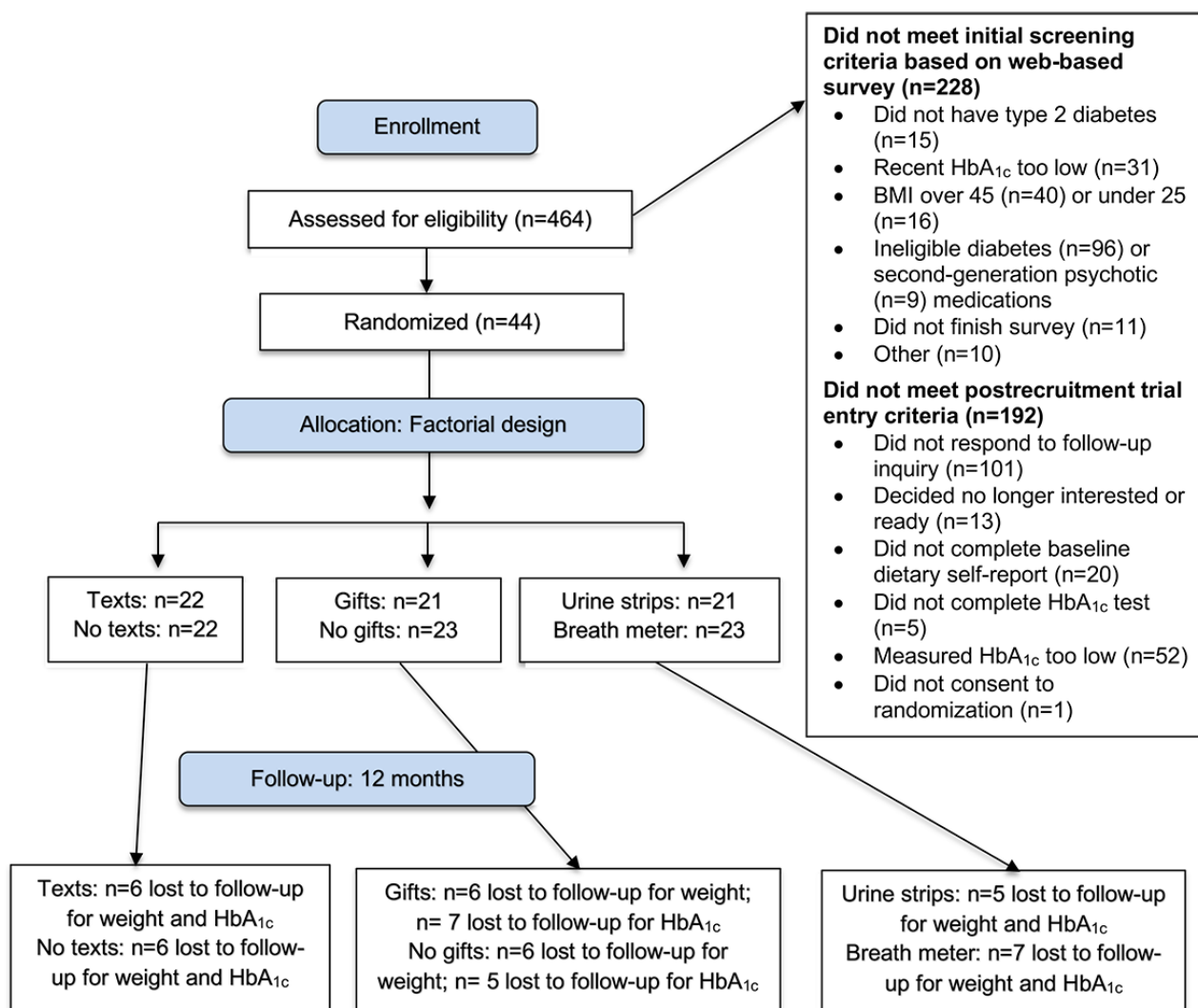


Table 2. Baseline participant characteristics (n=44).

Characteristics	Participants
Sex, n (%)	
Men	11 (25)
Women	33 (75)
Age (years), mean (SD)	51.7 (11.0)
Race or ethnicity, n (%)	
American Indian or Alaska Native	1 (2)
Asian or Pacific Islander	5 (11)
Black	7 (16)
White	33 (75)
Latino or Latina	0 (0)
Duration of diabetes (years), mean (SD)	5.3 (4.1)
Smoker, n (%)	2 (4)
HbA _{1c} ^a (%), mean (SD)	8.4 (2.2)
Weight (kg), mean (SD)	100.2 (20.1)
BMI (kg/m ²) mean (SD)	35.7 (5.6)
College graduate, n (%)	27 (61)
Married or long-term partner, n (%)	22 (50)
Total household income (US \$), n (%)	
≤35,000	13 (29)
35,001-75,000	18 (41)
≥75,001	12 (27)

^aHbA_{1c}: glycated hemoglobin.

We retained 73% (32/44) of the participants at 12 months. For HbA_{1c}, of the 11 participants who lacked a 12-month follow-up, month 8 data were carried forward for 4 participants, month 4 data were carried forward for 5 participants, and baseline data were carried forward for 2 participants. For weight, of the 12 participants who lacked a 12-month follow-up, month 8 data were carried forward for 4 participants, month 4 data were carried forward for 6 participants, and baseline data were carried forward for 2 participants.

The VLC web-based multicomponent intervention, across all conditions, led to improvements in glucose control and body weight at 12-month follow-up. In the ITT analyses (including all participants), the mean HbA_{1c} decreased by 1.0%, and the mean weight was reduced by 5.3% ($P<.001$). Overall, 27% participants (12/44) achieved excellent control of their type 2 diabetes (HbA_{1c}<6.5%), 43% participants (19/44) lost at least 5% of their body weight, and 23% participants (10/44) lost at

least 10% of their body weight. For study completers, the mean HbA_{1c} was reduced by 1.2%, and the weight was reduced by 6.3% ($P<.001$). Of completers, 31% (10/32) achieved excellent control of their type 2 diabetes (HbA_{1c}<6.5%), 47% participants (15/32) lost at least 5% of their body weight, and 31% participants (10/32) lost at least 10% of their body weight.

In ITT and completers-only analyses, none of the extra enhancement strategies exerted a statistically significant impact on either HbA_{1c} or weight (all $P>.10$). Among study completers, 2 enhancement strategies met our a priori threshold of Cohen d of 0.5 or greater for differential effect sizes: text messages (vs no text messages) for HbA_{1c} reduction and urine ketone self-monitoring (vs breath ketone self-monitoring) for weight reduction (Table 3). None of the enhancement strategies met our Cohen d threshold in ITT analyses. Although the effect size for gifts did not meet our a priori threshold, it did have a small effect size, as Cohen d ranged from 0.2 to 0.3.

Table 3. Change in outcomes over 12 months.

Variable	Absolute HbA _{1c} change relative to baseline				Percent weight change relative to baseline			
	All (ITT ^a)	<i>P</i> value	Completers	<i>P</i> value	All (ITT)	<i>P</i> value	Completers	<i>P</i> value
Overall								
Change (%), mean (SD)	-0.98 (1.58)	.001	-1.20 (1.65)	.001	-5.25 (6.04)	<.001	-6.32 (6.36)	<.001
Cohen <i>d</i>	-0.35	–	-0.56	–	-.27	–	-0.48	–
Text messages								
Yes (%), mean (SD)	-1.24 (1.89)	–	-1.59 (1.91)	–	-5.44 (6.70)	–	-6.95 (7.13)	–
No (%), mean (SD)	-0.74 (1.24)	–	-0.85 (1.35)	–	-5.08 (5.52)	–	-5.76 (5.76)	–
Difference (%), mean (SD)	-0.50 (0.48)	.30	-0.75 (0.58)	.21	-0.36 (1.84)	.85	-1.19 (2.28)	.61
Cohen <i>d</i>	-0.32	–	-0.46	–	-0.06	–	-0.18	–
Gifts								
Yes (%), mean (SD)	-1.14 (1.60)	–	-1.41 (1.88)	–	-5.78 (6.80)	–	-7.26 (7.08)	–
No (%), mean (SD)	-0.83 (1.59)	–	-1.03 (1.48)	–	-4.77 (5.37)	–	-5.48 (5.74)	–
Difference (%), mean (SD)	-0.31 (0.48)	.53	-0.39 (0.59)	.52	-1.01 (1.84)	.59	-1.79 (2.27)	.44
Cohen <i>d</i>	-0.19	–	-0.23	–	-0.17	–	-0.28	–
Ketone measurement								
Urine (%), mean (SD)	-0.97 (1.91)	–	-1.28 (2.07)	–	-6.61 (6.13)	–	-7.80 (6.37)	–
Breath (%), mean (SD)	-1.00 (1.26)	–	-1.12 (1.16)	–	-4.01 (5.82)	–	-4.83 (6.19)	–
Difference (%), mean (SD)	0.03 (0.49)	.95	-0.16 (0.59)	.79	-2.60 (1.80)	.16	-2.96 (2.22)	.19
Cohen <i>d</i>	0.02	–	-0.10	–	-0.43	–	-0.47	–

^aITT: intent-to-treat.

Feedback About Enhancement Strategies

Through open-ended questions in a web-based survey, we asked participants about their experiences with the different enhancement strategies. Some participants reported that the texts came at inconvenient times or were annoying. Others noted that the texts were very helpful and encouraging (eg, “I felt as though a friend was reminding me to stop rushing around, relax and be mindful”; “They give me occasional reminders that I am not on this journey alone”; and “They were good reminders to stay focused”). We asked participants who received the texts to rate how much they would recommend that we include them in the next study on a scale ranging from 1 (“don’t include them, they were not helpful”) to 7 (“you must include them, they were very helpful”). On average, participants rated the texts as helpful (mean 5.36, SD 1.99). We asked participants to rate their overall satisfaction with the program on a scale ranging from 1 (“not at all satisfied”) to 7 (“very satisfied”). Both groups were satisfied with the program overall: those receiving the texts rated the program (mean 6.21, SD 0.89) and those not receiving the texts rated it (mean 6.12, SD 1.27; with a Cohen *d* of the difference between the groups of 0.08; *P*=.81).

In terms of the food and book gifts, participants reported that these helped them try new foods (eg, “...helped me to venture outside of my regular LCHF [low-carb, high-fat] menu”; “...let me try things first before spending lots of money on them”; “Very inspiring, and made trying new things possible”; and “OMGoodness these help soooooo much!”). We asked

participants who received gifts to rate how much they would recommend that we include them in the next study on a scale ranging from 1 (“don’t include them, they were not helpful”) to 7 (“you must include them, they were very helpful”). On average, participants rated the gifts as very helpful (mean 6.47, SD 1.30). Both groups were satisfied with the program overall: those receiving the gifts rated it (mean 6.40, SD 0.99) and those not receiving the gifts rated it (mean 5.94, SD 1.18; Cohen *d*=0.42; *P*=.25).

Some participants found the breath meter hard to use (eg, “I couldn’t ever get it to work properly”; “I wanted the breath ketone meter [Ketonix] to work, but the readings are difficult to decipher”; and “I could never get the software to work on my computer [after several attempts]”). Others enjoyed using it (“I love the Ketonix! It’s so easy to use and makes me aware of ketosis. I try to use it every day or at least 3 times a week now.”)

Participants did not make many comments about the Ketostix (urine strips), but one perceived it to be of potentially limited utility (“For me Ketostix indicators only showed small trace ketosis during my most successful weeks on the program so they don’t really work well for me in terms of knowing if I’m successful or not on the program.”)

We asked participants to rate how much they would recommend that we include them in the next study from 1 (“don’t include them, they were not helpful”) to 7 (“you must include them, they were very helpful”). On average, participants rated the

ketone self-monitoring approaches as somewhat helpful: urine: mean 4.47 (SD 2.07); breath: mean 4.29 (SD 2.09; Cohen $d=0.09$, $P=.82$). Both groups were satisfied with the program overall: those receiving the urine strips rated it (mean 6.50, SD 0.73) and those receiving breath meter rated it (mean 5.80, SD 1.32; Cohen $d=0.66$; $P=.07$).

Medication Changes

Although we intended to only recruit participants on no glucose-lowering medication (or only metformin), we erroneously randomized one participant who was taking sitagliptin. As metformin has a relatively low risk of hypoglycemia, physicians do not quickly reduce its dose. Therefore, as we intended to exclude participants on diabetes medications other than metformin, we had a limited ability to observe changes in glucose control medication. Overall glucose control medication changes (which were either for metformin or sitagliptin) included 3 discontinuations, 8 reductions (including the participant taking sitagliptin), 28 remaining the same, and 5 increases. Four participants were able to reduce their blood pressure medications, and 2 participants discontinued them.

Other Health Changes

Self-reported adverse events that we considered attributable to the intervention included only minor complaints from a minority of participants, such as acne, constipation, nausea, and dizziness. Other self-reported adverse events that we do not believe are attributable to the intervention included one case each of cancer (skin and thyroid), injuries (back, knee, and shoulder), kidney stone, and surgeries (eye and herniated disc).

Many participants self-reported improvements in a variety of conditions or measures including low energy (“I have more energy now”), pain-related foot neuropathy (“Tingling, soreness, and pain have all gone away”), general pain (“No longer experience the almost daily body aches”), limited mobility (“Walking up stairs is not as grueling as it used to be”), headaches (“had frequent headaches [almost daily] which have completely resolved”), number of infections, allergic responses, acid reflux (several discontinued related medications), ability to focus their eyes, and high cholesterol and triglyceride levels.

Discussion

The purpose of this study was to compare the addition of 3 intervention enhancement strategies (text messages, gifts, and urine vs breath ketone self-monitoring) that may help enhance the outcomes of a 12-month web-based *ad libitum* VLC diet and lifestyle intervention for adults with type 2 diabetes. Overall, among all participants, using ITT analyses, the mean HbA_{1c} was reduced by 1.0% and weight was reduced by 5.3%. Participants who completed the 12-month assessment reduced their mean HbA_{1c} by 1.2% and their weight by 6.3%. All these pre-post changes in mean HbA_{1c} and weight were statistically and clinically meaningful.

First, we examined the impact of sending intervention-relevant text messages to participants. Adding text messages to an intervention may add expense and complexity to the program,

in addition to potentially increasing participant burden. However, among completers, the impact of text messages did meet our a priori threshold of Cohen d of 0.5 or greater for HbA_{1c} reduction. The mean differences in change in HbA_{1c} between those who received text messages and those who did not were 0.7% and 0.5% for completers and the full sample, respectively. This is similar to results from a previous meta-analysis of text message interventions used in patients with type 2 diabetes, which demonstrated a mean decrease in HbA_{1c} of 0.8% [11]. Moreover, our participants' feedback suggested that they generally enjoyed the text messages and that they found them to be helpful. Future trials may benefit from sending participants intervention-relevant text messages.

Second, we tested the impact of mailing 6 rounds of gifts of diet-relevant foods and cookbooks. Providing gifts has been recommended as a strategy to enhance retention [43], and it may help with weight loss [12,13], but the use of food samples and cookbooks to assist with dietary changes is, to our knowledge, novel. Although the associated effect sizes of 0.2 to 0.3 fell short of our a priori threshold, participants rated the gifts positively and found them useful, and gifts may have improved participant enjoyment of the intervention (Cohen $d=0.4$). However, it is difficult to discern if these results were because of the fact that participants were receiving an incentive or if they were because of the impact of having these particular resources. Even so, if ample funding is available, then this strategy might benefit future trials.

Third, we assessed the impact of urine versus breath ketone self-monitoring. Self-monitoring may increase behavioral adherence [15,16] and can improve diabetes self-management [17] as well as weight loss and dietary adherence [18]. Yet, no previous trial, to our knowledge, has compared these 2 self-monitoring approaches. Among completers, the weight loss effect for urine ketone self-monitoring (vs breath ketone self-monitoring) met our a priori threshold. In contrast, several participants found the ketone breath meter difficult to use, and it is considerably more expensive than urine strips. Participants receiving the urine strips (vs the breath meter) may have enjoyed the program more overall (Cohen d of 0.7). Thus, future trials that include ketone testing may benefit from using urine-based rather than breath-based self-monitoring.

There are limitations to this study. The most notable limitation is the lack of statistical power to detect differences between the 2 levels of each of the 3 factors tested, because of the small sample size. This may have also reduced the stability of our estimates of effect sizes and changes. However, these preliminary results may provide insight into potentially effective methods for improving health outcomes in such a diet and lifestyle study.

Conclusions

The results suggest that using text messages and urine-based ketone self-monitoring may be worthwhile enhancements for helping individuals with type 2 diabetes to adhere to a VLC diet intervention, which, in turn, is associated with reductions in HbA_{1c} and/or weight. In addition, diet-congruent food and cookbook gifts may improve participants' overall intervention

experience. Future research could investigate other enhancement strategies to help create even more effective approaches for treating type 2 diabetes.

Acknowledgments

The authors would like to thank their dedicated participants; Linda Collins, Marlene Otto, Gina Dahlem, and Alison O'Brien for their help; and the Consulting for Statistics, Computing, and Analytics Research group at the University of Michigan. The research was supported by a grant from the Carl Purcell Endowed Nursing Research Fellowship Fund to LS. LS was supported by a K01 award from the National Institutes of Health (NIH), DK107456, from the National Institute of Diabetes and Digestive and Kidney Diseases. AM was supported by a K award, K23HL133442, from the NIH's National Heart, Lung, and Blood Institute. MO was supported by a P grant from the NIH's National Institute of Nursing Research, P20NR015331. JM was supported by NIH grant K24 MH093225 from the National Institute of Mental Health. FH was supported by NIH grant K24 AT007827 from the National Center for Complementary and Integrative Health. The funders had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Conflicts of Interest

FH was on the Scientific Advisory Board for Virta Health during some of this research but is no longer on the Scientific Advisory Board. LS's partner, HB, is an inventor of software used in this study, which purchased a software services agreement for its use. The other authors have no conflicts of interest to declare.

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Abbreviations

HbA_{1c}: glycated hemoglobin

IRB: institutional review board

ITT: intent-to-treat

NIH: National Institutes of Health

VLC: very low-carbohydrate, ketogenic diet

Edited by G Eysenbach; submitted 15.11.19; peer-reviewed by X Gu, L Horrell; comments to author 11.03.20; revised version received 24.06.20; accepted 25.06.20; published 09.09.20.

Please cite as:

Saslow LR, Moskowitz JT, Mason AE, Daubenmier J, Liestenfeltz B, Missel AL, Bayandorian H, Aikens JE, Kim S, Hecht FM
Intervention Enhancement Strategies Among Adults With Type 2 Diabetes in a Very Low-Carbohydrate Web-Based Program: Evaluating the Impact With a Randomized Trial

JMIR Diabetes 2020;5(3):e15835

URL: <http://diabetes.jmir.org/2020/3/e15835/>

doi: [10.2196/15835](https://doi.org/10.2196/15835)

PMID: [32902391](https://pubmed.ncbi.nlm.nih.gov/32902391/)

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Original Paper

Technology-Assisted Self-Monitoring of Lifestyle Behaviors and Health Indicators in Diabetes: Qualitative Study

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Abstract

Background: Self-monitoring is key to successful behavior change in diabetes and obesity, and the use of traditional paper-based methods of self-monitoring may be time-consuming and burdensome.

Objective: This study aimed to explore participant experiences while using technology-assisted self-monitoring of lifestyle behaviors and health indicators among overweight or obese adults with type 2 diabetes.

Methods: Qualitative data collected from the intervention group of a 6-month, three-arm (control, paper diary, and technology-assisted self-monitoring groups) randomized clinical trial were analyzed. Study participants in the intervention group monitored their diet, exercise, and weight using the LoseIt! app, and their blood glucose levels using a glucometer and the Diabetes Connect app. Semistructured group discussions were conducted at 6 weeks (n=10) from the initiation of the behavioral lifestyle intervention and again at 6 months (n=9). All group interviews were audiotaped and transcribed verbatim. Using a combination of thematic and comparative analysis approaches, two trained professionals coded the transcriptions independently and then discussed and concluded common themes for the 6-week and 6-month discussions separately.

Results: The sample (n=10), which primarily involved African American participants (n=7) and female participants (n=8), had a mean age of 59.4 years. The following eight themes emerged: (1) perceived benefits of technology-assisted self-monitoring; (2) perceived ease of use (eg, barriers: technical difficulties and lack of self-discipline; facilitators: help from family, friends, and the program); (3) use of technology-assisted self-monitoring; (4) facilitators of engaging in healthy lifestyle behaviors (eg, visualization and awareness of calorie input/expenditure); (5) positive lifestyle change; (6) barriers of engaging in healthy lifestyle behaviors (eg, event influence); (7) learning curve; and (8) monitored data sharing. The first six of these themes were shared between the 6-week and 6-month timepoints, but the codes within these themes were not all the same and differed slightly between the two timepoints. These differences provide insights into the evolution of participant thoughts and perceptions on using technology for self-monitoring and subsequent behavioral lifestyle changes while participating in lifestyle interventions. The findings from the 6-week and 6-month data helped to paint a picture of participant comfort and the integration of technology and knowledge overtime, and clarified participant attitudes, difficulties, behavioral processes, and modifications, as well as health indicators that were experienced throughout the study.

Conclusions: Although there were some barriers, participants were able to identify various individual and external facilitators to adjust to and engage in technology-assisted self-monitoring, and it was concluded that the technology-assisted self-monitoring approach was beneficial, safe, and feasible to use for positive lifestyle change. These patient perspectives need to be considered in future research studies when investigating the effectiveness of using technology-assisted self-monitoring, as well as in clinical practice when recommending technology-assisted self-monitoring of lifestyle behaviors and health indicators to improve health outcomes.

KEYWORDS

technology; monitoring; lifestyle; diet; exercise; weight; glucose; diabetes management

Introduction

Diabetes has become a worldwide public health concern, contributing to 10% of global health expenditure [1]. Approximately 31 million adults are living with diabetes in the United States, with an additional 88 million adults living with prediabetes, and their numbers are expected to increase greatly in the future [1,2]. The burden of diabetes is high and can be attributed to underlying complications and exacerbation of coexisting conditions. The total direct and indirect costs of diagnosed diabetes nationally increased from US \$261 billion in 2012 to US \$327 billion in 2017 [2].

Type 2 diabetes accounts for over 90% of all diabetes cases [2], and mounting evidence shows that most risk factors for type 2 diabetes are modifiable [3-5]. Some common modifiable risk factors for diabetes-related complications are being overweight or obese (BMI of 25.0 kg/m² or over), having an unhealthy diet, being physical inactivity, and having a glycated hemoglobin (HbA_{1c}) value of 7.0% or higher [2]. Research has demonstrated the success of self-monitoring interventions in influencing modifiable behavior change, weight management, and HbA_{1c} control in diabetes [6-10].

Self-monitoring approaches for lifestyle behaviors (eg, diet and physical activity), body weight, and blood glucose have been identified as some of the strongest predictors of weight loss and HbA_{1c} management [8,11]. For instance, a systematic review evaluating the effectiveness of self-monitoring interventions demonstrated a decrease in total sedentary time in the intervention group compared with the finding in the control group [7]. Consequently, behavioral modifications can lead to improved diabetes health outcomes, including but not limited to body weight, glycemic control, and prevention of diabetes-related complications [11-14]. Self-monitoring of blood glucose can lead to weight loss and better HbA_{1c} levels through increased adherence to dietary recommendations [8,10,12,15]. Furthermore, evidence suggests that the use of interventions involving self-monitoring of blood glucose leads to decreased rates of morbidity, mortality, and diabetes-related complications [12,13,16].

Despite the benefits of traditional paper-based methods of self-monitoring on healthy lifestyle behaviors [17-19], recent studies have revealed weaknesses and limitations in utilizing paper-based methods, such as untimeliness, time consumption, falsification of frequency and time, and lack of veracity [19,20]. On the contrary, compared with conventional approaches (eg, paper-based approaches) of health and behavioral management, technology-based methods have been drawing increasing attention owing to rapidly evolving innovation in the technological advances of self-monitoring. Studies have identified numerous benefits in both type 2 diabetes and weight control when utilizing technology for self-monitoring [8-10]. Accessibility and portability are the key features of

technology-based methods when addressing issues encountered with paper-based methods. Technology-based self-monitoring is also more objective, offering customizable options for the user [6,21-23]. Users are able to set goals, view and sync real-time data for analysis and comparison, and engage in immediate reinforcement of healthy behaviors [9,22,24]. In addition, the burdens of locating appropriate references and performing calculations are conveniently accessible and automated through software applications, and they are compatible for use on multiple electronic devices [6,24,25].

Among the numerous advantages, some disadvantages of utilizing technology in self-monitoring were also revealed and were typically categorized as individual-specific or product-specific barriers. Individual-specific barriers include failure to record accurate or all data, decreased use over time, perceptions of the disease (not needing to self-monitor), skepticism of technology, and lack of technology or health literacy [25,26]. Discontentment with devices was also identified as a common barrier [26]. However, other studies contradict this finding of individual-specific barriers and suggest that more users are satisfied with the esthetics of how data are presented (eg, visual displays and graphs), reporting greater gratification of self-monitoring apps, especially when they are recommended by providers [25,26]. Product-specific barriers include users needing to constantly wear or carry devices for data processing, inaccuracy of the data captured, and data connectivity issues for specific geographical populations [24,25]. According to the European Association for the study of Diabetes and the American Diabetes Association, major barriers of concern include potential security breaches, inadequate processes of standardization, and exclusion of evidence-based practices; however, feasible recommendations have been provided to rectify these issues [21]. Some research has considered the difficulty in the use of technology as an age-related barrier, specifically for engaging in technology-based self-monitoring [7], and some studies have reported other barriers such as trial-and-error frustration levels and lack of knowledge, which can be potentially overcome by clear instructions and repetition [27,28]. A recent study evaluating mobile use and synchronization of virtual tools in a primarily older underserved population of adults who had comorbid overweight or obesity with type 2 diabetes reported high retention rates (96% at 3 months and 92% at 6 months) regarding patient engagement when using mobile technology [29].

The above advantages and disadvantages of using technology in self-monitoring are consistent with the elements in the technology acceptance model (TAM). This model includes five major related components as follows [30-32]: A person's *intent to use* (acceptance of technology) predicts the *usage behavior* (actual use) of a technology, which is driven by a person's perceptions of the specific technology's *ease of use* and *usefulness* (benefits from using the technology), and lastly, the perceptions of ease of use and usefulness are affected by

external variables such as individual differences (eg, age, gender, and education). The TAM, an information technology framework created to understand how users accept and use technology, has been widely utilized as a way to assess health technology usage, especially in the rapid evolution of health technology within the health care system [25,31-34].

The rapid evolution of technology and increasing dependence on smart devices continue to create a pathway for new developments and exploration in health care advancements. However, despite documented findings of the benefits and barriers of using self-monitoring through technology, there are gaps regarding the learning process of using technology-assisted self-monitoring of lifestyle behaviors and health indicators, and the potential of incorporating tracked and recorded data into health care. Therefore, this study aimed to explore participant experiences of using technology-assisted self-monitoring of lifestyle behaviors and health indicators among overweight or obese adults with type 2 diabetes at 6-week and 6-month timepoint discussions during a lifestyle intervention.

Methods

Study Population

Participants were recruited from an American Diabetes Association-certified diabetes education program in a community health center primarily serving uninsured or underinsured individuals living in Harris County, Texas. A total of 26 participants were recruited and randomized to a control group (n=6), a paper diary group (n=9), or an intervention group (n=11; one withdrew). Participants in the intervention group were instructed to use a smartphone for self-monitoring of diet, exercise, and weight through the LoseIt! app (FitNow, Inc). Participants were also given a Bluetooth-enabled glucometer (Entra Health Systems LLC) to self-monitor blood glucose. The device transferred glucose data to the Diabetes Connect app (PHRQL Inc) automatically with the touch of a button. [Table 1](#) illustrates the functions, features, and participant responsibilities for each of the devices and apps used in the study. The details of the study design and intervention have been reported previously [29]. Consent was obtained from each participant, and the study was approved by the Institutional Review Board of the University of Texas Health Science Center at Houston.

Table 1. Summary of the features, functions, and participant responsibilities for devices and apps.

Device or app	Features and functions	Participant responsibilities
LoseIt! app	Monitoring of diet, exercise, and weight in one app	Diet: log all food intake Exercise: log exercise type and duration Weight: enter weight scale reading in the app
Bluetooth-enabled glucometer	Finger stick-based glucometer Bluetooth function	Test blood glucose; testing frequency is recommended by the primary care physician (minimum once daily). Open Diabetes Connect app and Bluetooth on the smartphone. After testing, hit a button on the glucometer so that data are automatically transferred from the glucometer to the Diabetes Connect app
Diabetes Connect app	Receives and stores glucose information	Use the app to track blood glucose values.
Weight scale	Regular weight scale	Encouraged to use the scale daily to take weight measurement and manually enter values in the LoseIt! app.

Data Collection

Qualitative data were collected between January 2013 and August 2013 from the intervention group (technology-assisted self-monitoring) at the following two timepoints: 6 weeks and 6 months after initiation of the lifestyle intervention. The study principal investigator facilitated focus group discussions using a semistructured interview guide. First, interviews were conducted with the 10 intervention participants 6 weeks after beginning the intervention, during which questions on six topics, including experience using the health devices, factors affecting monitoring and recording of weight, and experience of self-monitoring blood glucose, were covered in the group discussion. Questions such as “What was your experience using the smart phone?” were asked, and follow-up probe questions were used whenever appropriate. Second, 6 months after

initiation of the intervention, participants were invited to another focus group discussion again involving a semistructured interview. Nine participants attended the 6-month focus group discussion (n=9), and one make-up individual interview (n=1) was conducted. In addition, participant preference of sharing tracked health information was explored at 6 months by asking questions like “Who would you like to share this information with?” in regard to participant health data. The interview time for group discussions was approximately 45 minutes, and the one make-up individual interview was about 10 minutes. Similar interview question guides were used during both interviews. The question guide topics are summarized in [Textbox 1](#). All group and make-up discussions were audiotaped and transcribed verbatim in Microsoft Office 365 Word Version 1902 (Microsoft Corporation) for analysis.

Textbox 1. Question guide topics for focus group discussions and one make-up individual interview.

Question topics

- Experience of using a phone or the LoseIt! app
- Experience of monitoring and recording weight
- Experience of self-monitoring blood glucose, and use of the Diabetes Connect app with a glucometer
- Factors affecting engaging in monitoring and recording
- Feedback regarding group sessions (only for 6 weeks)
- Comparison regarding individual versus group sessions
- Safety and security of personal health information (only for 6 months)
- Voluntary sharing of personal health information (only for 6 months)

Data Analysis

A combination of inductive and deductive thematic analyses along with a constant comparative analysis approach was used to analyze the data, incorporating both the data-driven inductive method and the deductive a priori template of codes [35,36]. Data analysis was conducted separately for the 6-week and 6-month data. The same step-by-step analysis procedures were used for analyzing each data set, and they are described below.

First, a graduate research assistant with prior qualitative analysis experience and a junior faculty member with years of qualitative study experience coded the data independently using an open coding method. Discrepancies were discussed and an agreement for each discrepancy was reached. Different and similar codes between the two timepoints were compared and discussed. Consultation with a senior qualitative scientist was initiated as deemed necessary. An initial code book was created for both 6-week and 6-month timepoints. Thereafter, codes were reconciled between the researchers and further grouped into higher order headings according to the TAM. Given that this study attempted to explore participant experiences of using self-monitoring of multiple healthy behaviors and health indicators, the TAM was not able to capture all emerged codes. Therefore, the research team modified the TAM based on the initial codes in this study.

Second, the modified TAM was further used by the two researchers to guide the second round of coding, but this time to capture some specific information in the modified model, which might not have been captured during the initial coding. The principle was not to force any concept to fall into the model. Codes, categories, and themes that emerged within each of the two data sets were further discussed between the two coders. Differences and similarities between the two data sets were also discussed and compared. A senior scientist was consulted and data were referred to whenever necessary during the analysis

process. Agreement was achieved for all themes, categories, and codes within both the 6-week and 6-month discussions.

Results

Sample

The sample (n=10), which primarily included African American participants (n=7) and female participants (n=8), had a mean age of 59.4 years and average BMI of 37.9 kg/m². Participant adherence to technology-assisted self-monitoring has been reported previously [29]. The median percentages of days with at least one self-monitoring entry for diet, physical activity, weight, and glucose were 96.6%, 37.3%, 49.7%, and 72.7%, respectively [29].

Themes

The following eight major themes emerged from the interview data (Table 2): (1) *perceived benefits of technology-assisted self-monitoring*; (2) *perceived ease of use*; (3) *use of technology-assisted self-monitoring*; (4) *facilitators of engaging in healthy lifestyle behaviors*; (5) *positive lifestyle change*; (6) *barriers of engaging in healthy lifestyle behaviors*; (7) *learning curve*; and (8) *monitored data sharing*. The first six of the eight themes were shared between the 6-week and 6-month timepoints, but the codes within these themes were not all the same and differed slightly between the two timepoints. These differences provide insights into the evolution of participant perceptions of using technology for self-monitoring of lifestyle behaviors and health indicators, as well as the attitudes and changes in lifestyle behaviors, difficulties, and processes through the study. This helped reflect the journeys and adaptations of participants throughout the study by analysis of thoughts and perceptions at each of the respective 6-week and 6-month timepoint discussions. Figure 1 and Figure 2 illustrate the themes and codes for the 6-week and 6-month discussions, respectively.

Table 2. Eight themes that emerged from the data.

Theme	Brief description
1. Perceived benefits of technology-assisted self-monitoring	Encompassed the usefulness, helpfulness, and enjoyment of the technology-assisted self-monitoring intervention.
2. Perceived ease of use	Encompassed the perceptions on how difficult, easy, or comfortable the study technology-assisted self-monitoring tools are to use, including barriers and facilitators.
3. Use of technology-assisted self-monitoring	Included the ways in which participants used technology assisted self-monitoring tools that would have an impact on their behavioral health and lifestyle.
4. Facilitators of engaging in healthy lifestyle behaviors	Incorporated the changes in attitude and perceptions of lifestyle to health, awareness, strategies, and other factors regarding how participants impacted their own healthy lifestyle behaviors, as well as how it further influenced their decisions and choices.
5. Positive lifestyle change	Detailed the positive lifestyle changes that have come about from participating in the technology-assisted lifestyle intervention
6. Barriers of engaging in healthy lifestyle behaviors	Encompassed participant comments on times when they came across struggles or barriers to engaging in a healthy lifestyle
7. Learning curve	Encompassed experiences of the learning process and adjustments that took place while participating in the study and learning during the study.
8. Monitored data sharing	Encompassed opinions about with whom to share data and what data to share.

Figure 1. Themes, categories, and codes of 6-week data. Information italicized and underlined represents themes or codes unique to 6-week data.

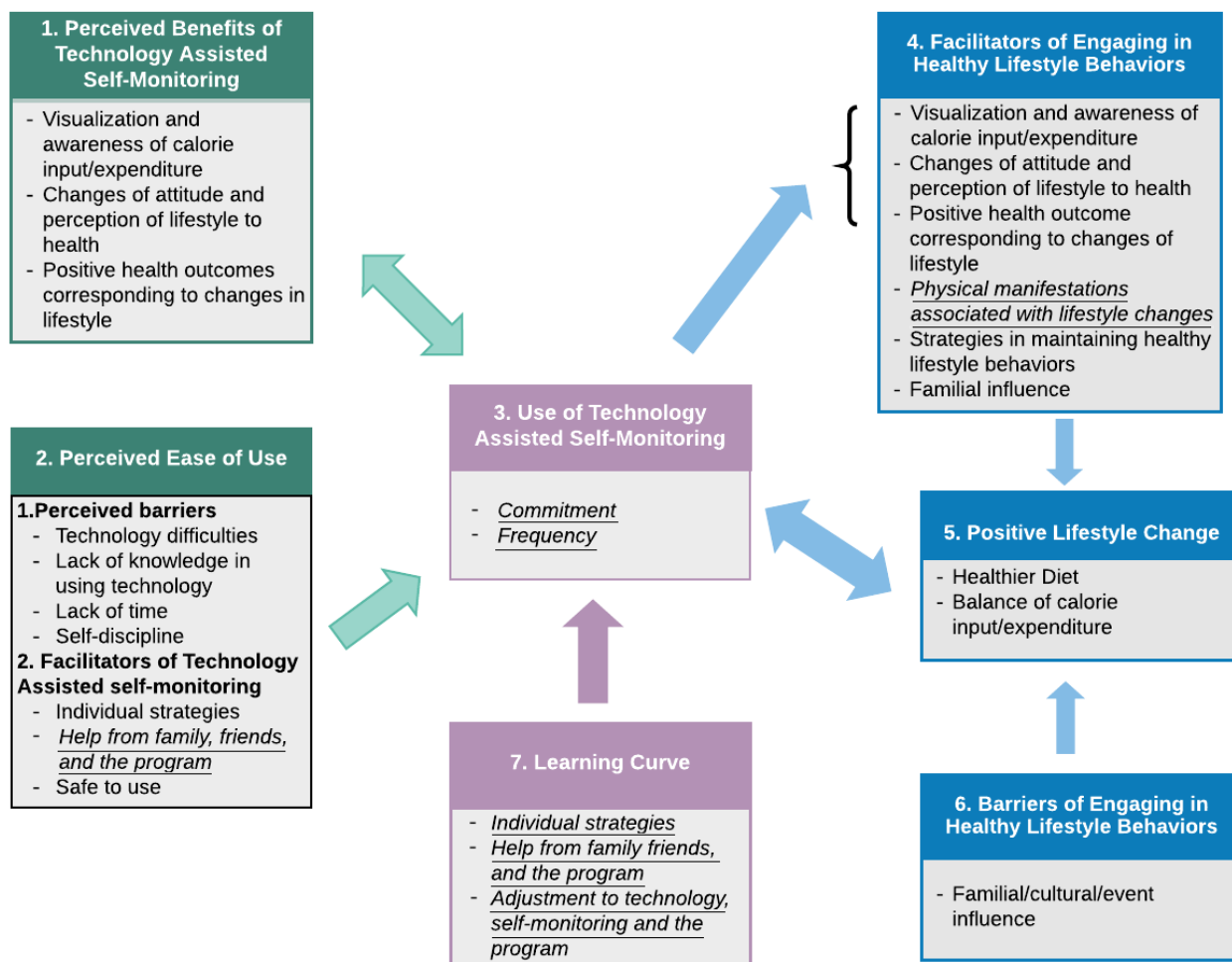
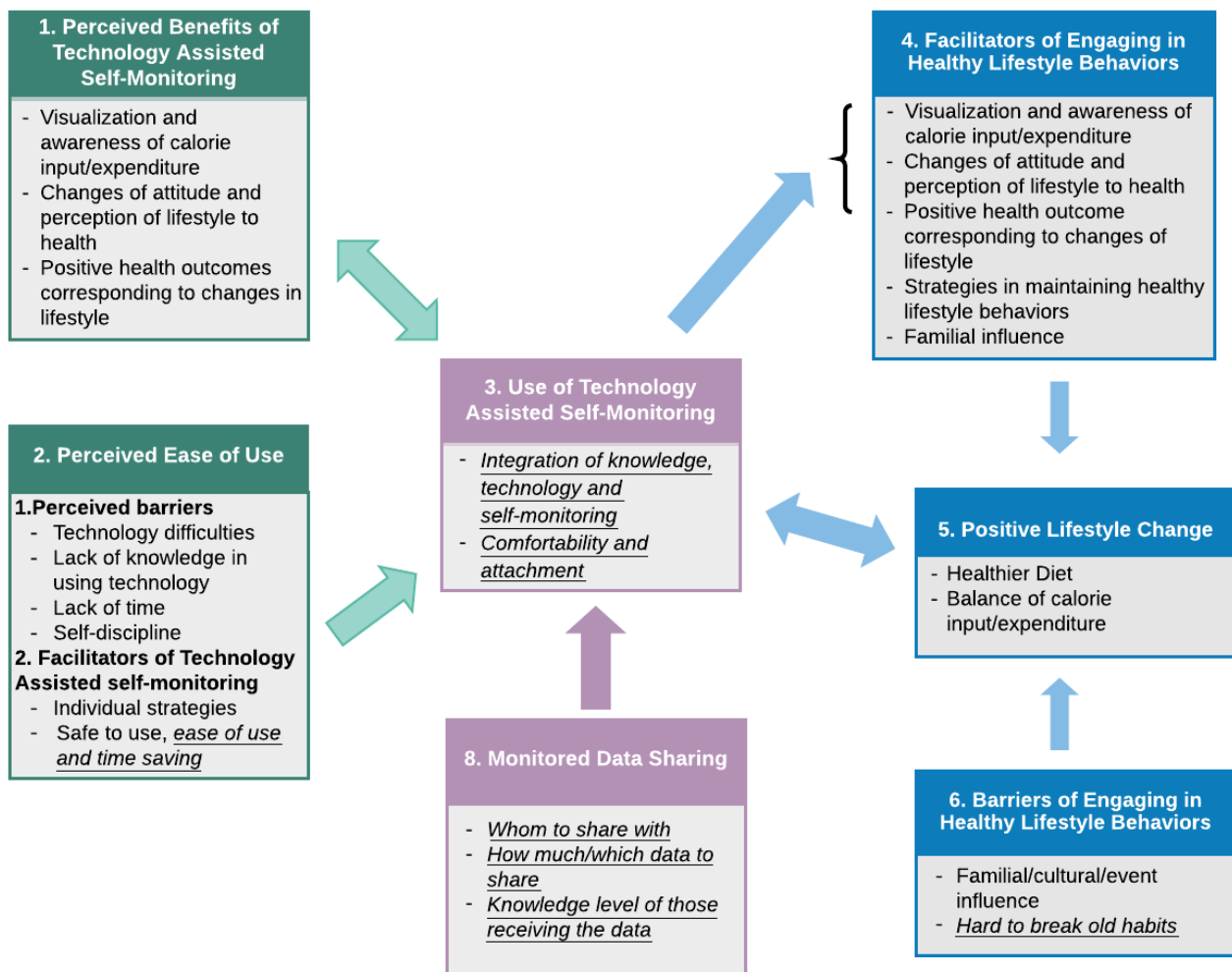


Figure 2. Themes, categories, and codes of 6-month data. Information italicized and underlined represents themes or codes unique to 6-month data.



Shared Themes Between the 6-Week and 6-Month Discussions

There were six themes consistent and shared between the 6-week and 6-month timepoint discussions. These themes encompass the thoughts and reactions that participants shared on their perceptions of the intervention and technology-assisted self-monitoring, and how these perceptions affected self-monitoring behaviors, healthy lifestyle change, and daily life.

Theme One: Perceived Benefits of Technology-Assisted Self-Monitoring

This theme encompassed the usefulness, helpfulness, and enjoyment of the technology-assisted self-monitoring intervention. Participants started noticing and deeming benefits right away, which continued through the study, as comments reflecting benefits were found at both timepoints. The perceived benefits from technology-assisted self-monitoring included the direct benefits participants found from technology, such as being able to visually see calorie counts and being more aware of calorie intake versus exercise expenditure.

...See and the phone when you put the food in, what you eat, it always give you like the net amount and it's kind of like watch out, you only have this much.

If you want to eat more, you have to do more exercise.
[Speaker F, 6-week discussion]

I like it [LoseIt! App]. You get to see visually what you're eating, how many calories involved. Once you visually see you put the pressure on your brain and you're remembering next time. It liked it, in spite of whatever you think that you don't like it. But it was good. I liked it. [Speaker J, 6-month discussion]

Theme Two: Perceived Ease of Use

This theme encompassed the perceptions on how difficult, easy, or comfortable the technology-assisted self-monitoring tools are to use. This theme had two categories. The first of the two was perceived barriers to technology use, which included participant struggles in the use of technology, such as technical difficulties (eg, logging food), lack of time, and lack of self-discipline.

I still have problems using the phone and putting in my diet. I guess I should do like (speaker A) says and put in your own food instead of searching for something close to it that is, you know, close to what I'm eating. [Speaker C, 6-week discussion]

...it's not that it [recording weight] was hard, it's that I think I just didn't do it; not that it was hard. I

just didn't follow through in doing it. [Speaker K, 6-month discussion]

The second category was facilitators of technology-assisted self-monitoring, which mainly included the individual strategies and external support (eg, family) that participants employed while using technology to facilitate its use, as well as the perceived safety (comfortability) of the technology in terms of storing and entering health data around others. Under this category, some codes were unique to either the 6-week or 6-month data, which are described in the *Shared Themes With Unique Codes in the 6-Week or 6-Month Discussion* section.

I guess that's what I should do is carry mine with me all the time. Right now, when I'm out, I write down what I've had but I wait until I'm back home to do it. It makes sense if you carry it with you all the time then you can automatically put it in. So that's what I should do. [Speaker D, 6-week discussion]

We try, my wife and I working together and we're trying to do it (recording food using LoseIt!) as we eat on a daily basis. Whenever we do a meal, we finish a meal, then we put it on. We've been working together on it (self-monitoring) slowly, but she fall out on it sometimes... laughter... [Speaker A, 6-week discussion]

Don't nobody know who it is. Even if they're looking at it, they can't figure out which person it is. I think it's pretty much safe. [Speaker K, 6-month discussion]

Under *theme two*, there were a few code differences between the 6-week and 6-month focus group interviews. For the facilitation of technology-assisted self-monitoring in 6-week discussions, participants referred to using help from family, friends, and those in the program to learn, work, and understand the technology.

But I had my granddaughter to kind of help me a bit now so I think I'm getting to know how to do it now because she put in a lot of stuff when she showed me how. So I'm getting the hang of it. But I was having a lot of problems putting in stuff. And then there's a little microphone on there. Like my granddaughter, well then she's just say what she wanted, so yeah she just said like "baked chicken", and then on the thing it brings up. I didn't know that. [Speaker C, 6-week discussion]

During the 6-month interviews, however, participant comments reflected a greater knowledge in terms of using technology, in addition to discussing the technology in terms of personal independent facilitation, time-saving features, and safety of the data entered.

It was hard but you know, we did it. We coped with it. We got through it. Had problems with our machines and stuff but we did that... [Speaker C, 6-month discussion]

I like the connection. One less step you have to do. [one of the speakers, 6-month discussion]

Theme Three: Use of Technology-Assisted Self-Monitoring

This theme included the ways in which participants used technology-assisted self-monitoring tools that would have an impact on their behavioral health and lifestyle. Although this theme was shared between the two timepoints, the codes they contained were vastly different and portrayed how participants adapted and learned over time.

Starting at the 6-week discussion, participant comments were focused on the frequency of technology-assisted self-monitoring use, and how their commitment to applying technology-assisted self-monitoring and health education increased during the study.

I've been really good about that [monitoring blood glucose]. I put that in as soon as I do it. As soon as I do it, I put the phone right by it and it goes in. [Speaker C, 6-week discussion]

At 6 months, discussions on the use of technology-assisted self-monitoring reflected participant integration of knowledge and technology-assisted self-monitoring, and perpetuated being aware of how this can help them in their life. Participants also commented on having greater comfort with the use of technology-assisted self-monitoring, not wanting to give it up at the end of the study, and being able to utilize and integrate study education into behavioral lifestyle.

...I got so now I depends on it, so when you take it back, I'm gonna miss it! [Speaker P, 6-month discussion]

By the different information that I received. A lot of the information that I didn't know, now that I know it. I can take that and use it to the best of my ability, that would help me, in what I need to do daily, you know, as far as eating, exercising. So I like it. [Speaker P, 6-month discussion]

Theme Four: Facilitators of Engaging in Healthy Lifestyle Behaviors

This theme incorporated the changes in attitude and perceptions of lifestyle to health, awareness, strategies, and other factors regarding how participants impacted their own healthy lifestyle behavior, as well as how it further influenced their decisions and choices. Some of these facilitators (eg, positive health outcomes corresponding to changes in lifestyle) were also benefits participants perceived from using technology-assisted self-monitoring (seen in *theme one*).

...I have my son and I go out try to keep up steps with him. Sunday I got up to 11,000 steps. [Speaker F, 6-week discussion]

...it made me aware of the food that I was eating, and my calories intake, and noticing, paying attentions to like what I was eating that was causing my sugar to spike, and I liked it. I really did. Because it was interesting to me, because I wasn't aware of what I was eating, what I wasn't eating, when I was eating, so it helped me. [Speaker P, 6-month discussion]

Under *theme four*, there were code differences between the 6-week and 6-month discussions. For the facilitators of engaging

in healthy lifestyle behaviors at 6 weeks, the code *physical manifestations associated with lifestyle change* emerged. This code includes participants discussing how their mind and body reacted differently to food after starting the program, such as salivating and becoming sick or nauseous when reverting back to an old diet.

I come from a family that loves sweets... But once I've learned how not to eat and learned, like my daughter bought ice cream, Bluebell the other night, and I took 2 tablespoons and I was going to have a little taste. Well I ate one portion of the half of the first tablespoon, I didn't want anymore. And I'm a sweet lover, you know I came from that background. But I find that I don't want it. My body does not want it. [Speaker G, 6-week discussion]

...It's like when you went out over there. When you haven't eaten greasy foods you start eating... Right, it makes you sick... It makes me nauseated now. I'm telling you, when I smell grease... [Speaker F, 6-week discussion]

Theme Five: Positive Lifestyle Change

This theme detailed the positive lifestyle changes that have come about from participating in the technology-assisted lifestyle intervention, such as having a healthier diet and being better able to engage in balancing calorie intake versus exercise expenditure.

...it made me aware of the food that I was eating, and my calories intake, and noticing, paying attentions to like what I was eating that was causing my sugar to spike, and I liked it. I really did. Because it was interesting to me, because I wasn't aware of what I was eating, what I wasn't eating, when I was eating, so it helped me. [Speaker P, 6-month discussion]

Theme Six: Barriers of Engaging in Healthy Lifestyle Behaviors

This theme encompassed participant comments on times when they came across struggles or barriers to engaging in a healthy lifestyle, such as family or cultural influences, as well as special or celebratory events that affected food and diet choices.

Yeah [events in your life] that's kind of hard. Like last night, I've got to admit I kind of goofed up last night. My niece had a little birthday party at Marco's last night, it's a Mexican restaurant. And I did eat the enchiladas that I probably shouldn't have. [Speaker C, 6-week discussion]

Under *theme six*, there was one code difference between the 6-week and 6-month discussions. Discussions about how to break old habits or having a hard time doing so appeared in the 6-month data but not in the 6-week data.

I'm a night person, so I eat later instead of earlier. I haven't broke that habit yet. I still eat 7, 8 o'clock. Nine. Just habit. [Speaker J, 6-month discussion]

Themes and Encompassed Codes Unique to Either the 6-Week or 6-Month Discussion

Theme Seven: Learning Curve

This theme encompassed codes that were unique to the 6-week discussion. It describes the learning process and adjustments that took place while participating in the study and learning during the study. Many participants referred to the learning curve as a slow process, but one that they were able to “get the hang of” and were willing to complete. The learning curve was fueled by participants using individual learning strategies, help from family and friends, and overall slow but steady adjustments to technology-assisted self-monitoring, program requirements, and behavioral modifications.

When we first started, you kind of, even though it was explained, it was explained in details. But still again, I don't care how you explained it, the first time you never get it right. So, it's a slow process and doing it, I'm slowly learning how to register and put the weight in, and also put the sugar in before the, you know before the phones and the meter together. But you know I had an issue with the scale; it wasn't working right and so we had to reset it again. So these are just some things you want to make a point to, but it's a slow process, and I'm learning it pretty well and I'm having no problems. [Speaker A, 6-week discussion]

Theme Eight: Monitored Data Sharing

This theme encompassed codes that were unique to the 6-month discussion. The theme at 6 months showed that participants used several digital self-monitoring tools, which gathered their health data while partaking in the study. Participants expressed who they wanted to share this data with and how much of the data or what data they wanted to share, and expressed the need to ensure that those on the receiving end of the health data are educated on what it means, how to read it, and what its implications are.

Yeah, but on the other hand, if they're not educated on what's what, they wouldn't understand. They'd almost have to have to go to a short study to know what is the reading, what is this, what is that. Cause they wouldn't know. Like, my daughter, I have to tell her, you see this, you see that. [Speaker J, 6-month discussion]

I would like that [to share with diabetes educator]. [Speaker K, 6-month discussion]

Family. It's really good detail. And it really helps to share with the family especially, for them to be aware of. [Speaker N, 6-month discussion]

Discussion

Principal Findings

This study used data collected from focus group discussions at two timepoints (6 weeks and 6 months) after initiation of a lifestyle intervention using technology-assisted self-monitoring of lifestyle behaviors and diabetic health indicators. Despite

barriers and challenges encountered during the technology-assisted self-monitoring intervention, overall, participants could identify various resources to overcome barriers, and it was concluded that technology-assisted self-monitoring was beneficial, safe, and feasible to use for positive lifestyle changes. In addition, although the similarities of the findings between the two timepoints were very important and numerous, the differences between them highlighted the progression, adjustment, learning curve, application, and individual strategies associated with the use of the technology, self-monitoring, and lifestyle modifications. Implications for future studies and clinical practice are further discussed below.

This study found that at both 6 weeks and 6 months, technology-assisted self-monitoring facilitated participants' ability to visualize and learn how their blood glucose reacted to their lifestyle, creating awareness for healthy lifestyle choices to manage diabetes and allowing engagement in healthy lifestyle behaviors. This finding echoes the conclusion of a meta-synthesis study, which concluded that being able to make sense of diabetic factors is critical in diabetes management [37]. Particularly, after reviewing 50 qualitative studies of diabetes self-management, the same study reported that individuals with diabetes frequently experience multiple gaps in their understanding to select appropriate actions and must make sense of new situations in order to construct their new reality. Our findings suggest that technology-assisted self-monitoring of lifestyle behaviors and diabetes-related health indicators helped the study participants understand the importance and rationale of selecting healthy choices and behaviors, and helped to make sense of why certain lifestyles must be adopted to control blood glucose. Health providers, such as diabetes educators, can incorporate this into clinical practice and encourage patients to adopt self-monitoring of their lifestyles and health indicators for better diabetes management.

In turn, visualization of calorie intake and expenditure, as well as how health outcomes correspond with lifestyle changes motivated participants to commit to self-monitoring. However, previous studies have reported that frustration related to high or low glucose readings is one of the barriers of committing to self-monitoring [38]. Therefore, health education may be needed for not only managing glucose control using self-monitoring technologies, but also managing emotions related to glucose fluctuations.

Despite the barriers and challenges participants encountered at the beginning of the intervention, they were able to identify strategies from various resources to overcome obstacles and cope with them. The identified barriers (eg, technology difficulties and lack of time) are similar to those reported previously [39]. Our study found that the involvement of family and friends, as well as the assistance from an intervention program could help overcome barriers and facilitate technology-assisted self-monitoring. Future interventions could consider involving a family member or a friend in the intervention program. Additionally, given the variations in how individuals integrated the process of self-monitoring, future lifestyle interventions may consider individualizing self-monitoring strategies to improve adherence.

Different findings at 6-week and 6-month timepoint discussions were notable. This study identified an overall learning curve in technology-assisted self-monitoring from the 6-week timepoint of the intervention to the 6-month timepoint. The learning curve experienced by participants might have led to the more positive outcomes seen at the 6-month discussion. While working through the learning curve seen at 6 weeks, participants focused more on factors that would help them adapt to technology-assisted self-monitoring, such as getting help from family and friends. At the 6-month discussion, they appeared to be individually sufficient with regard to knowledge and technology in a more experienced way than before. In addition, at 6 months, the identified additional facilitators of engaging in self-monitoring included ease of use and time saving, which were not identified at 6 weeks. A study examining digital health systems for personalized lung disease management reported that patients become faster at completing their digital symptom log over time, which partially confirmed our findings [40]. Further, at the end of the 6-month discussion, participants seemed more comfortable and integrated in using technology-assisted self-monitoring of lifestyle behaviors and health indicators. The barriers of engaging in technology-assisted self-monitoring (eg, technology difficulties) have been extensively studied [34,38,39]. The learning curve of using technology-assisted self-monitoring for disease management, however, has rarely been comprehensively studied. Our study provides findings of initial exploration of the learning curve in technology-assisted self-monitoring. Future studies with longer follow-up are warranted to explore the learning curve for different populations, as well as to determine whether participants would get fatigued with self-monitoring and begin to engage less in self-monitoring overtime, and consequently, relapse back to their previous unhealthy lifestyles.

Lastly, at the 6-month discussion, participants perceived that recording lifestyle data was safe and commented that they were willing to share the recorded data with health care providers, friends, and family members. The relevant questions on sharing health data were not asked at the 6-week interview, so it did not appear in the 6-week discussion. The results are consistent with the findings of previous studies that older adults would like to share their tracked health data with health care providers, friends, and family members [41]. Their willingness to share health data with health care providers may help the physician-patient dyad to better improve patient health outcomes. Additionally, willingness to share data with friends and family members may lead to patients getting help from others for overcoming barriers to engaging in self-monitoring and may encourage positive lifestyles, as identified in this study. Further, awareness among friends and family members about how health indicators correspond to lifestyle behaviors may foster or create a positive atmosphere around patients to promote positive lifestyle changes and better health outcomes. Future lifestyle intervention programs may consider including both patients and their loved ones in diabetes management programs if possible.

Limitations

There are several limitations in this study. First, all devices and supplies were provided to participants, so the study was not

able to identify other important barriers for self-monitoring engagement, such as the costs of health devices, test strips, and lancets [38]. Second, the study used a convenient sample with a small sample size and with all study participants enrolled in a lifestyle intervention program with diabetes management health education provided. The study findings may not be generalizable to other individuals for technology-assisted self-monitoring of lifestyle without health education support. However, our findings highlighted that there is a learning curve when using technology-assisted lifestyle monitoring, and individuals not participating in a health education program may identify various resources to promote self-monitoring and positive lifestyle changes. Third, the study was not designed to explore participants' perceptions of factors related to positive lifestyle changes. Therefore, the captured factors associated with lifestyle changes were limited in this study.

Conclusion

Although there were some barriers, the study participants were able to identify various individual and external strategies to adjust to and engage in technology-assisted self-monitoring, and it was concluded that technology-assisted self-monitoring was beneficial, safe, and feasible to use. The learning curve, along with other differences identified between the 6-week and 6-month discussions, suggested the adaptability process of engaging in technology-assisted self-monitoring for diabetes management. These patient perspectives need to be considered in future research studies when investigating the effectiveness of using technology-assisted self-monitoring for diabetes management, as well as in clinical practice when recommending technology-assisted self-monitoring of lifestyle behaviors and health indicators to improve health outcomes.

Acknowledgments

We would like to thank LoseIt! and PHRQL for technological assistance. We appreciate the time provided by our study participants and the assistance provided by our research assistants. The study was funded by UT Health School of Nursing Dean's Research Awards and Partners Award. JW is supported by the Robert Wood Johnson Foundation Nurse Faculty Scholars and Hugh Roy Cullen Professorship at UT Health San Antonio School of Nursing. YD is supported by the Translational Science Training TL1 Award (NIH/NCATS, TL1 TR002647).

Conflicts of Interest

None declared.

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Abbreviations

HbA1c: glycated hemoglobin

TAM: technology acceptance model

Edited by G Eysenbach; submitted 07.06.20; peer-reviewed by Z Yu, S Pit; comments to author 24.06.20; revised version received 02.07.20; accepted 27.07.20; published 28.08.20.

Please cite as:

Du Y, Dennis B, Rhodes SL, Sia M, Ko J, Jiwani R, Wang J

Technology-Assisted Self-Monitoring of Lifestyle Behaviors and Health Indicators in Diabetes: Qualitative Study

JMIR Diabetes 2020;5(3):e21183

URL: <http://diabetes.jmir.org/2020/3/e21183/>

doi: [10.2196/21183](https://doi.org/10.2196/21183)

PMID: [32857056](https://pubmed.ncbi.nlm.nih.gov/32857056/)

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Original Paper

Facebook as a Medium for the Support and Enhancement of Ambulatory Care for People With Diabetes: Qualitative Realist Evaluation of a Real-World Trial

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Abstract

Background: There is a growing focus on the potential uses, benefits, and limitations of social media in the context of health care communication. In this study, we have sought to evaluate an initiative pioneered at a hospital in Denmark that uses Facebook to support and enhance patient-provider communication about diabetes.

Objective: This paper aims to evaluate the success of the trial according to its initial objectives and to assess its potential scalability.

Methods: The study was undertaken in a clinic for diabetes and hormonal diseases at a large regional hospital in Denmark. Using a realist evaluation approach, we identified 4 key components in the program theory of the initiative, which we formulated as context-mechanism-outcome configurations (eg, complex and iterative chains of causality). These configurations informed data gathering and analysis. Primary data sources were the activity and content in the Facebook group, in the form of posts, likes, and comments, and interviews with patients (n=26) and staff (n=6) at the clinic.

Results: New developments in diabetes technology were the most popular posts in the forum, judged by number of likes and comments. Otherwise, information specific to the clinic received the most attention. All 4 components of the program theory were compromised to varying degrees, either as a result of failings in the anticipated mechanisms of change or contextual factors derived from the mode of implementation.

Conclusions: Social media serves well as a conduit for imagining positive change, but this can be a strength and weakness when attempting to enact change via concrete interventions, where stakeholder expectations may be unreasonably high or incompatible. Nonetheless, such initiatives may possess intangible benefits difficult to measure in terms of cost-effectiveness.

(*JMIR Diabetes* 2020;5(3):e18146) doi:[10.2196/18146](https://doi.org/10.2196/18146)

KEYWORDS

online patient-provider interaction; social media; Facebook; realistic evaluation

Introduction

Background

Diabetes mellitus is a complex and multifarious health condition that impacts millions of people globally, giving rise to both personal and societal costs on a large scale [1]. In recent years, incidence and prevalence of diabetes mellitus has been on the increase, with more people than ever before confronting the day-to-day challenges associated with diabetes management [2]. This increase puts pressure on individuals, but also challenges health care systems. More and more resources within health care are consumed by the treatment of diabetes mellitus and its complications [3]. In this climate, innovation, both technical and organizational, is widely seen as key to confronting challenges anticipated in the future.

Social media platforms are oft-touted as one possible area of innovation that can be of benefit within health care [4-6]. Use of social media has, for example, been shown to enhance relationships with health care professionals (HCPs), with people feeling empowered and better able to engage in shared decision making about their care [7,8]. In the case of the social media platform Facebook, it has been shown that online exchanges between patients and relatives can influence treatment decisions and emotional support in everyday life [9], though some of the factual content of the information being exchanged was deemed to be questionable from a strictly clinical perspective [10].

The recent emergence and growth of the diabetes online community (DOC) presents opportunities and challenges to health care professionals and health care systems [11-16]. People with diabetes can now interact with one another irrespective of time or place, and this impacts how knowledge about diabetes is acquired and exchanged [17]. For people with diabetes who are willing and able to participate in the DOC, there is apparently much to be gained by this development. The rapid pace of change observed with respect to the communication between people living with chronic conditions such as type 1 and type 2 diabetes is not yet fully matched by concomitant changes in modes of communication between health care professionals and the people they provide care for.

Traditional roles in health care communication are thrown into flux by the advent of social media [18], and HCPs and health care systems are still struggling to define or redefine their position. The spread of social media creates new ethical dilemmas within health care [19]. Taking the specific case of Facebook, a significant concern among HCPs is the potential threat it poses to personal privacy and a fear that the private sphere will be overwhelmed by the professional sphere [20]. In addition, there is a concern that social media forums foster inaccurate information, posing both practical and ethical dilemmas to HCPs interested in using these media as channels for communication.

There is a growing focus on the potential uses, benefits, and limitations of social media in the context of health care communication [4]. In the case of type 1 diabetes, it has been proposed that, where appropriate, clinicians need to be more proactive in supporting their patients to engage with social

media [21] and that exchanges on social media can provide a potential source of information for the health care professions, which can be used to inform new health-related interventions [22]. Where Facebook has been used to engage patients, it has generally not been used to interact directly with them but more commonly to provide general guidance and correct what HCPs perceive to be misleading or spurious online information, as described in Benetoli et al [23].

Aside from the ethical and legal concerns associated with social media-facilitated health care communication [24,25], a further limitation for promoting such engagement by health care systems and HCPs is the fact that, with some exceptions [26,27], the use of Facebook by HCPs has not been associated with outcomes justifying the use of time and resources required to sustain this type of intervention [28]. This is striking because, at face value, Facebook is a medium that is well and widely established in countries like Denmark, where it is estimated that there are up to 3 million regular users in a country of approximately 5 million inhabitants. Part of the challenge here rests in the fact that social media interventions are essentially complex, since the component parts are difficult to isolate from one another and from other wider contexts, thereby challenging traditional research and evaluation methods [29].

In this study we have sought to evaluate an initiative, pioneered at a hospital in Denmark, to use Facebook to communicate directly from HCP to people with diabetes. At the time our evaluation was undertaken, the Facebook group being used to facilitate this initiative had been active for approximately 18 months. At the outset, the initiative was not designed as an intervention, the impact of which might be directly or indirectly measured. Nonetheless, after seeing membership of the Facebook group grow substantially from its inception and in view of the effort required to maintain the group, the owner of the initiative (the head physician) considered that it was timely to determine whether the group was achieving the objectives for which it was developed. In view of the difficulties noted above concerning evaluation of such initiatives, it was agreed by the partners involved in this work that the optimal approach would be to undertake a theory-driven evaluation. Theory-driven evaluation represents an ideal approach to the appraisal of complex real-world interventions [30]. Evaluation thus proceeds from an identification of the theories that have informed the development and implementation of the intervention, and these theories are subsequently used to shape the approach of the evaluation, determining the primary points of focus and the questions that need to be posed.

In this study, we chose to apply a particular form of theory-driven evaluation known as realist evaluation (RE) [31]. This choice was influenced by the fact that this approach is well suited for social interventions, where outcomes are determined by stakeholder actions and interactions [32], a point very apposite to the topic we were focusing upon. Likewise, RE is particularly concerned with both the psychological and motivational impact of initiatives that lead to change [33], and this focus is not only important in itself for the purposes of our specific evaluation but also more broadly in terms of the lessons that the evaluation we present in this study might have for other similar initiatives.

Goal of This Study

This study aims to evaluate the success of a concrete intervention using Facebook as a means to support and enhance ambulatory care among people with type 1 and type 2 diabetes. Additionally, we sought to identify more generic factors influencing the use and uptake of social media in the context of health care. Finally, we sought to apply and exemplify the use of realist evaluation as a methodology for apprehending complex outcomes within a complex, real-world intervention.

Methods

The Setting

The study was undertaken in a clinic for diabetes and hormonal diseases, which is part of a large regional hospital in provincial Denmark. The outpatient clinic caters to people with both type 1 and type 2 diabetes, with a capacity for approximately 2500 consultations per annum for people with diabetes. The clinic employs 3 chief consultants, 2 residents, 5 diabetes nurses, and 5 dieticians.

The Virtual Setting

The Facebook group, Diabetes Viborg (DIAVIB), was established by a consultant endocrinologist in the clinic in January 2017. DIAVIB was not established with an explicit set of aims and objectives, but the initiative was motivated by the interests and concerns of this consultant endocrinologist regarding the use of social media by people with diabetes. It was set up as a closed group, requiring registration by potential members, and it targeted people with diabetes, their family members, and anyone with an interest in diabetes. The Facebook

group focused primarily on users of the clinic but also stated that it was open to anyone with an interest in diabetes. At the time of our evaluation, there were approximately 500 registered members, of whom approximately two-thirds were women (at the time of writing, this figure is now 630, with the sex distribution unchanged). In terms of age distribution, the lowest proportion of users was seen in the age range of 18 to 24 years, with the next lowest in the 65+ years age range. The majority of users lived in the catchment area of the clinic. Communication on DIAVIB was almost exclusively conducted in Danish, although some links were provided to external content that was only available in English.

Data Material and Participants

The study draws upon 2 primary data sources: the activity and content on DIAVIB, in the form of posts, likes, and comments observed over the period from June 1, 2017, to August 22, 2018, and interviews with patients and staff at the clinic. Interview participants were sought via posts on DIAVIB, a leaflet posted in the clinic, and by a nurse in the clinic, who phoned people visiting the clinic on the days on which interviews were planned. We sought to recruit a representative sample of the clinic's overall population, seeking variation according to age, gender, social class, and both users and nonusers of DIAVIB. Patient characteristics can be seen in [Table 1](#).

Two potential participants declined the invitation to participate when asked directly, primarily due to a general dislike of social media and practical issues with available interview times. In addition to the consultant who founded DIAVIB, other HCPs in the clinic were also interviewed, namely 2 nurses, 2 consultants, and 2 dieticians.

Table 1. Study participant characteristics (N=26).

Characteristic	Value
Age (years), median (range)	48.1 (19-77)
Diabetes duration (years), median (range)	13 (3-57)
Diabetes type, n (%)	
Type 1	15 (58)
Type 2	11 (42)
Gender, n (%)	
Male	12 (44)
Female	15 (56)
BMI (kg/m ²), median (range)	28.7 (21-42)
HbA_{1c}^a (mmol/mol), median (range)	
Type 1	67.6 (46-89)
Type 2	57.2 (40-71)
Existing DIAVIB ^b member (yes), n (%)	11 (42)
Employment status, n (%)	
In employment	15 (58)
Unemployed	1 (4)
Pensioned	3 (12)
Disability pensioned	5 (19)
Student	2 (8)

^aHbA_{1c}: glycosylated hemoglobin (used to measure average blood glucose levels over time).

^bDIAVIB: Diabetes Viborg.

Data Analysis

In cases where there is no clear set of theoretical principles explicitly coupled to an intervention, the first task for evaluators working with theory-driven approaches is to articulate a program theory. This is undertaken in collaboration with those who have developed the intervention, in this case the consultant at the clinic. With numerous informal discussions and a 2-hour semistructured interview, we initially identified 4 distinct objectives, which we were then able to investigate and assess.

In addition to the interview data, we also gathered and analyzed data from DIAVIB itself. These data were analyzed in terms of their general characteristics (eg, a comment, a question, a like, etc) and in terms of their content. BC undertook the first analysis and thematization of the content, and this was subsequently discussed and consensually verified within the author group. It was relatively straightforward to achieve high levels of consensus within the author group because the content being analyzed was, for the most part, very concrete and prosaic in what it was addressing.

Theory-based evaluations that draw upon the realist evaluation approach take it as axiomatic that context is a key mediator between desired objectives and actual outcomes. Context contains numerous dimensions and is not easily demarcated, but in the case of our evaluation, its impact is seen in at least 3 levels: social, organizational, and individual. A further crucial

dimension of RE is the mechanism, or what might be deemed the underlying causality that explains why certain actions lead to particular outcomes. The overarching model for RE is context-mechanism-outcome (CMO) configurations, that is, the causal but often convoluted relationship between conditions and outcomes. In undertaking RE, therefore, we have sought to identify and gauge which contextual factors have influenced the outcomes, whether these contexts were anticipated in the design of the intervention, and to what extent mechanisms of change imagined at the outset were confirmed in the outcomes.

Ethical approval for the study was obtained from Region Midtjylland's research board (May 18, 2018). All data extracted from the DIAVIB group were anonymized before being put to use. Likewise, all interview participants were required to sign an informed consent form, guaranteeing their anonymity but allowing researchers unhindered access to the interview transcripts.

Results

Overview

In the period observed, the administrator of the site initiated 109 unique communication threads across a wide range of subjects related to diabetes. In 30 of these threads, the message was accompanied by a link to some external source of information. In 14 cases, the administrator initiated a thread to

conduct a poll among the members of DIAVIB. The 109 threads received a total of 780 likes from members of the group, and there were 232 follow-up comments. Many members of the group commented on multiple occasions and the 232 comments were authored by 76 individual members of the group.

The topics attracting the most likes and comments were related to both general diabetes information and information pertaining specifically to the clinic. New developments in diabetes technology were by far the most popular posts in relation to general diabetes information, judged by number of likes and comments. For example, a post about the implantable glucose sensor Eversense XL (Senseonics Holdings) received 54 likes and was commented on 25 times. Of the information specifically pertaining to the clinic, it was personal information about staff members joining or leaving the team that was the most popular on the metric of likes and comments. For example, a thread

about a nurse who was leaving the clinic to take retirement received 44 likes and 18 comments.

At the outset of the project, we identified 5 objectives that represented the underlying program theory of DIAVIB. We have subsequently discarded one of these objectives, relating to peer support, on the basis that the setup of DIAVIB was not actually suited to facilitate peer support and the data we acquired from participants reflected this fact. As such, it was deemed to be something that could not be reasonably evaluated. From the 4 remaining objectives, we posited 4 different CMO configurations.

CMO 1: DIAVIB as a Source of Knowledge

A nonexhaustive summary of this process is exemplified in table form, as seen in Table 2 for the CMO configuration, DIAVIB as a source of knowledge.

Table 2. Context-mechanism-outcome configuration 1: Diabetes Viborg as source of knowledge about diabetes.

CMO ^a	Objective	Context	Mechanism	Outcome
CMO 1: Source of knowl- edge	DIAVIB ^b should provide people with a reliable source of knowledge about diabetes.	Individual: People with diabetes and their relatives. Social: Information landscape of diabetes (internet, social media, popular media, etc).	People feel overwhelmed by amount of available information about diabetes and have doubts about its veracity. People trust the knowledge and integrity of their HCPs ^c and will attach value and validity to information provided by their clinic on Facebook.	DIAVIB is used as a primary information source about diabetes by its users. Anxiety/distress related to diabetes information is reduced.

^aCMO: context-mechanism-outcome.

^bDIAVIB: Diabetes Viborg.

^cHCPs: health care professionals.

In our interview data, participants did express concerns relating to the volume of information about diabetes, both in general and on the internet, and the challenge of determining its veracity:

I've been on the internet and looked at different things, but I think people say a lot of different things there. Some say something, and others say something else. That can make things all a bit more confusing.
[Woman with type 2 diabetes, aged 64 years]

The extent to which this was viewed as a problem varied, but there was a clear distinction in the degree to which people with diabetes viewed it as a problem and the degree to which health care professionals saw it as such. Rightly or wrongly, people with diabetes did not experience it as essentially problematic because they felt able, in one way or another, to find a way to normalize things for themselves:

Once you've had it for a while you get more and more information, so you just learn. I don't think there is too much. [Man with type 2 diabetes, aged 66 years]

I've learnt to filter it out. I've grown up with diabetes, so I know what I need to relate to. [Woman with type 1 diabetes, aged 31 years]

If there is anything you are in doubt about then you can always look it up. You can look up everything

these days. [Woman with type 1 diabetes, aged 40 years]

In contrast, every HCP interviewed expressed concern about people being exposed to inaccurate information and the consequences this might have.

However, while interview participants did not indicate a sense of being overwhelmed by information, there was recognition that information provided through DIAVIB did carry extra credibility compared with other more random sources. In fact, for some participants, their contact with the clinic was perceived to provide them with all the information that they needed about diabetes:

I get [information about diabetes] from here [the clinic]. It's not something I read about. If you start to read about it, you will immediately get 10 more symptoms and I don't want that. I trust what they do here, and I do what they say and I'm fine with that.
[Man with type 2 diabetes, aged 67 years]

CMO 2: Forum for Patient-Provider Interaction

The next CMO configuration we identified was DIAVIB as a forum for patient-provider interaction, exemplified in Table 3.

Table 3. Context-mechanism-outcome configuration 2: forum for patient-provider interaction.

CMO ^a	Objective	Context	Mechanism	Outcome
CMO 2: Forum for interaction	DIABIB ^b should be a forum in which people with diabetes and HCPs ^c can interact with one another.	Individual: People with diabetes and their relatives; HCPs working with people with diabetes. Social: Juridical system, health care ethics, professional cultures, etc. Organizational: Work organization, task accreditation.	People with diabetes are interested in communicating with their HCPs in online forums because they have needs and concerns that are not addressed in the conventional point of contact with the health care system. HCPs can provide cost-effective support to people with diabetes via online interaction, which will also provide insight into the prevailing concerns among people with diabetes.	People with diabetes and HCPs use DIABIB to interact with one another. DIABIB can be used to communicate with patients in a way that supports mutually beneficial and progressive patient-provider interaction.

^aCMO: context-mechanism-outcome.

^bDIABIB: Diabetes Viborg.

^cHCPs: health care professionals.

The possibility of two-way communication between HCPs and people with diabetes was, in principle, something that could be facilitated by DIABIB. However, this possibility was limited by the fact that it was only the administrator of the group (the consultant) who could initiate posts. So, while it was possible for members to comment on posts, they were not able to determine the topics under discussion. For some, this represented a limitation that lessened the appeal of engaging with the group:

Yes, I think it would be a good thing. I know that there are other Facebook groups with people who share experiences, so ... for me it's not likely I'd join the group if they only share information because I think that I can do this myself, also with respect to being critical of the sources. So, if there are no elements besides that in the Facebook group, then I don't think it's so interesting for me. [Woman with type 1 diabetes, aged 20 years]

Others voiced a wish for more communication, expressing dissatisfaction with the way in which dialogue had been handled within DIABIB:

I think it could be better in the way that, if there are questions in there, then they should make sure to answer them. They should be a bit more active. Sometimes there are long gaps before anything gets posted. [Woman with type 1 diabetes, aged 59 years]

In general, however, there was uncertainty about opening up DIABIB to more direct two-way communication, expressed as

a concern about the type and quality of exchanges that would ensue:

I think it's a professional tool. I think it's important that the things that get written are based on professional knowledge. The things posted in here should come from doctors or nurses, so there isn't any misunderstanding about what is and isn't true. [Woman with type 1 diabetes, aged 50 years]

It was also seen as open to question what kind of communication someone would want to have:

Is this really the right forum, if I've got a need to get in touch with my Doctor? Then it would be more about me and not something that I would want to share in an open group. [Woman, with type 1 diabetes, aged 34 years]

An underlying factor in the general ambivalence toward the use of DIABIB as a forum for direct interaction with HCPs could also be inferred from the fact that participants did not express frustration with the degree of contact that they had with HCPs. The interview data presented an overwhelmingly positive impression of a clinic and clinic personnel that were attentive and accessible.

CMO 3: HCP Engagement With Health Communication

DIABIB was conceived to inspire HCP engagement with health communication, and the CMO configuration derived from this objective is exemplified in [Table 4](#).

Table 4. Context-mechanism-outcome configuration 3: Diabetes Viborg supports health care professional engagement with health communication.

CMO ^a	Objective	Context	Mechanism	Outcome
CMO 3: HCP ^b engagement with health communication	DIABIB ^c should foster an interest in innovative health care communication among HCPs	Individual: HCPs working with people with diabetes. Social: Informed patients, patient-centered care, etc. Organizational: Resources and time dedicated to task.	HCPs are challenged by the expansion of publicly available knowledge and by time limitations in their encounters with people with diabetes.	The opportunities for direct communication offered by DIABIB will motivate HCPs to engage more in the dissemination of valid and relevant knowledge, which addresses the everyday needs of patients with diabetes.

^aCMO: Context-mechanism-outcome.

^bHCP: health care professional.

^cDIABIB: Diabetes Viborg.

All the HCPs interviewed acknowledged that the advent of the internet had made some impact on their interactions with people with diabetes. This was viewed as something with both positive and negative consequences. It was, however, primarily the negative consequences that were emphasized by HCPs, who felt that inaccurate information could lead to false expectations and even dangerous actions among people with diabetes. While the notion that there is a need for innovative approaches to health communication is supported in these observations, not all HCPs agreed that posting on Facebook was viable. One concern expressed related to the complexity of the information being conveyed and the challenge of supplying information at a general level, thereby omitting the more personal judgements involved when conveying information to people with diabetes:

I mean, when you're talking about diet, there's all sorts of information that you can write about which the patient will see. And I just think, the things we write should be quite specific when you know that a lot of patients are going to read it and you don't know how they're going to react to it. That's something we talk about a lot—what we should and shouldn't say—where you need to make a judgement based on the individual and that's just easier when you're in an individual consultation with the patient. [Dietician, aged 44 years]

More prosaically, reservations were voiced in relation to the time needed to maintain the group. Even though the clinic's personnel were sympathetic to the initiative, it also evoked more negative emotions:

So, it's a bit like there is a mild pressure to contribute, and that's fair enough, but it's like, argh, when is there going to be time for that, to actually sit down and provide something worthwhile... We could do more, but I don't know when or how it should be. [Dietician, aged 52 years]

Although there had been discussions within the clinic about making DIABIB a collective responsibility, because it was not something that was integrated into the clinic's everyday practice, it emerged as an exclusively individually driven initiative. DIABIB was only officially supported to the extent that it existed nominally under the auspices of the regional hospital

and clinic, but the time used to set up and maintain the site was not financially reimbursed.

Aside from the issue of time and reimbursement, personnel at the clinic also felt that Facebook imposed limitation in terms of what could be communicated. An important aspect of this related to privacy, both that of the HCP and users of the clinic:

My first thought was, that's an innovative and visionary initiative. My second thought was, I don't want to be personally part of that... And I mean, it's clear that we can't have personal information. If there's anything that's even remotely identifiable they have to use their digital post box, so it just doesn't work on Facebook. So, I don't really know what I could help them with, apart from really general information, like insulin can't cope with 30°C heat. [Nurse, aged 42 years]

The personnel interviewed in our evaluation were aware of the innovative and unrealized potential of Facebook to communicate, such as the consultant who imagined it might serve to capture the hardly reached:

I thought it might be a good way to reach those people who don't come [to the clinic], but who are always on their Facebook pages, you know. [Doctor, aged 38 years]

Despite this, interviews with the clinic's personnel ultimately left an overriding sense of DIABIB falling short in activating the potential to reach hardly reached patients, a feeling captured by the same consultant reflecting on his own idea:

So that could be a way to get some more people in. But, it's not really integrated into my way of working. It's not like I sit here and say, you should do this and this and you can see it on our Facebook group. I'm not there yet... I don't know, maybe it's because I don't really use Facebook much myself. [Doctor, aged 38 years]

CMO 4: Improved Empowerment and Outcomes

The final CMO configuration we identified anticipated that DIABIB would help patients to achieve improved empowerment and outcomes, as exemplified in [Table 5](#).

Table 5. Context-mechanism-outcome configuration 4: Diabetes Viborg improves empowerment and clinical outcomes.

CMO ^a	Objective	Context	Mechanism	Outcome
CMO 4: Improves empowerment and outcomes	DIABIB ^b should enable people with diabetes to achieve an improved illness understanding.	Individual: People with diabetes and their relatives. Social: Knowledge sharing.	People's diabetes management practices are related to their level of knowledge about diabetes. Enhanced knowledge will enable improved diabetes management.	People with diabetes in the clinic will become better at diabetes management and thereby improve their diabetes-related outcomes (eg, HbA _{1c} ^c)

^aCMO: context-mechanism-outcomes.

^bDIABIB: Diabetes Viborg.

^cHbA_{1c}: glycosylated hemoglobin, type A_{1c}.

This CMO configuration was ultimately the most abstract to evaluate, since there were no means by which to measure participants' level of engagement with DIABIB and equate it to changes in clinical outcomes. It was, however, possible to investigate the premise for the proposed mechanism of change and find support for the notion in principle:

You should try to know more about your illness. Knowing more about it, you're better able to control it. [Man with type 2 diabetes, aged 70 years]

At the same time, we also identified individual strategies relating to diabetes knowledge that pushed in the opposite direction. Information overload in relation to diabetes does not only come from what one can hear and read about it. Dealing with diabetes on a day-to-day basis can also be experienced as a type of information overload. In view of the potentially endless information that is available, it is also important that people can delimit what they do and do not need to know:

Interviewee: *I know that I could read a whole lot more about diabetes, but there are just so many other things that I would rather do.* [Woman with type 1 diabetes, aged 40]

Interviewer: *Yeah, life is about more than diabetes?*

Interviewee: *Yeah, where I just think that if there is something that I need to know, well, then I'll take an interest in it. And if I don't need to know about it, then I don't see any reason to take an interest in it.*

Discussion

Summary of Findings

Our evaluation of DIABIB indicates that while acceptance of the initiative was apparent in the numbers who joined the group and the overall positive attitude expressed during the interviews, levels of direct engagement were much lower. This possibly reflects more fundamental challenges in health care communication, where there is generally a lack of clear guidelines for how best to generate content and strategies for communication and engagement with people living with chronic health conditions such as type 1 and type 2 diabetes [29]. At the same time, there are more specific challenges related to designing Facebook groups and pages that are acceptable to all relevant stakeholders [29], not least in achieving congruency about what the purpose is.

Although many HCPs express concerns about the veracity of online information in general, there is no overwhelming evidence that clinically inaccurate information is flooding online diabetes forums [34]. The interview data we obtained did not support a view of people feeling overwhelmed by information and not knowing what to believe. In a recent published commentary, the authors proposed that sifting through the plethora of diabetes-related online information and determining what is and is not meaningful is more of an art form than a scientific process [35]. Although the authors also suggest that greater engagement by HCPs in guiding people with diabetes through this minefield might improve the situation, it is likely that some level of individual interpretation will remain. For better or worse, "patienthood" is becoming a more and more skilled practice [36]. Our informants were happy to use DIABIB as a source of knowledge about diabetes, and their familiarity with the real-world context in which it was being produced inclined them to ascribe high levels of credibility to the information. At the same time, however, this was something that they generally experienced as nice to have and not as something that they needed to have.

The nature of the communication on DIABIB was also influenced by the setup of the group (ie, a closed Facebook group associated with a physical diabetes outpatient clinic in a regional hospital, in which only the administrator can initiate topics for discussion and which is primarily being maintained by one individual, for the most part as a hobby rather than something being officially recognized and rewarded). These architectural affordances of the group inevitably impact the type and level of interaction and the respective roles of people with diabetes and HCPs [37]. Rather than transforming modes of interaction between patients with diabetes and HCPs, the architectural affordances of DIABIB tend to recapitulate them [38]. The empowering potential of social media is, in this sense, somewhat constrained, and a more open architecture within the group may have offered different types and patterns of communication.

Online interaction between patients and providers has previously been shown to be problematic, with a discrepancy between the concerns being voiced by patients and the nature of replies being provided by HCPs, particularly in regard to the use of inclusive and supportive language [39]. Interviews with HCPs indicated that there were concerns about finding the right tone in potential online communication with people with diabetes, especially in the absence of social cues that they would use to tailor their

communication and advice in face-to-face encounters. This would support the idea that the advantages afforded by social media may be best realized in cases where there is a preexisting good relationship between those who are interacting [40]. In our case, however, by far the greatest barrier from the HCP perspective was the fact that there was no official recognition of the initiative, and in the absence of guidelines and earmarked resources, DIAVIB was, from an organizational perspective, an essentially vulnerable initiative primarily supported by the commitment of one individual.

It remains unclear whether participation in online support groups serves to establish collective empowerment or whether the collective identity fostered in such groups only serves to generate individual empowerment [41]. Different media can foster different types of empowerment, and forums such as DIAVIB, which are promoted under the auspices of health care organizations, are probably more conducive to the promotion of individual empowerment. Ultimately, our data did not provide any strong indication of DIAVIB members obtaining a sense of empowerment or, for that matter, seeking to obtain a sense of empowerment as such. Nonetheless, by providing a source of reliable information that can contribute to enhancing people's illness understanding, individual empowerment, in the sense of being able to make more informed decisions regarding care and treatment, may be something that individuals are able to obtain from social media-mediated interaction with their HCPs. This is, however, a question which requires more systematic investigation, although identifying strong evidence for a direct link between participation in groups such as DIAVIB and improved clinical outcomes is likely to remain elusive.

At the current time, there remain concerns about whether the advance of social media and its increasing pervasiveness in all aspects of life may also engender a situation in which certain groups of people are actually disempowered. This applies, for example, in the case of engaging older people with diabetes via social media, where more support is often needed to overcome the barriers they experience [42]. Low health literacy is also negatively associated with ability to accurately assess the quality of online health information [43], and although this is also an issue more generally, in health care there may be specific contours of eHealth literacy [44] that need to be attended to in the case of social media-mediated interactions between people with diabetes and their HCPs.

DIAVIB was very clearly a complex intervention involving various stakeholders located in diffuse contexts and, as such, it was suited to a theory-driven approach to its evaluation. For reasons highlighted above, we adopted a realist evaluation framework to structure our investigation. RE's approach is not

always easy to follow in relation to mechanisms of change, and it assumes a rationality regarding these mechanisms that is not necessarily in place [45]. There are, moreover, diverging views regarding the nature of "mechanism" and the difference between mechanism and essential context condition [46]. However, acknowledging these challenges, the framework provided by RE has also provided clear benefits. Dealing with an intervention that emerged organically, the RE approach compelled both the program developer and the evaluators to explicate the underlying theoretical framework. This exercise had clear value to the task at hand, subsequently framing the analytical focus, for example, in the iteration of interview guides. At the same time, it also gave cause for more general reflection on the criteria by which initiatives such as DIAVIB need to be assessed and the mechanisms and contexts that are likely to influence the success or failure of such initiatives.

Conclusion

DIAVIB was an initiative that was inspired by motives rooted in genuine and contemporary concerns about supporting people with diabetes in the best possible way. It sought to exploit the potential for new modes of patient-provider interaction seemingly allowed by social media and, at the same time, aimed to provide support for people with diabetes in a world in which flows of information are not necessarily anchored in conventional understandings of knowledge and truth. However, from the perspective of the objectives it was anticipated to address, the success of the initiative is limited. Part of this rests in the expectations, which were highly ambitious. Social media serves well as a conduit for imagining positive change, but this can be a strength and weakness when attempting to enact change via concrete interventions. This is especially true of initiatives like DIAVIB, which are developed organically rather than systematically.

Having stressed the limited extent to which DIAVIB represents a successful intervention when seen through the lens of a theory-driven evaluation, it should finally be noted that such an evaluation does not necessarily capture more intangible benefits. Whatever its limitations, the fact that more than 600 individuals have actively sought membership in DIAVIB suggests that it has tapped into a seam of interest in the possibilities allowed by social media in the context of health care that, as of yet, are not fully realized. Although our study suggests that there remain numerous and serious obstacles on the path towards the realization of such potential, pioneering initiatives such as DIAVIB and the lessons that can be drawn from them represent important milestones along this seemingly inexorable route.

Acknowledgments

The authors would like to express their appreciation to Anna Kristina Moeller, who provided invaluable assistance in recruiting participants to the study. Appreciation is also due to the staff at Viborg Regional Hospital for their willingness to contribute to the project. Finally, and most importantly, the project could not have been undertaken without the people living with diabetes who volunteered to contribute their time in order to provide us with invaluable insights, and for this we are extremely grateful.

Conflicts of Interest

None declared.

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Abbreviations

CMO: context-mechanism-outcome

DIABIB: Diabetes Viborg

DOC: diabetes online community

HCP: health care professional

RE: realist evaluation

Edited by K Mizokami-Stout; submitted 07.02.20; peer-reviewed by E Da Silva, A Kulanthaivel, M Bardus; comments to author 22.04.20; revised version received 01.07.20; accepted 10.07.20; published 14.09.20.

Please cite as:

Cleal B, Willaing I, Hoybye MT, Thomsen HH

Facebook as a Medium for the Support and Enhancement of Ambulatory Care for People With Diabetes: Qualitative Realist Evaluation of a Real-World Trial

JMIR Diabetes 2020;5(3):e18146

URL: <http://diabetes.jmir.org/2020/3/e18146/>

doi: [10.2196/18146](https://doi.org/10.2196/18146)

PMID: [32924958](https://pubmed.ncbi.nlm.nih.gov/32924958/)

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Original Paper

Internet-Based Lifestyle Intervention to Prevent Type 2 Diabetes Through Healthy Habits: Design and 6-Month Usage Results of Randomized Controlled Trial

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Abstract

Background: Type 2 diabetes can be prevented through lifestyle changes, but sustainable and scalable lifestyle interventions are still lacking. Habit-based approaches offer an opportunity to induce long-term behavior changes.

Objective: The purposes of this study were to describe an internet-based lifestyle intervention for people at risk for type 2 diabetes targeted to support formation of healthy habits and explore its user engagement during the first 6 months of a randomized controlled trial (RCT).

Methods: The app provides an online store that offers more than 400 simple and contextualized habit-forming behavioral suggestions triggered by daily life activities. Users can browse, inspect, and select them; report their performances; and reflect on their own activities. Users can also get reminders, information on other users' activities, and information on the prevention of type 2 diabetes. An unblinded parallel RCT was carried out to evaluate the effectiveness of the app in comparison with routine care. User engagement is reported for the first 6 months of the trial based on the use log data of the participants, who were 18- to 70-year-old community-dwelling adults at an increased risk of type 2 diabetes.

Results: Of 3271 participants recruited online, 2909 were eligible to participate in the RCT. Participants were randomized using a computerized randomization system to the control group (n=971), internet-based intervention (digital, n=967), and internet-based intervention with face-to-face group coaching (F2F+digital, n=971). Mean age of control group participants was 55.0 years, digital group 55.2 years, and F2F+digital 55.2 years. The majority of participants were female, 81.1% (787/971) in the control group, 78.3% (757/967) in the digital group, and 80.7% (784/971) in the F2F+digital group. Of the participants allocated to the digital and F2F+digital groups, 99.53% (1929/1938) logged in to the app at least once, 98.55% (1901/1938) selected at least one habit, and 95.13% (1835/1938) reported at least one habit performance. The app was mostly used on a weekly basis. During the first 6 months, the number of active users on a weekly level varied from 93.05% (1795/1929) on week 1 to 51.79% (999/1929) on week 26. The daily use activity was not as high. The digital and F2F+digital groups used the app on a median of 23.0 and 24.5 days and for 79.4 and 85.1 minutes total duration, respectively. A total of 1,089,555 habit performances were reported during the first 6 months. There were no significant differences in the use metrics between the groups with regard to cumulative use metrics.

Conclusions: Results demonstrate that internet-based lifestyle interventions can be delivered to large groups including community-dwelling middle-aged and older adults, many with limited experience in digital app use, without additional user training. This intermediate analysis of use behavior showed relatively good engagement, with the percentage of active weekly users remaining over 50% at 6 months. However, we do not yet know if the weekly engagement was enough to change the lifestyles of the participants.

Trial Registration: ClinicalTrials.gov NCT03156478; <https://clinicaltrials.gov/ct2/show/NCT03156478>

(*JMIR Diabetes* 2020;5(3):e15219) doi:[10.2196/15219](https://doi.org/10.2196/15219)

KEYWORDS

digital behavior change intervention; internet intervention; web-based intervention; behavior change support system; type 2 diabetes, habit

Introduction

Background

The prevalence of diabetes is rapidly increasing globally and is now almost 10% among adults aged 25 years and older [1], with type 2 accounting over 90% of the cases [2]. According to the International Diabetes Federation, the cause of type 2 diabetes is not completely understood, but it is largely connected to excess body weight, increasing age, ethnicity, and family history [3]. Type 2 diabetes can be prevented or delayed by influencing modifiable risk factors through healthy lifestyles [3].

The key challenges in type 2 diabetes prevention are scaling up interventions, selecting the most appropriate intervention, tailoring interventions to different populations and settings, and ensuring clinically meaningful, cost-effective outcomes [4]. There are increasing efforts to provide readily accessible, cost-effective type 2 diabetes interventions to the general public [5]. Interventions using digital technology are of special interest because they may be easier to disseminate and maintain compared with diabetes prevention programs delivered by health care professionals or peers [5].

Systematic reviews have shown that digital interventions can be effective, and effectiveness is mediated by factors related to health behavior change and intervention characteristics related to user engagement in the intervention [6]. Development of digital behavior change interventions should be driven by direct and indirect evidence and behavior change theory [7]. While many different theories, approaches, and techniques have been used in behavior change research, most digital behavior change interventions fail to take habitual behavior into account [8]. Habits are central in changing health behaviors because an estimated 50% to 95% of daily life behaviors are habits, performed relatively automatically with little thought or regard to current goals or intentions [9,10].

Habit-formation approaches promote the repetition of behavior until it becomes habitual, provide context cues to trigger the behavior, and give rewards that help strengthen the association between the context cues and the behavior [11]. Promoting the repetition of behaviors is about creating opportunities for and encouraging frequent repetition of specific responses (eg, through visual advertisements of providing possibilities to rehearse the new habit) [11]. According to Wood and Neal [11], the provided context cues should be stable and can include times of day, locations, prior actions in a sequence, or presence of other people. People can be encouraged to create plans (ie, implementation intentions) to perform a behavior in a given context. Interventions can also tie a new healthy behavior to an existing habit, which is called piggybacking. Provision of rewards may help in habit forming especially at the early stages

of habit formation [11]. A recent review on digital behavior change interventions shows that only 3 interventions out of 85 targeted formation of new healthy habits [12].

Another important factor for sustained engagement in behavior change is the quality of motivation [13]. Self-determination theory (SDT) [14] defines a continuum from controlled to autonomous motivation, where controlled motivation is driven by external factors such as sanctions, rewards, social pressure, etc, and autonomous motivation by internal factors such as individual values and enjoyment, thereby fulfilling the individual's basic psychological needs: perceptions of autonomy, control or self-efficacy, and relatedness [14]. Interventions to prevent type 2 diabetes are based on evidence from a limited set of lifestyle objectives describing what [15,16] people should achieve, but programs could provide individuals freedom of choice on how to reach these objectives. If individuals could select in which order to start and from whom to receive the necessary support, it would increase their autonomy in the selection of the changes they pursue, their sense of self-efficacy resulting from achievement, and their feelings of relatedness with peers or significant others, resulting in improved fit with their daily lives and higher odds for maintenance.

Using habit-based approaches and SDT as the behavior change theories to guide digital intervention development holds great promise to induce long-term behavior changes and bring lasting public health benefits.

Objectives

The purpose of this study was to describe an internet-based intervention targeted for people at risk for type 2 diabetes to support formation of healthy habits and explore use behavior during the first 6 months of a randomized controlled trial (RCT).

Methods

Design and Randomization

The internet-based intervention, called the BitHabit app, was developed in a national research project studying the real-world implementation of evidence-based type 2 diabetes prevention programs. The study was a 1-year unblinded parallel RCT [NCT03156478] conducted across 3 regions in Finland (Northern Savo, Päijät-Häme, and Southern Carelia). The detailed protocol and design for the study were reported elsewhere [17].

Participants in the trial were randomized using a computerized randomization system, and they were allocated to one of 3 groups: (1) control group, (2) internet-based intervention (digital), or (3) internet-based intervention with face-to-face group coaching (F2F+digital). Allocation to the intervention groups was made 1:1:1 using a computerized randomization

system. This is an intermediate analysis focusing on the use behavior of the participants allocated to the intervention groups.

Participants were recruited online between March 2017 and February 2018 through a digital risk-screening tool that was provided through the project's website. Participants were attracted to the website by varied means including social media, newspapers, radio, television, websites, health care and social service units, and community pharmacies in collaboration with municipal services, employers, patients associations, and other nongovernmental organizations [17]. Individuals identified to be eligible and willing to participate in the study were given instructions on how to contact a nurse in a local health care center for examination visits.

The study was approved by Research Ethics Committee of the Hospital District of Northern Savo (statement number: 467/2016). Written informed consent to participate in the study and for the use of data from national health care registers was obtained from all participants. The informed consent procedure is described in detail in the trial protocol article [17]. The study is conducted according to the Responsible Conduct of Research by the Finnish Advisory Board on Research Integrity and the Declaration of Helsinki.

Participants

The inclusion criteria were (1) aged between 18 and 70 years; (2) increased risk of type 2 diabetes based on a Finnish Diabetes Risk Score ≥ 12 points [18] or a history of gestational diabetes or repeated impaired fasting glucose (fasting plasma glucose 6.1 to 6.9 mmol/L) or impaired glucose tolerance (2-hour plasma glucose 7.8 to 11.0 mmol/L in 2-hour oral glucose tolerance test); (3) living in the province of Northern Savo, Päijät-Häme, or Southern Carelia; (4) access to a computer, smartphone, or tablet with internet connection; (5) having a phone number of their own; and (6) having adequate Finnish language skills. The exclusion criteria were (1) type 1 or type 2 diabetes; (2) pregnancy or breastfeeding; and (3) active cancer or less than 6 months from cancer treatment.

Requirements for the Internet-Based Intervention

The overall development of the internet-based intervention was guided by the Medical Research Council Guidelines on Development of Complex Health Interventions [19]. Identifying the evidence base from the literature proceeded in parallel with ideation, benchmarking, and prototyping. After feasibility testing, changes were made in both content and functionality.

The two lines of behavior change theory that formed the basis of app development were habit formation approaches and SDT. These approaches were considered to be suitable to support maintenance of behavior change, which is a challenge in lifestyle interventions [13]. SDT and especially autonomy support have been associated with higher effectiveness in the long-term, and habit-based approaches also show promise in this respect [13].

In the habit formation approach, it is important to offer tiny behaviors that can be easily repeated and expanded from one-time or occasional behaviors to repeated sequences of behaviors and finally to permanent behaviors [20]. Furthermore, the frequent repetition of these behaviors needs to be sufficiently

supported in a stable context in order for the users to be able to form a cognitive association between context cues and responses and provide some kind of reward to strengthen the association [11]. Thus, the app was designed to promote selection of tiny behaviors that were linked to a specific trigger and boost execution of the behaviors until they become automatic habits.

SDT as the evidence base also provided some key requirements for the app. In order to promote autonomy, a broad selection of behaviors was required to foster freedom of choice. To enhance self-efficacy, the behaviors needed to be feasible for the users, and they also had to be behaviors that users were already familiar with. Finally, enhancing relatedness and sense of community was a challenge. Traditionally, it has been perceived as the sense of being respected, understood, and cared for by health care professionals, forming experiences of connection and trust [21]. We decided to enhance relatedness and sense of community through other participants of the study by providing a possibility for the users to learn about other users' activities in the app.

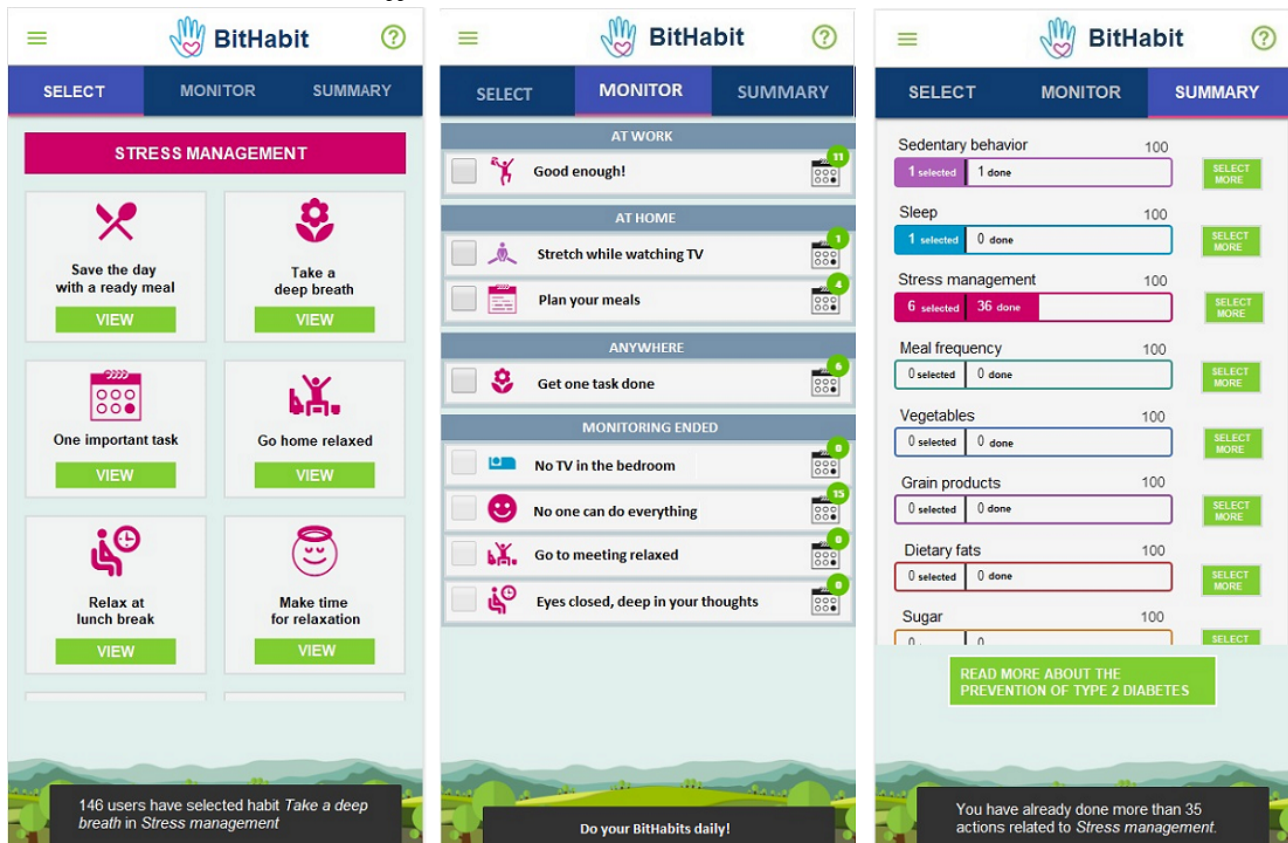
Other requirements were derived from benchmarking, feasibility testing with a group of end users representing people at risk for type 2 diabetes, and the research consortium that had real-time access to the app during its development. There was a need to design a scalable app that could be automatically taken into use after randomization by community-dwelling middle-aged and older adults—many with limited experiences in digital app use—without any additional support. It was found that smartphone use is much less common among people aged over 45 years, especially among women [22]. Thus, it was necessary to implement a web-based app suitable for all smart devices without requiring installment of a native app. The feasibility study showed that participants did not always know how to use their smartphones and had difficulties with wireless networks, passwords, and touch screens. In addition, they were used to using search engines for accessing websites and not the address bar. Thus, there was a need to develop an easy way to access the app.

Internet-Based Intervention

We decided to provide an experience similar to online shopping, which most adults are familiar with [22]. Rather than traditional health apps, we took the online store as our model, with the idea of offering health behaviors as the products organized in different departments or categories. The BitHabit app provides an extensive habit library we called a store of habits that was developed by translating lifestyle guidelines and recommendations into simple habit-forming behavioral suggestions, which we named BitHabits.

Users could log in to the app via a personalized link that they received via email and text message. When they clicked the link, the app opened up in a web browser. When users logged in for the first time, a brief health behavior questionnaire was launched. After that, they entered the app, which has 3 main views: (1) select view for browsing, inspecting, and selecting habits; (2) monitor view for reporting performances; and (3) summary view for reflecting on activities (Figure 1).

Figure 1. Three main views of the BitHabit app.



At their first visit, users landed in the select view where they could browse, inspect, and select BitHabits. Each BitHabit has a brief title, a more detailed description, and a health fact derived from the existing knowledge. Selected BitHabits appeared in the monitor view, a shopping basket. To promote execution and automation, BitHabits were presented per physical contexts common in the users' everyday lives; home, work, grocery store, and so on.

After users made at least one selection, they landed in the monitor view. Users were expected to report the performance of BitHabits on a daily basis, but they could also add performances afterward through the calendar view (Figure 2). Intended dose was not recommended for them. An additional feature included in the calendar view was a choice to stop monitoring a BitHabit.

The summary view presented an overview of user selections and performances per lifestyle category in a horizontal bar graph. The left side of the bar showed the number of selections per category. As soon as users made at least one selection, the bar color changes and seems full. The right side of the bar showed the number of performances. The maximum number for performances was 100, but users could collect more if they

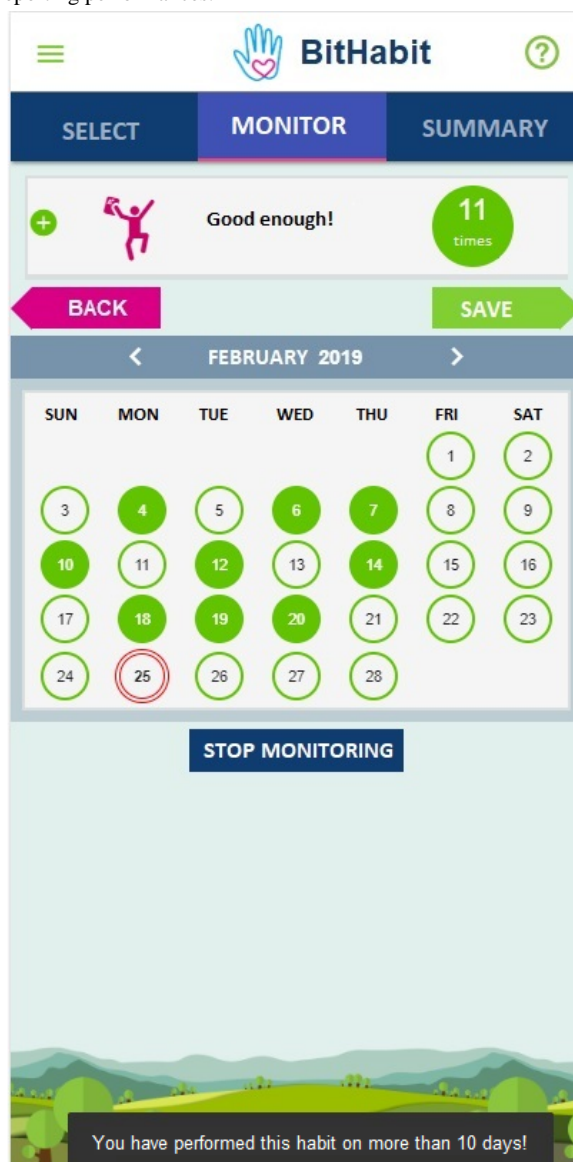
liked. Users were able to go directly from this view to browsing, inspecting, and selecting new BitHabits.

Use instructions with privacy notice were available through the green question mark icon. In addition, pop-up functionality sent use instructions during the first use sessions and provided simple feedback. Feedback consisted of anonymous information on other users' selections during the habit selection (eg, 160 users have selected this BitHabit), and automatic feedback related to a certain habit (eg, you have been performing this BitHabit for 30 days) or number of performances in different lifestyle categories (eg, you have already performed over 35 BitHabits from the meal frequency category).

Reminders were sent when (1) user received a link to the intervention app but was not logged in, (2) user was logged in but had not made any selections, (3) user made selections but had not reported them, and (4) user had logged in at least once but had not used the app for a week. Reminders 2 and 3 were added shortly after the app was launched.

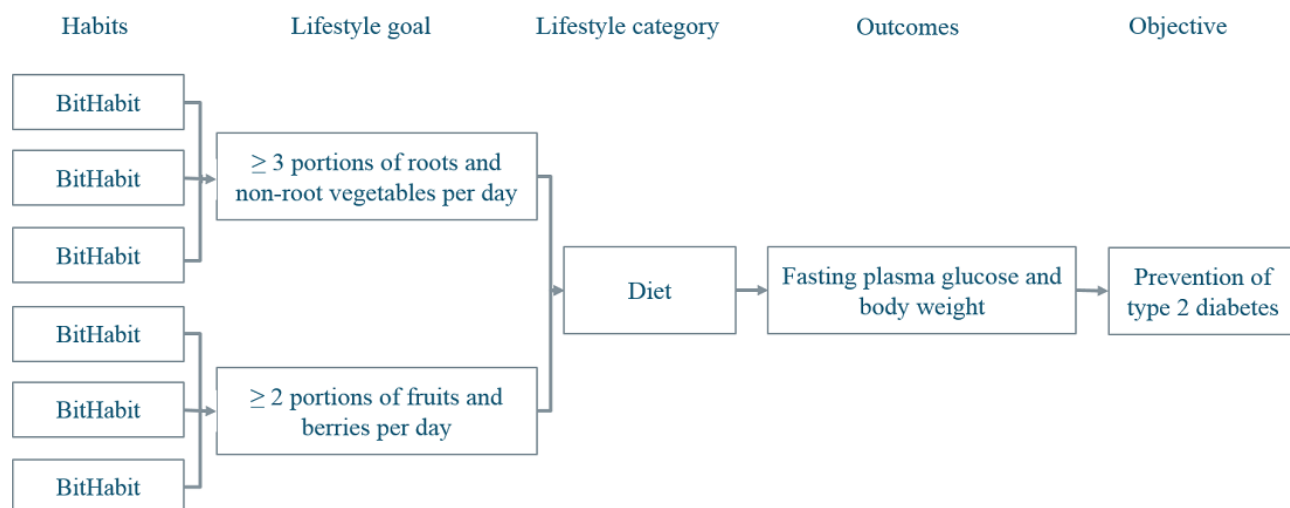
The order of the categories in the user interface was determined by the brief health behavior questionnaire presented in the beginning. The categories where the improvement potential was highest were presented first. A system-level description of the BitHabit app is available in [Multimedia Appendix 1](#).

Figure 2. Calendar-functionality enables reporting performances.



The store contained 489 BitHabits divided into 13 categories: meal frequency (43 habits), vegetables (53 habits), dietary fat (38 habits), grain products (24 habits), sugar (20 habits), alcohol and other drinks (19 habits), everyday physical activity (64 habits), conditioning physical activity (68 habits), sedentary behavior (36 habits), sleep (42 habits), positive mood (37 habits), stress management (23 habits), and nonsmoking (22 habits). Sleep, stress management, and positive mood were

incorporated into the design with the more traditional type 2 diabetes risk factors because of increasing evidence of their relevance to cardiometabolic diseases and increasing prevalence of comorbidity between type 2 diabetes and common mental disorders [23,24]. We also wanted to promote the use of the app among those who were not comfortable in making changes related to diet or physical activity. The sample of a content-related logic model is presented in [Figure 3](#).

Figure 3. Simplified content-related logic model.

Internet-Based Intervention With Face-to-Face Group Coaching

Both groups got access to the BitHabit app in the same way, through the personalized link they received via email and text message. In addition, the participants allocated to the face-to-face coaching plus digital intervention (F2F+digital) group were invited to participate in group coaching consisting of 6 meetings organized in local health care centers. Topics of these meetings were type 2 diabetes, rhythm of daily life, healthy diet, physical activity, automating activity to everyday life, and self-evaluation of program outcomes [17]. Internet-based intervention and group coaching share the same overarching behavior change theory, SDT [14], and they share the same lifestyle goals [17].

The groups were facilitated by nurses or other health care professionals. The BitHabit app was introduced to them during their training program, and they also got access to the app. Later they had an opportunity to participate in a professional development day where app use as part of the group coaching was discussed. However, group facilitators were not expected to give advice related to app use. In the participant workbook, app use was mentioned very briefly using app-related tasks such as searching a habit related to the topic at hand.

Measurements and Data Analysis

For this intermediate analysis, use data from the BitHabit app during the first 6 months of the study were available. The BitHabit app automatically collected log files of user interactions, selected habits, and habit performances in the app. The user interactions log contained a time stamped log of each page view in the app. The log of selected habits contained all habit selections during the course of the app use. The habit performance log collected all habit performances as marked by the user in the monitor and calendar views along with dates when the user claims to have performed the habit. In addition, a limited set of baseline data was available to describe the demographics of the intervention groups. The other measurements of the study are described elsewhere [17].

Relevant variables included use sessions, use days, duration of use, percentage of users accessing the app on a daily and weekly level, number of visits to each view of the app, start times of the identified use sessions, and selected and performed habits per categories. The research questions for engagement in this intermediate analysis are focused on describing the overall use activity and use behavior:

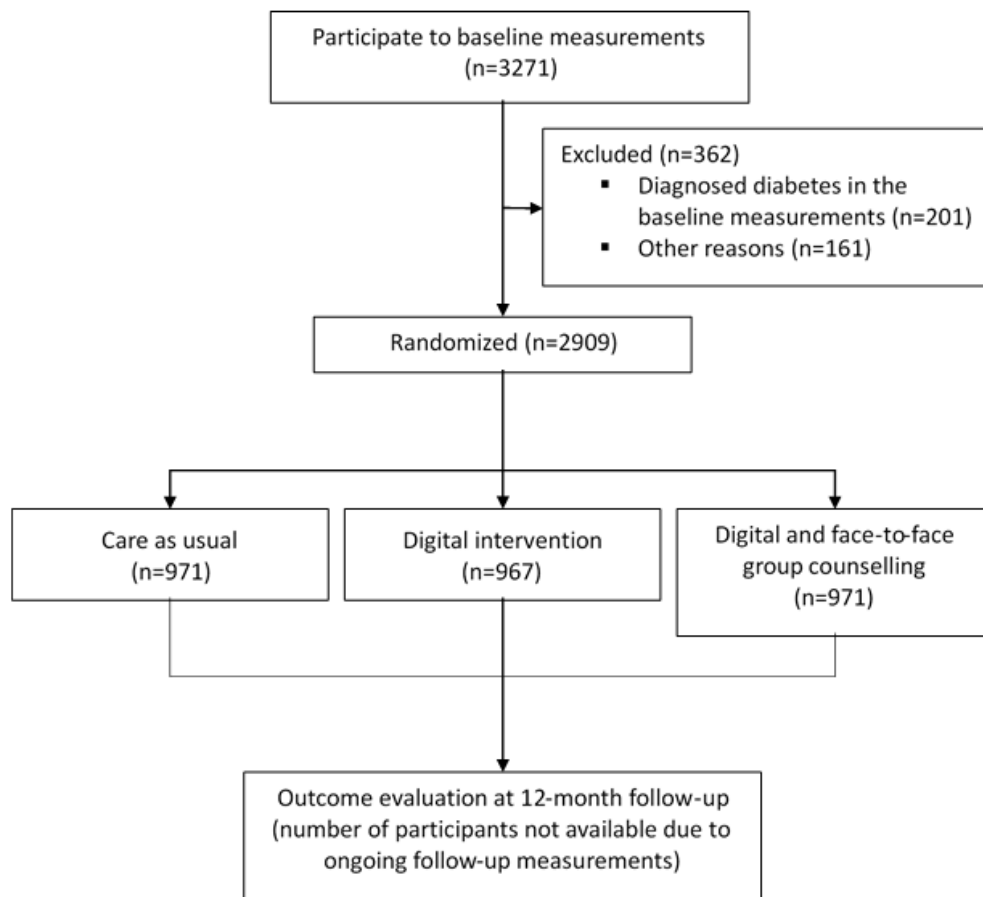
- How well were participants able to access the app and try out its basic functionalities?
- How actively was the app used over the course of the first 6 months?
- In which ways was the app used and how did the use evolve during the first 6 months?
- How were the app use times distributed during the day?
- How were the selections and performances of habits distributed among the different categories?
- Were there any differences between the intervention groups?

The analysis covers the first 6 months, or more accurately 26 weeks, of the intervention, starting from the date the participants received the invitation to the app. As the distributions of the use metrics are very skewed, medians and interquartile ranges (IQR) of the use metrics are reported. Comparison of the use metrics between groups was done with Mann-Whitney *U* tests. The analyses were conducted with Matlab R2017a (The Mathworks Inc) and SPSS Statistics version 26 (IBM Corp). Statistical significance was set at $P < .05$.

Results

Participant Recruitment

A total of 3271 individuals were recruited to participate in the study. Of these, 362 participants were excluded, 201 due to being diagnosed with type 2 diabetes in the baseline measurements and 161 for other reasons. Finally, 2909 participants were randomized, of which 971 were allocated to the control group, 967 to the internet-based intervention, and 971 to the internet-based intervention with face-to-face group coaching. The flow diagram of the Stop Diabetes intervention study is presented in Figure 4.

Figure 4. Flow diagram of the Stop Diabetes intervention study [17].

Participant Characteristics

Baseline participant characteristics are reported in [Table 1](#). The mean age of the control group was 55.0 (SD 9.9) years, digital group 55.2 (SD 9.9) years, and F2F+digital 55.2 (SD 10.1)

years; 81.1% (787/971) of the control group, 78.3% (757/967) of the digital group, and 80.7% (784/971) of the F2F+digital group participants were women. More than half of the participants were working (1693/2909, 58.20%), and almost one-third (803/2909, 27.60%) were retired.

Table 1. Participant characteristics (n=2909).

Characteristics	Control group (n=971)	Digital intervention (n=967)	Face-to-face coaching and digital intervention (n=971)
Age in years, mean (SD)	55.0 (9.9)	55.2 (9.9)	55.2 (10.1)
Gender, n (%)			
Women	787 (81.1)	757 (78.3)	784 (80.7)
Men	184 (18.9)	210 (21.7)	187 (19.3)
Weight (kg), mean (SD)	87.1 (16.9)	86.5 (17.4)	85.7 (17.0)
Body mass index (kg/m ²), mean (SD)	31.3 (5.4)	31.0 (5.4)	30.9 (5.4)
Waist circumference (cm), mean (SD)	102 (13.2)	101.5 (13.3)	101.1 (13.0)
Education, n (%)			
Elementary school	45 (4.6)	45 (4.7)	50 (5.2)
Middle school	24 (2.5)	18 (1.9)	35 (3.6)
Vocational school	223 (23.0)	239 (24.7)	214 (22.0)
High school	44 (4.5)	37 (3.8)	39 (4.0)
Institute degree	287 (29.6)	270 (27.9)	270 (27.8)
Bachelor's degree	195 (20.1)	195 (20.2)	221 (22.8)
Higher academic degree	153 (15.8)	163 (16.9)	142 (14.6)
Work status, n (%)			
Wage earner	522 (53.8)	504 (52.1)	489 (50.4)
Entrepreneur	55 (5.7)	60 (6.2)	63 (6.5)
Unemployed	56 (5.8)	50 (5.2)	54 (5.6)
Student	21 (2.2)	25 (2.6)	23 (2.4)
Pensioner	254 (26.2)	275 (28.4)	274 (28.2)
Other	63 (6.2)	53 (5.5)	68 (7.0)
Marital status, n (%)			
Married	616 (63.4)	608 (62.9)	582 (59.9)
Cohabitation	106 (10.9)	120 (12.4)	124 (12.8)
Registered relationship	1 (0.1)	0 (0)	1 (0.1)
Unmarried	64 (6.6)	76 (7.9)	83 (8.6)
Divorced	154 (15.9)	140 (14.5)	143 (14.7)
Widowed	30 (3.1)	23 (2.4)	38 (3.9)

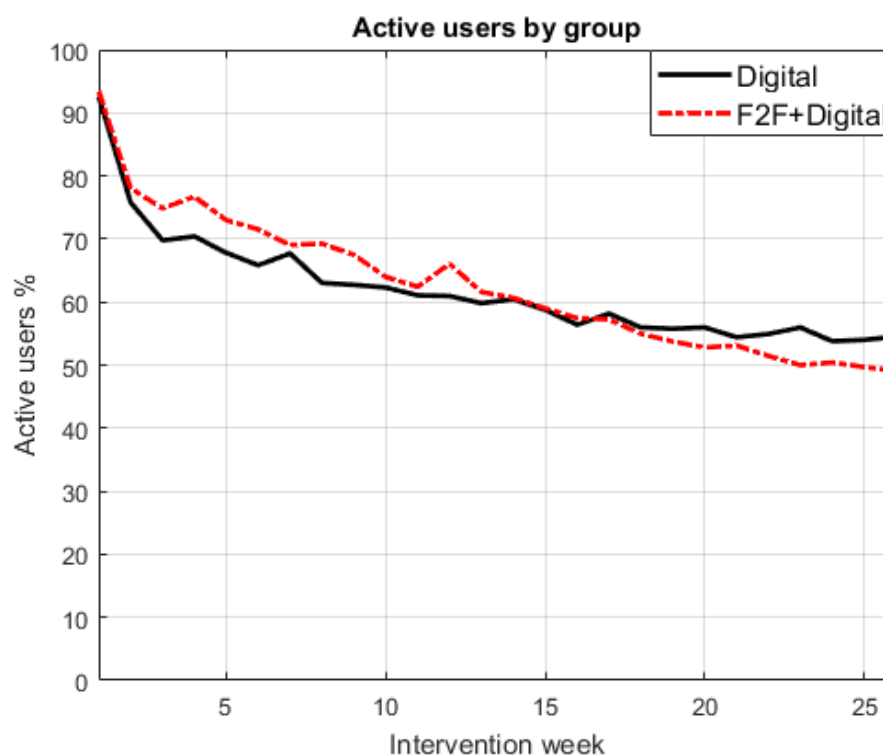
Access to BitHabit App and Trying Out the Basic Functionality

Almost all participants were able to access the app with their own smart device and try out the basic functionality of selecting habits and reporting them. Of the participants allocated to the digital and F2F+digital groups, 99.53% (1929/1938) logged in to the app at least once; they will be henceforth called app users. Of the app users, 98.55% (1901/1929) selected at least one habit. At least one habit performance was reported by 95.13% (1835/1929) of app users.

Use Activity During the First Six Months

During the first 6 months, the number of active users on a weekly level varied from 93.05% (1795/1929) in week 1 to 51.79% (999/1929) in week 26. The daily use activity was not as high; on any given day during the first 6 months, a median of 17.21% (332/1929; IQR 15.3%-20.3%) of users accessed the app. [Figure 5](#) presents the percentage of active users by group per intervention week.

Cumulative use metrics for the two groups are summarized in [Table 2](#). The digital and F2F+digital groups used the app on a median of 23.0 and 24.5 days and for 79.4 and 85.1 minutes total duration, respectively.

Figure 5. Percentage of active users per intervention week.**Table 2.** Cumulative use metrics for the first 6 months.

Use metric	Digital, median (IQR)	F2F+Digital ^a , median (IQR)
Use sessions	26.0 (13.0-48.0)	28.0 (13.8-50.0)
Use days	23.0 (12.0-42.0)	24.5 (12.0-42.0)
Use weeks	18.0 (8.00-23.0)	18.0 (10.0-23.0)
Session duration, average (minutes)	3.05 (1.79-5.14)	3.25 (1.95-5.12)
Total duration (minutes)	79.4 (37.0-167.0)	85.1 (37.3-188.4)
Selected habits	24.0 (13.0-44.0)	24.0 (12.0-45.0)
Reported performances	263.0 (59.8-703.3)	277.0 (66.0-747.5)
Days with performances	45.0 (14.0-131.0)	52.0 (17.0-131.0)
Categories of reported habits	9.0 (6.0-12.0)	9.0 (5.0-12.0)

^aF2F+digital: face-to-face coaching plus digital intervention.

Ways of Use

Most page views were related to the use of the monitor view (ie, monitoring and reporting of performed habits). Only during the first month was the use of the select view to browse, inspect, and select habits more popular. The summary view was not used very frequently compared with the other views.

The use of the monitor view increased over time as more use focused on reporting performances and also because the view

became the landing page as soon selections were made. The use of the calendar view under the monitor view increased over time, probably indicating that users started marking more performances through the calendar view and thus, marking several days' performances at a time instead of marking them daily. The use of the select view (ie, browsing, inspecting and selecting new habits) decreased over time. Table 3 shows the distribution of views visited over the 6 months.

Table 3. Distribution of views visited and changes over months.

View	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
Browse	19.97	11.77	9.23	7.89	7.52	6.80
Browse/Inspect	30.85	15.74	11.99	10.22	9.34	8.06
Monitor	34.47	47.15	51.72	54.19	55.92	57.25
Monitor/Calendar	9.74	19.22	21.15	21.62	21.60	22.44
Reflect	4.97	6.12	5.91	6.08	5.61	5.46

App Use Times During the Day

The use of the BitHabit app was quite well spread over the assumed waking hours of the users. The most active hours were

from 8:00 pm to 10:00 pm, when 18.5% of the sessions were started. [Table 4](#) presents a summary of use with respect to the time of day in the intervention groups.

Table 4. Use of the BitHabit app according to the time of day.

Time of day	Percentage of sessions
00:00-00:59	0.84
01:00-01:59	0.33
02:00-02:59	0.14
03:00-03:59	0.16
04:00-04:59	0.29
05:00-05:59	0.66
06:00-06:59	1.84
07:00-07:59	2.88
08:00-08:59	4.34
09:00-09:59	4.37
10:00-10:59	5.39
11:00-11:59	5.61
12:00-12:59	5.17
13:00-13:59	4.67
14:00-14:59	4.54
15:00-15:59	4.82
16:00-16:59	5.22
17:00-17:59	5.39
18:00-18:59	6.14
19:00-19:59	7.33
20:00-20:59	9.04
21:00-21:59	9.48
22:00-22:59	7.53
23:00-23:59	3.84

Selections and Performances in Different Habit Categories

Most habits were selected from the stress management, positive mood, and vegetables categories. In addition, meal frequency, everyday physical activity, and alcohol and other drinks were selected by over 700 users in both groups. A total of 1,089,555 habit performances were reported during the first 6 months of the study. [Table 5](#) presents a detailed summary of habit

selections and performances. For each habit category, the number of selections and number of users who selected habits from the category, number of habit performances, and number of users who performed habits from each category are presented for both groups.

Differences Between the Intervention Groups

There were no significant differences in use metrics between the groups with regard to cumulative use metrics ([Table 2](#)), and

selected habit categories were very similar in both groups. In the digital group, most performances were reported in the meal frequency, positive mood, and stress management categories. In the F2F+digital group, most performances were reported in

the vegetables, stress management, and meal frequency categories (Table 5). In both groups, the most popular categories achieved over 60,000 reported habit performances.

Table 5. The number of selections and users and the number of habit performances and users per group.

Habit category	Selections, digital		Selections, F2F+digital ^a		Performances, digital		Performances, F2F+digital	
	Total	Users	Total	Users	Total	Users	Total	Users
Meal frequency	2652	708	2558	709	64,244	656	60,248	643
Vegetables	3148	732	3125	739	57,509	672	65,319	681
Grain products	1843	622	1825	631	37,497	559	36,677	564
Dietary fat	2809	565	2721	670	46,583	596	46,628	617
Sugar	1938	614	1905	607	16,491	532	17,113	528
Conditioning physical activity	2653	688	2575	695	29,930	610	30,954	631
Everyday physical activity	2854	708	2796	696	29,197	625	32,528	615
Sedentary behavior	1931	620	1951	629	19,625	529	21,524	534
Alcohol and other drinks	2460	722	2375	737	56,815	678	52,200	689
Nonsmoking	417	211	286	176	5781	172	4155	142
Sleep	2400	647	2327	641	59,830	584	54,313	584
Stress management	4402	807	4340	815	61,664	737	63,890	755
Positive mood	3407	718	3254	688	63,212	646	55,628	620

^aF2F+digital: face-to-face coaching plus digital intervention.

Discussion

Achievement of Objectives

The purpose of this study was to describe an internet-based lifestyle intervention targeted to support healthy habits and to explore use behavior during the first 6 months. We developed the idea of an app providing an online store offering habit-forming behavioral suggestions that could be easily adopted in everyday life. We were able to recruit over 3000 participants, of whom 1938 were allocated in the active intervention groups using the BitHabit app. Participants were mainly middle-aged and older adults, and the majority of them were women. They were a relatively typical participant group for a type 2 diabetes prevention program [25]. Our research questions for engagement in this intermediate analysis were focused on describing the overall use activity and use behavior.

Principal Findings

Among our participants, almost all (1929/1938) opened the app at least once, and almost all who logged in selected at least one habit and reported at least one performance. Based on this, it can be concluded that the app was accessible by our target group.

On a weekly level, the percentage of active users varied from 93.1% to 51.8%. This use activity compares favorably with previous studies of similar technologies. For example, the shape of the graph of active users resembles the one for mobile apps in Mattila et al [26], but their percentage of active users was only about 30% at 6 months. The difference in favor of the BitHabit app may partly be explained by the reminder feature.

In Kaipainen et al [27], where a publicly available online healthy eating and weight loss program was studied, 25% of the participants who started the program returned for a follow-up. In Helander et al [28], where a free mobile app for dietary self-monitoring was studied, 2.58% used the app actively. On a daily level, use activity of the BitHabit app was lower than expected, with a median of 17.2% of users accessing the app on any given day during the first 6 months. This implies that we failed to create a daily pattern of use of the app but supported weekly use instead. However, we cannot yet say whether daily use of the app is actually required. The relationship between use and health-related outcomes may be complex, and sufficient engagement with the intervention to achieve intended outcomes (ie, effective engagement) needs to be determined empirically, keeping in mind that it can also be dependent on individual users' characteristics and context of use [29,30]. Decreasing use may not always imply disengagement from the intervention; it may be due to achievement of desired health outcomes or behavior changes [31]. An early study on mobile self-monitoring found that after a period of frequent self-monitoring, participants felt they learned to self-monitor without the app, which decreased the frequency of monitoring, especially for food-related events [32].

The analysis of ways of use showed that the app was mostly used for monitoring and reporting the performed BitHabits. Only during the first month were browsing, inspecting, and selecting habits more popular than monitoring and reporting. This was expected because the monitor view was the landing page (ie, first page that opened for the users every time they entered the app), and users were supposed to report their habits

on a daily or weekly basis. The least visited view was the view presenting a summary of the all performances in different categories. Our original objective was to provide feedback of performances in a simple visual way with elements of gamification—such as a colored bar that could be filled by performances—that would also serve as a booster for selecting and reporting more BitHabits. However, our findings suggest that the view with its functions was not able to fulfill the objectives and hence requires further development.

The analysis of use times showed that use of the BitHabit app was quite well spread over the assumed waking hours of the users, and the most active hours were in the evening. Context recognition and timely reminders would encourage use throughout the day, but we were not able to provide such features because wide accessibility through a web-based app was deemed more important. Also, the evidence related to reminders is not indisputable. Based on the literature, time cues might even prevent habit formation. According to Lally et al [33], prospective memory research indicates that situations permit external cueing of an intended action whereas time cues require monitoring to identify the time to act [34].

The most actively selected habit categories were stress management, positive mood, and vegetables and fruits in both groups, and it was a bit surprising that stress management and positive mood were among the top 3 categories. Originally these not-so-obvious type 2 diabetes risk factors were incorporated into the design because there was increasing evidence of their relevance to cardiometabolic diseases, and we also wanted to promote the use of the app among those who are not comfortable in making changes related to diet or physical activity. On the other hand, the prevalence of stress and other mental health issues is rapidly increasing. Mental and behavioral disorders was the largest disease group causing disability leading to disability pension in Finland in 2018, causing 43% of all disability pensions [35]. In the United Kingdom, stress, depression, or anxiety accounted for 44% of all work-related ill health cases in 2018 [36].

Interestingly, both intervention groups used the app in a similar way. Torbjørnsen et al [37] reported similar results where the use of the app was not particularly different between the intervention groups. There is evidence from previous research that support from peers or counselors is usually an effective way to increase intervention engagement and effectiveness [38–40], but this was not observed in our study. There were some differences between the groups, however, with the reported habit performances. The habit categories with the most performances were meal frequency, positive mood, and stress management in the digital group and vegetables, stress management, and meal frequency in the F2F+digital group. This can be partly explained by the content of the face-to-face group coaching where nurses promoted the use of vegetables as part of a healthy diet.

Implications

This study has some implications for research and practice. First, results demonstrate that internet-based lifestyle interventions can be delivered to large groups including community-dwelling middle-aged and older adults, many with

limited experience in digital app use, without additional user training. Interventions can be used independently or in addition to face-to-face group coaching. Second, user engagement is critical, and possibilities to disengagement should be identified in advance and tackled with appropriate solutions such as reminders. Our results indicate that use sessions of the BitHabit app were short and relatively frequent, which was the intended way of using the app to boost habit formation by repetition of tiny behaviors. Third, the popularity of habits related to stress management and positive mood indicates that there is a huge need for solutions addressing mental health issues. Following Stein et al [41], there should be an integrated response to mental disorders and other chronic diseases in health systems because mental disorders share common features with other chronic communicable and noncommunicable diseases.

Limitations

This study has some limitations. We cannot yet know if the weekly engagement was enough to change lifestyles of the participants because the effective engagement is not yet known and needs to be determined empirically when the outcomes are available [30]. According to Miller et al [42], engagement to digital interventions is a multidimensional concept, including both the extent to which an intervention is used and the subjective experience of the user. Unfortunately we did not have qualitative data from the first 6 months of the study available for analysis, but it would have been valuable to inform explanations for the patterns observed. One possible user experience problem is that the app offered a broad selection of BitHabits with tailoring affecting the order of categories but not the content. Although it was expected that the abundance of suggestions ensured that there was enough variety for each user and quick browsing would ensure users could easily find what was relevant for them, some users might have expected more personalization.

Recommendations for Further Research

There are many possibilities to further research. Following the logic of habit theories that suggest complex tasks may be less prone to become automatic than simple tasks [9] and adapting the tiny habit concept by Fogg [20], the BitHabits presented by the app were designed to be simple enough and contextualized to be carried out in the participants' daily lives. It will be important to study whether participants were able to form spans and paths as expected and how these link with habit automaticity measures [43] included in our study questionnaire. Furthermore, in order to understand habit formation better, we will need to analyze our use and questionnaire data more carefully to identify determinants for use trajectories. Our rich data will provide unique opportunities to analyze behavior change processes.

Conclusion

Our aim was to develop a scalable solution as a tool for lifestyle modification for type 2 diabetes prevention that could be adopted easily by community-dwelling middle-aged and older adults, many with limited experiences in digital app use, without additional user training to promote users' autonomy and help them change their habits. We found that our solution was accessible by the participants with their own smart devices and

almost all tried out the basic functionality of selecting habits and reporting them. This intermediate analysis of use behavior showed relatively good engagement, with the percentage of active weekly users remaining over 50% at 6 months. However, we cannot yet know if the weekly engagement was enough to change the lifestyles of participants. Sufficient engagement with the intervention to achieve intended outcomes (ie, effective

engagement) still needs to be determined empirically when outcomes are available [30]. A total of 1,089,555 habit performances were reported during the first 6 months. Categories related to the nontraditional type 2 diabetes risk factors stress management and positive mood were among the most popular ones in both groups.

Acknowledgments

We would like to thank the Strategic Research Council at the Academy of Finland for funding our “Stop Diabetes—from knowledge to solutions” project in 2016-2019 (303537). We would also like to acknowledge the valuable contribution of the research consortium, our national and international collaborators, primary health care providers involved in the study, citizens who participated in the feasibility testing, and citizens who enrolled in the study. The Strategic Research Council at the Academy of Finland had no role in designing the study or collecting, managing, or analyzing the data; interpreting the results; writing the manuscript; or deciding to submit the manuscript for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1
System description.

[\[PDF File \(Adobe PDF File\), 62 KB - diabetes_v5i3e15219_app1.pdf \]](#)

Multimedia Appendix 2

CONSORT-eHEALTH checklist (V 1.6.1).

[\[PDF File \(Adobe PDF File\), 2377 KB - diabetes_v5i3e15219_app2.pdf \]](#)

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Abbreviations

F2F+digital: face-to-face coaching plus digital intervention

IQR: interquartile range

RCT: randomized controlled trial

SDT: self-determination theory

Edited by G Eysenbach; submitted 27.06.19; peer-reviewed by BT Tulbure, L Morrison; comments to author 14.09.19; revised version received 29.11.19; accepted 29.02.20; published 11.08.20.

Please cite as:

Harjumaa M, Absetz P, Ermes M, Mattila E, Männikkö R, Tilles-Tirkkonen T, Lintu N, Schwab U, Umer A, Leppänen J, Pihlajamäki J

Internet-Based Lifestyle Intervention to Prevent Type 2 Diabetes Through Healthy Habits: Design and 6-Month Usage Results of Randomized Controlled Trial

JMIR Diabetes 2020;5(3):e15219

URL: <https://diabetes.jmir.org/2020/3/e15219>

doi: [10.2196/15219](https://doi.org/10.2196/15219)

PMID: [32779571](https://pubmed.ncbi.nlm.nih.gov/32779571/)

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Corrigenda and Addenda

Figure Correction: The Effect of a Cellular-Enabled Glucose Meter on Glucose Control for Patients With Diabetes: Prospective Pre-Post Study

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Related Article:

Correction of: <https://diabetes.jmir.org/2019/4/e14799/>

(*JMIR Diabetes* 2020;5(3):e21993) doi:[10.2196/21993](https://doi.org/10.2196/21993)

In “The Effect of a Cellular-Enabled Glucose Meter on Glucose Control for Patients With Diabetes: Prospective Pre-Post Study” (*JMIR Diabetes* 2019;4(4):e14799), the authors noted an error in the caption of Figure 6.

The caption formerly said:

Change in hemoglobin A_{1c} (HbA_{1c}) from baseline by timepoint for type 2 diabetes with insulin use.

This has been revised to:

Change in hemoglobin A_{1c} (HbA_{1c}) from baseline by timepoint for all participants with insulin use.

The correction will appear in the online version of the paper on the JMIR Publications website on July 28, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

Submitted 30.06.20; this is a non-peer-reviewed article; accepted 13.07.20; published 28.07.20.

Please cite as:

Bollyky JB, Melton ST, Xu T, Painter SL, Knox B

Figure Correction: The Effect of a Cellular-Enabled Glucose Meter on Glucose Control for Patients With Diabetes: Prospective Pre-Post Study

JMIR Diabetes 2020;5(3):e21993

URL: <http://diabetes.jmir.org/2020/3/e21993/>

doi:[10.2196/21993](https://doi.org/10.2196/21993)

PMID:[32721921](https://pubmed.ncbi.nlm.nih.gov/32721921/)

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Publisher:
JMIR Publications
130 Queens Quay East.
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