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Contents

Original Papers

Original Paper

Mobile Clinical Decision Support System for the Management of Diabetic Patients With Kidney Complications in UK Primary Care Settings: Mixed Methods Feasibility Study

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Abstract

Background: Attempts to utilize eHealth in diabetes mellitus (DM) management have shown promising outcomes, mostly targeted at patients; however, few solutions have been designed for health care providers.

Objective: The purpose of this study was to conduct a feasibility project developing and evaluating a mobile clinical decision support system (CDSS) tool exclusively for health care providers to manage chronic kidney disease (CKD) in patients with DM.

Methods: The design process was based on the 3 key stages of the user-centered design framework. First, an exploratory qualitative study collected the experiences and views of DM specialist nurses regarding the use of mobile apps in clinical practice. Second, a CDSS tool was developed for the management of patients with DM and CKD. Finally, a randomized controlled trial examined the acceptability and impact of the tool.

Results: We interviewed 15 DM specialist nurses. DM specialist nurses were not currently using eHealth solutions in their clinical practice, while most nurses were not even aware of existing medical apps. However, they appreciated the potential benefits that apps may bring to their clinical practice. Taking into consideration the needs and preferences of end users, a new mobile CDSS app, "Diabetes & CKD," was developed based on guidelines. We recruited 39 junior foundation year 1 doctors (44% male) to evaluate the app. Of them, 44% (17/39) were allocated to the intervention group, and 56% (22/39) were allocated to the control group. There was no significant difference in scores (maximum score=13) assessing the management decisions between the app and paper-based version of the app's algorithm (intervention group: mean 7.24 points, SD 2.46 points; control group: mean 7.39, SD 2.56; t_{37}=–0.19, P=.85). However, 82% (14/17) of the participants were satisfied with using the app.

Conclusions: The findings will guide the design of future CDSS apps for the management of DM, aiming to help health care providers with a personalized approach depending on patients' comorbidities, specifically CKD, in accordance with guidelines.

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KEYWORDS

eHealth; clinical decision support application; diabetes mellitus; chronic kidney disease; feasibility study

Introduction

Diabetes mellitus (DM) is one of the most common chronic diseases worldwide. The World Health Organization estimated that 422 million adults worldwide had diabetes in 2014 and 1.5 million died from it in 2012, while DM became the 7th leading cause of death in 2016 [1]. In the United Kingdom, the DM prevalence is estimated to rise to 5 million by 2025 [2]. The economic burden of the disease is equally high, with most of the costs associated with its complications [3]. Specifically, type 2 DM with chronic kidney disease (CKD) costs 49% more annually than type 2 DM without CKD [4]. Most of the complications of DM can be avoided with regular monitoring and good management [5,6]. Patient and health care education are important in diabetes care. Hence, a promising step is to consider using information technology in diabetes management, such as mobile apps and other eHealth solutions [7-9].

Advances in technologies may help understand and implement current guidelines more quickly. Doctors spend nearly 64% of their online time searching for information to support clinical decisions. The use of mobile clinical decision support system (CDSS) devices allows health providers to make rapid and more accurate decisions [8,10-12]. The World Health Organization recognizes that an increasing proportion of the population uses mobile health apps. As a result, the need for evidence-based guidance on the use of mobile health is required to advance integrated person-centered health services [13]. Attempts to use eHealth for diabetes management have been reported going back to the late 1970s and show promising outcomes [14-16]. More than 1100 apps relating to DM had been reported as of 2015 [17], but only 7%-8% of them were provider-directed [18,19].

Limited studies have evaluated CDSS app use in diabetes care [20-22], while the number of studies documenting implementation and evaluation is even lower [23]. Moreover, the existing literature has weaknesses in the quality of reporting methodological domains, cost-effectiveness of the apps, care providers' assessment, and adverse effects of mobile intervention in clinical practice.

Based on the limitations of the existing literature, we conducted a feasibility study aimed at developing and evaluating a mobile app developed exclusively for health care providers to manage DM and CKD. To our knowledge, this is the first published feasibility study developing a provider-directed CDSS app specifically for management of patients with DM and comorbidities, such as CKD. The developed mobile app was evaluated in a controlled setting for its usability and impact on workflow and adherence to clinical guidelines.

Methods

Ethics Approval and Ethical Considerations

The University of Warwick's Biomedical and Scientific Research Ethics Sub-Committee approved all stages of the study (RFGO-2014-786). Nurses were fully informed about the study and were given the participant information leaflet and participant consent form. Ethics approval and ethical considerations are described in detail at Multimedia Appendix 1.

Research Framework

This study is based on the 3 key stages of the user-centered design framework, which is a generic, multidisciplinary, and user-oriented approach to software development, putting the intended users, their needs, and their requirements at the center [24].

First Step: Requirements Gathering

Research Design and Setting

The first part of the study consisted of an exploratory qualitative study using face-to-face semistructured interviews with DM specialist nurses from hospitals and community health centers across West Midlands, United Kingdom. Diabetes Specialist Nurses who worked at local National Health Service (NHS) facilities and had a minimum of 2 years' experience working with people with DM were eligible for the study.

Recruitment and Interview Process

The recruitment was performed mainly via emails or word-of-mouth. Once eligibility and consent were confirmed, an interview was scheduled. Interviews lasted 15-30 minutes and took place in a meeting room or office at the hospital or practice where the nurses worked. The interview topic was the use of mobile CDSS apps that assist nurses in managing aspects of diabetes. All interviews were recorded using a digital recorder. The recruitment, choice of interview type (face-to-face, semistructured), and further details are provided in Multimedia Appendix 2.

Sample Size and Qualitative Data Synthesis

A minimum sample size estimate of 10 DM specialist nurses was chosen, with continued sampling until the saturation point [7,25,26]. Saturation was reached after 15 interviews at which time the recruitment was stopped.

Thematic analysis was used, and interview recordings were transcribed verbatim by the researcher [9,27]. The computer-assisted qualitative data analysis software NVivo (version 10) was used to assist in the analysis process. In an attempt to minimize bias in the interpretation of the data, an experienced qualitative researcher was consulted on the conduct and analysis of this research.

Second Step: Design and Development of the Mobile, Clinical Decision Support App

Requirements

The nurses' feedback at the "requirements gathering" stage, other requirements gathered from the literature, and requirements from feedback and suggestions from 2 diabetes and endocrinology consultants were considered during step 2. The total requirements were divided into 3 categories: functional, technical, and medical. These are analyzed further in Multimedia Appendix 3.

Design and Development

The app was built by a software developer (Medic Genie), and the development process included two parts: design and coding. Both parts were done by visual programming, while a junior doctor provided well-defined guidance and verification of the correctness of the management pathway. Development of the app involved generating management pathways using the most recent National Institute for Health and Care Excellence (NG28) guidelines on DM, CKD, and hypertension. The guidelines used in the development of the management pathways, developed decision algorithm, and table of dose adjustments for CKD are provided in Multimedia Appendix 4, Multimedia Appendix 5, and Multimedia Appendix 6, respectively.

Third Step: Evaluation Stage

Research Design

This component used multiple methods and quantitative and qualitative designs. The 3 main methods used for this part of the study included a randomized controlled experiment, usability testing, and a satisfaction questionnaire (Multimedia Appendix 7), with an aim of demonstrating the impact and acceptability of the app.

Recruitment

Two types of end users were considered as participants: junior doctors and DM specialist nurses.

The junior doctors were recruited for the randomized controlled experiment from the University Hospitals Birmingham NHS Foundation Trust as part of a teaching session on DM and renal complications. At the teaching session, 39 doctors were recruited through convenience sampling. During the piloting phase, junior doctors were randomly divided into 2 groups using software-generated random numbers. The intervention group had access to the developed app "Diabetes & CKD," while the control group had access to paper-based guideline algorithms that informed the app's development. At this stage, 2 case scenarios were prepared by a diabetes and endocrinology consultant from the University Hospitals Birmingham NHS Foundation Trust. The evaluation was conducted to assess how the app could support health care providers in terms of (1) workflow efficiency (measured by time to complete the tasks) and (2) adherence to clinical guidelines (measured by accuracy of the decision made, compared to the use of paper-based guideline algorithms). Those in the control group had access to paper-based guideline algorithms that informed the app development, while participants in the intervention group were given a link to the app. Both groups were asked to deal with 2 simulation-based case scenarios (Multimedia Appendix 8). Decisions made in each group were written on the provided answer sheets. At the end, intervention participants were asked to complete the satisfaction questionnaire (Multimedia Appendix 9).

The DM specialist nurses from the interview study who expressed interest in taking part were included. Although 15 DM specialist nurses were invited via email to take part in the usability testing session, only 3 were recruited at the Sandwell & West Birmingham Hospitals NHS Trust, United Kingdom. During the testing phase, nurses were asked to perform tasks using the case scenarios and to verbalize what they are doing while they were doing it. Broad questions were used to explore participants' views and opinions during the session.

Statistical Analysis

The answers for both groups in the randomized controlled experiment were blinded and scored against a model answer prepared in advance by the consultant. In the scoring scale, minor and major decisions were not scored equally; the weight varied. The scoring was carried out by an independent clinician not directly involved in the preparations of the case scenarios. Scores were compared and analyzed using independent samples *t* tests or Mann-Whitney U tests for hypothesis testing, as appropriate. Statistical analysis was carried out using SPSS software (version 20.0). For the satisfaction questionnaire, basic analysis was undertaken. Responses were read carefully several times; then, major patterns and trends were identified in the responses and summarized. The usability testing session was audiotaped and transcribed verbatim by a professional transcription company and analyzed using a narrative synthesis approach.

Results

First Step: Requirements Gathering

Participant Characteristics

Interviews were conducted with 15 DM specialist nurses from 4 hospitals and 2 community health centers across the West Midlands regarding the use of the mobile CDSS app. All were female, with an average age of 45 years and an average duration as a nurse specializing in DM of 10 years. The participants' characteristics are summarized in Multimedia Appendix 10. They all were owners of a tablet or smartphone. Moreover, 14 of 15 (93%) used a device provided by the Trust during clinical practice.

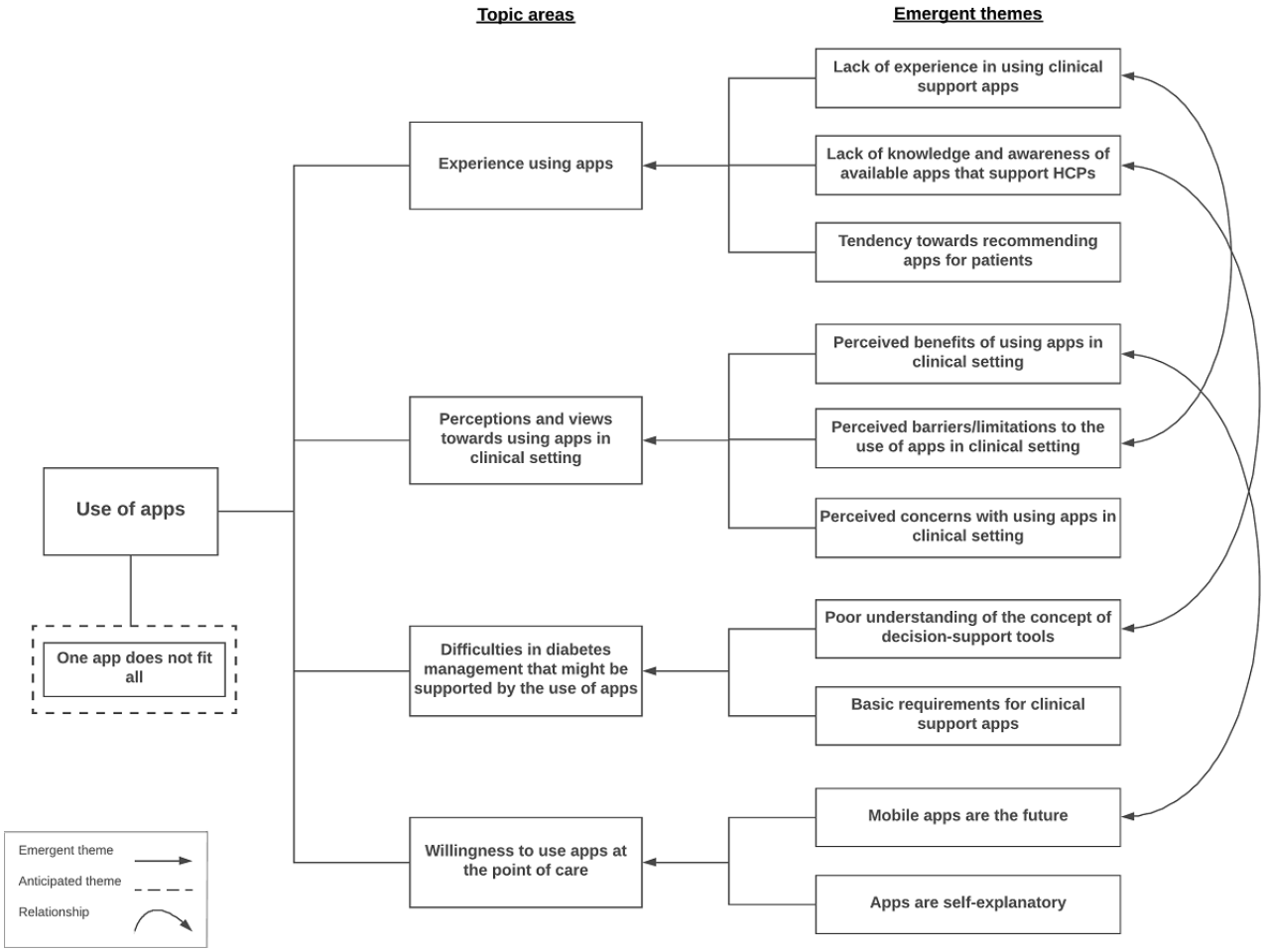
Interview Findings

The interviews with nurses identified varying themes related to 5 main areas: prior experience with using apps, perceptions and views of using apps in clinical practice, challenges in DM management, willingness to use apps, and one app does not fit all. The "one app does not fit all" area emerged during the interviews but did not fit under any of the 4 main investigated areas. People have different needs and preferences, range of skills, and degree of motivation, so one app will not fit all, as believed by most nurses. The themes identified by the interview

and their relationships are shown in Figure 1. Examples of the DM specialist nurses' answers that helped formulate the conclusions are provided in Multimedia Appendix 11.

Generally, nurses urged for apps that are simple, short, and to the point. Clinical support apps need to work across multiple mobile platforms, not require a WiFi connection, be visual, be interactive, and not require the inputting of too many details. Finally, they agreed that clinical apps need to be customized locally. Overall, nurses expressed a strong willingness to use apps in clinical practice.

Figure 1. Themes identified during the interviews in the "requirements gathering" stage and their relationships with each other. HCP: health care professional.



Second Step: Design and Development of the Mobile, Clinical Decision Support App

At this stage, the "Diabetes & CKD" mobile CDSS app for the management of adult patients (≥18 years old) with type 2 DM and CKD was designed and built [28]. The aim of the functionality of the app is to work out a personalized treatment plan based on patient's parameters. The app provides an easy-to-follow interface. When possible, dropdown menus, predefined lists, or checkboxes were considered in an attempt to reduce the amount of typing required for data input. Error checks for numerical variables were applied to ensure that the inputted value was in range. The app consists of 3 main types of screens: home screen (Figure 2), data entry screens (Figure 3), and recommendation screen (Figure 4). The home screen welcomes the user to the app and guides the user to 2 possible choices: follow either the glycemic control guidelines or the hypertension guidelines. At the next screen, patient's personalized data are inputted by the health provider, and the app provides recommendations based on guidelines to treat the patient accordingly.

Figure 2. Home screen of “Diabetes and CKD” app.

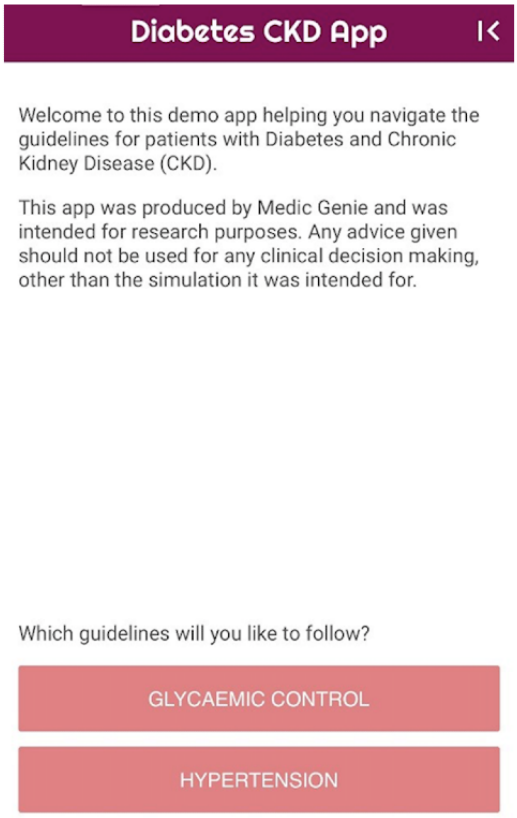


Figure 3. Examples of data entry screens.

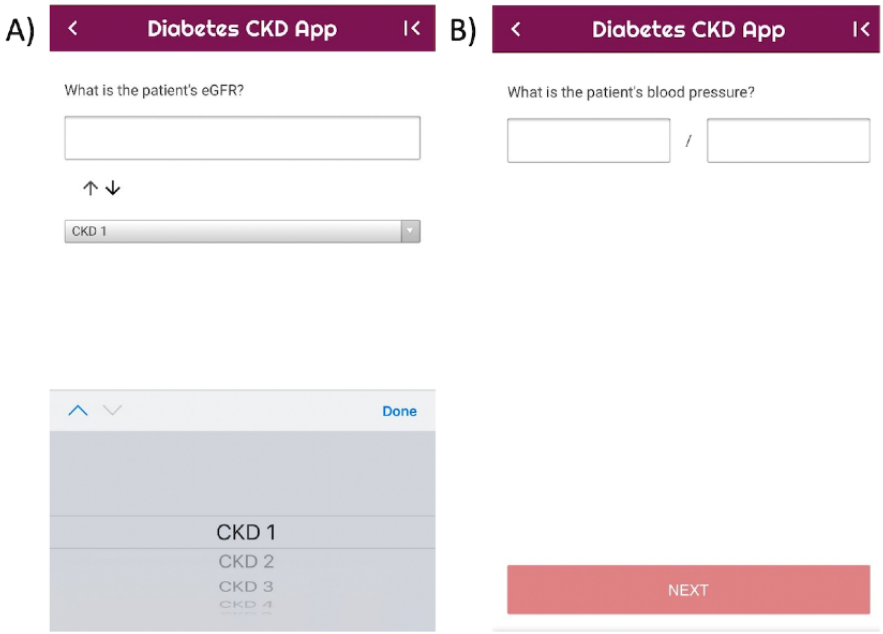
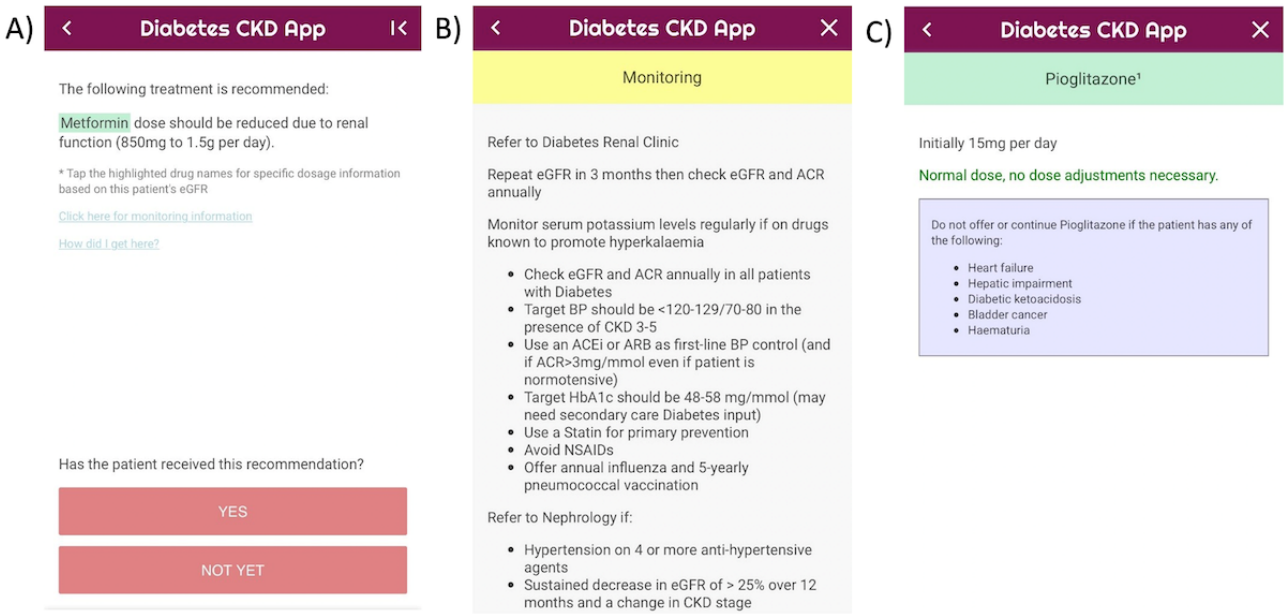


Figure 4. Examples of recommendation screens.



Third Step: Evaluation

Participant Characteristics

In the controlled experiment, 39 junior foundation year 1 doctors were included (17/39, 44% male). Of them, 44% (17/39) were allocated to the intervention group, and 56% (22/39) were allocated to the control group. The usability testing session involved 3 DM specialist nurses. All were female, 30-46 years old, and working in the DM field for 6-16 years.

Pilot Randomized Controlled Experiment

As the intervention and control groups were normally distributed, an independent samples *t* test was performed. There was no significant difference in the scores between the intervention group (mean 7.24, SD 2.46) and control group (mean 7.39, SD 2.56; t_{37}=–0.19, *P*=.85; maximum score was 13). The frequency distribution of the scores for both groups is presented in Multimedia Appendix 12.

These results suggest that, for the given 2 case scenarios, no difference was observed in the accuracy of the decision made using the app compared to the use of paper-based guideline algorithms.

A score of 8 was determined as the minimum standard of safe care for the given 2 case scenarios. In the intervention group, 9 doctors (9/17, 53%) scored ≥8, whereas only 7 doctors (7/22, 32%) in the control group scored ≥8. However, when comparing their scores for each case individually, 10 doctors (10/17, 59%) and 17 doctors (17/22, 77%) from the intervention and control groups, respectively, scored a minimum of 3 in the first case scenario, while 10 doctors (10/17, 59%) and 11 doctors (11/22, 50%) from the intervention and control groups, respectively, got a minimum score of 5 in the second case scenario.

Satisfaction Questionnaire

All 17 questionnaires were completed, providing a 100% response rate (intervention arm). Nearly 50% (9/17) of the junior doctors indicated prior experience using a CDSS app. With regard to their overall impression, 83% (14/17) were satisfied or somewhat satisfied with the app. Ease and simplicity of the app were the most emphasized features: easy to use, user-friendly, straightforward, quick, simple flow, good presentation, intuitive user interface, clear design, easy to input information, gives a good recommendation based on results, not too wordy, good font size, and much easier to use than the algorithm. By contrast, the most common negative points were the ambiguity of the navigation between pages or recommendations and difficulty scrolling up and down. Regarding usability, some respondents reported that they encountered some technical bugs during the session.

In terms of suggestions for improvement, participants expressed the need for easy and clear navigation; information on doses supported with links to evidence; additional information on drug side effects, for example weight loss or gain; the possibility to save previous searches to go back to them easily; the ability to enter patient's current medications to help streamline the options at the end; and more specific advice regarding which combinations of dual or triple therapy would be more appropriate.

All participants thought that the app seemed useful and were willing to use such apps in their clinical practice, specifically for more complex patients when they are uncertain and to avoid searching through guidance.

Usability Testing

The DM specialist nurses faced several usability problems. The ambiguity of the navigation between pages or recommendations as well as app crashes were described as the most frustrating part of the app. Additionally, some DM specialist nurses felt that some data items were irrelevant, for example, when the app asks for blood pressure while looking at glycemic control. By contrast, they asked to add some data items such as BMI.

Nurses indicated several positive aspects of the app. They found it very useful that they could click on the drug names for further information. The DM specialist nurses stated also that the app

was a good idea, particularly from a practice point of view. Although usability issues were experienced with the app, they did not hinder completion of the tasks. Moreover, they liked having the button "how did I get here," which allowed them to check if they have inputted something incorrectly at any point. They also suggested having this screen compulsory in order to enable users to make sure their information was correct.

Several further suggestions were given by the DM specialist nurses to improve the app; for instance, when the app recommended monitoring the patient, nurses wondered about how to monitor; they indicated a preference to use other gestures when communicating with the app such as swiping; and there were thoughts that providing background information (such as basic guidelines or treatment pathways) on the home page would be helpful.

Discussion

Principal Findings

The current feasibility study aimed to develop and evaluate the impact, usability, and acceptability of a mobile CDSS app from the perspectives of health care providers for patients with DM and CKD. DM specialist nurses were found not to be currently using apps in their clinical practice, while most nurses were not even aware of existing medical apps. However, they appreciated the potential benefits that apps may bring to their clinical practice. Taking into consideration the needs and preferences of end users, a new mobile CDSS app, "Diabetes & CKD," was developed. The evaluation of this app showed that there was no significant difference between using the app and the paper-based version of the app's algorithm. Furthermore, the results from the satisfaction questionnaires found that most participants were satisfied with the app.

Limitations

The results of the present study should be interpreted taking into account potential strengths and limitations. As regards external validation, the generalizability of findings to the entire population of health care providers is limited due to the sampling method used in the interview study and absence of statistical power in the controlled experiment. Other groups of health care providers, such as male nurses or general practice doctors, or another setting might yield a different result. Another aspect to be considered is that blinding of the intervention group is impossible due to the use of the app. Furthermore, this was the first time all the participants had used the app. Therefore, a learning effect should be taken into account. Finally, a possible weakness of the experimental design is the inability to control, completely, for all other confounders that might influence the outcome.

Comparison With Prior Work

Limited small-scale, quantitative, efficacy studies have evaluated the use of mobile apps in diabetes care, although studies have become more numerous since 2014. In these studies, apps were mainly developed for self-management and were evaluated by patients with DM and rarely by health care providers [19,29-31]. When these apps were evaluated by experts in the field of health care–related mobile apps, it seems that only 9 of 65 apps could be helpful for self-management of DM based on the included variables [32]. Regarding health care providers' perspectives and intention to adopt mobile technology, they seem to be positive [33], with perceived benefits and value to mainly motivate physicians to use mobile diabetes monitoring [34]. Therefore, the development of more apps, based on guidelines and intended for use by health care providers, seems to be not only acceptable and desirable but also of major importance.

In a recently published study, a CDSS app was developed for patients with type 1 DM. The authors took into account the needs and perspectives of patients with type 1 DM as well as of their parents in order to develop an app that provides patient-doctor communication, a diabetes diary, diabetes education, peer support, blood glucose test reminder, and abnormal blood glucose reminder. However, this app was not further evaluated after the development. Also, although doctors or nurses will be called to use this app in order to see patients' diaries or laboratory results, they were not interviewed either for their needs or for their final impression of the app [35]. An application for type 2 DM was developed in 2017, using 3 main steps: identification of end users' needs and perspectives, development, and evaluation of the final app. Importantly, authors recruited both patients with DM and health care providers in order to provide a more holistic approach [36]. The findings of the current study are not comparable with these studies even though these studies are in the field of DM and health care providers will use them. None of the studies described have the same aim and objectives as the current study and, thus, have different findings. This is because they have different designs, settings, and reported outcomes. Although the aim and design of currently published studies are different, the general message remains in accordance with our results, that technology is well accepted from both patient and health care worker perspectives [37]. Additionally, appropriate utilization in clinical practice could provide great benefits in the management of patients with DM [38,39].

Following a review of available literature, only 1 publication was identified that explored similar aims to those in our study. Kart et al [40] published a protocol for an upcoming study aiming to develop a user-friendly CDSS for the screening, diagnosis, treatment, and monitoring of DM diseases for physicians and patients in primary care. The clinical result of the decisions made by the app will be evaluated following a 6-month usage period. However, the results of this study have not yet published.

Conclusions

To our knowledge, this is the first study to design, develop, and evaluate a CDSS app for DM and CKD based on the principles of user-centered design for health care providers. The methodology chosen ensured a rigorous exploration of a complex intervention. The study design carefully considered the needs and preferences of end users in order to increase its acceptability and utilization. Moreover, the pilot randomized controlled trial was the first attempt to test a mobile diabetes CDSS app for health care providers in a controlled environment using case scenarios.

The outcome of this feasibility study will guide the design of future CDSS apps in the field of DM, aiming to help health care providers with a personalized approach depending on patients' needs (such as comorbidities), but always in accordance with guidelines. As the current findings indicate a lack of apps for health care providers but also positive feedback and acceptance from providers, the development of CDSS in the field of DM seems crucial and requires further robust evaluation.

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Authors' Contributions

HA was responsible for the organization of the study, data collection, analysis, and formulation of the final paper. CA proposed the structure of and formulated the paper. JC, WH, SS, and SP critically appraised the paper and made final suggestions. PS and KN proposed the idea, critically appraised the paper, and made final suggestions.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Ethics approval and ethical considerations for the first step.
[DOCX File , 30 KB - diabetes_v5i4e19650_app1.docx]

Multimedia Appendix 2
Recruitment and interview process.
[DOCX File , 31 KB - diabetes_v5i4e19650_app2.docx]

Multimedia Appendix 3
Requirements.
[DOCX File , 32 KB - diabetes_v5i4e19650_app3.docx]

Multimedia Appendix 4
Guidelines used in the development of the management pathways.
[DOCX File , 33 KB - diabetes_v5i4e19650_app4.docx]

Multimedia Appendix 5
Decision algorithms.
[DOCX File , 434 KB - diabetes_v5i4e19650_app5.docx]

Multimedia Appendix 6
Dose adjustments in chronic kidney disease.
[DOCX File , 35 KB - diabetes_v5i4e19650_app6.docx]

Multimedia Appendix 7
Details for the 3 methods used in the evaluation procedure.
[DOCX File , 13 KB - diabetes_v5i4e19650_app7.docx]

Multimedia Appendix 8
Evaluation stage: simulation-based case scenarios.
[DOCX File , 14 KB - diabetes_v5i4e19650_app8.docx]

Multimedia Appendix 9
Evaluation stage: satisfaction questionnaires.
[DOCX File , 13 KB - diabetes_v5i4e19650_app9.docx]

Multimedia Appendix 10

Participants characteristics in the “requirements gathering” step.
[DOCX File , 12 KB - diabetes_v5i4e19650_app10.docx]

Multimedia Appendix 11
Examples of diabetes specialist nurses’ answers.
[DOCX File , 15 KB - diabetes_v5i4e19650_app11.docx]

Multimedia Appendix 12
Frequency of scores in the control and intervention groups from the pilot randomized controlled experiment.
[DOCX File , 45 KB - diabetes_v5i4e19650_app12.docx]

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Abbreviations

CDSS: clinical decision support system
CKD: chronic kidney disease
DM: diabetes mellitus
NHS: National Health Service

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Original Paper

Relationship Between Diabetes, Stress, and Self-Management to Inform Chronic Disease Product Development: Retrospective Cross-Sectional Study

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Abstract

Background: Technology is rapidly advancing our understanding of how people with diabetes mellitus experience stress.

Objective: The aim of this study was to explore the relationship between stress and sequelae of diabetes mellitus within a unique data set composed of adults enrolled in a digital diabetes management program, Livongo, in order to inform intervention and product development.

Methods: Participants included 3263 adults under age 65 who were diagnosed with diabetes mellitus and had access to Livongo through their employer between June 2015 and August 2018. Data were collected at time of enrollment and 12 months thereafter, which included demographic information, glycemic control, presence of stress, diabetes distress, diabetes empowerment, behavioral health diagnosis, and utilization of behavioral health-related medication and services. Analysis of variance and chi-square tests compared variables across groups that were based on presence of stress and behavioral health diagnosis or utilization.

Results: Fifty-five percent of participants (1808/3263) reported stress at the time of at least 1 blood glucose reading. Fifty-two percent of participants (940/1808) also received at least 1 behavioral health diagnosis or intervention. Compared to their peers, participants with stress reported greater diabetes distress, lower diabetes empowerment, greater insulin use, and poorer glycemic control. Participants with stress and a behavioral health diagnosis/utilization additionally had higher body mass index and duration of illness.

Conclusions: Stress among people with diabetes mellitus is associated with reduced emotional and physical health. Digital products that focus on the whole person by offering both diabetes mellitus self-management tools and behavioral health skills and support can help improve disease-specific and psychosocial outcomes.

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KEYWORDS

diabetes mellitus; behavioral health; mental health; stress; technology

Introduction

Diabetes mellitus currently affects over 10.5% of the United States population, or over 34 million Americans, and comes with significant medical, psychological, and economic burdens [1]. It is the leading cause of kidney failure, nontraumatic lower limb amputations, and blindness; a major cause of cardiovascular disease and stroke; and the seventh leading cause of death among adults in the United States [2]. It is also related to behavioral health concerns. People with diabetes mellitus are two to three times more likely to be diagnosed with major depressive disorder than people without diabetes mellitus and have a 20% greater prevalence of anxiety disorders than those without [3,4]. The economic burden of diabetes mellitus includes cost to the individual as well as that to their employers and the healthcare system. People with diabetes mellitus spend an average of US $13,700 annually on medical expenses, which is more than double that of people without [5]. The US healthcare system spends an average of US $245 billion annually

on diabetes, including expenses related to disability, work loss, and premature mortality [5].

Diabetes mellitus is a chronic and challenging illness, which requires patients to engage in complex, lifelong self-management of their condition. For an individual with diabetes mellitus, effective self-management is a daily routine of healthy eating, exercising, self-monitoring of blood glucose, adhering to medications, problem solving, reducing the risk of diabetes mellitus-related complications, and practicing healthy coping skills [6]. Managing these varied tasks can be a stressful experience, such that 18%-35% of people with diabetes mellitus experience high levels of "diabetes distress" or "significant negative emotional reactions to the diagnosis of diabetes, threat of complications, self-management demands, unresponsive providers, and/or unsupportive interpersonal relationships" [7]. Additionally, people with diabetes mellitus experience stress that is not condition related, just as people without diabetes mellitus do. This short- or long-term stress can come in many different forms such as, but not limited to, daily hassles, chronic stress, interpersonal stress, or work stress. Several studies have found associations between stress, self-management, and blood glucose control in people with diabetes mellitus. People who have coping deficits or who have high disease-related distress are less likely to engage in self-management behaviors, more likely to exhibit poor blood glucose control, and more likely to be at greater risk for diabetes complications [7,8].

Given the relationships between stress, self-management, and blood glucose control in people with diabetes mellitus, clinicians and researchers have long been interested in developing and refining methods to measure and treat stress. With regards to measuring stress, ecological momentary assessment is one now well-established method. Ecological momentary assessment involves the real-time collection of an individual's in-the-moment thoughts, feelings, and behaviors, typically in the convenience of their natural environment [9]. This is in contrast to older, more traditional methods of measuring behavioral constructs that require individuals to recall past activity or mood. The advantages of ecological momentary assessment in the measurement of stress include more accurate assessment and a finer understanding of the way in which stress unfolds [9]. With regards to treating stress, several interventions exist that empower patients with the skills and tools to manage their emotional, mental, and physical health. Traditionally, these interventions have taken the form of in-person diabetes mellitus self-management education and support programs or in-person stress management training. Examples include Funnell et al's [10] empowerment-based program, Hill-Briggs et al's [11] problem-solving approach, Lorig's [12] Chronic Disease Self-Management Program, and Surwit's [13] stress management program. As technology has become increasingly ubiquitous, internet and mobile phone–based interventions have also been developed to deliver diabetes mellitus self-management education and support, of which many include stress management training [14].

However, both ecological momentary assessment and diabetes mellitus stress management interventions have largely been confined to research environments. Although numerous studies have shown them to be effective in measuring psychological constructs, increasing participants' diabetes mellitus knowledge and self-care, improving blood glucose control and other physical health measures, and increasing quality of life, there is still a need to understand the real-world needs of people who are using technology to improve their health [12,15-18]. Currently, a search for the keyword "diabetes" in the Apple App Store alone produces hundreds of potential apps, yet it is unclear how many of these apps have been developed with a nuanced understanding of the day-to-day needs of the people with diabetes mellitus. Thus, the aim of the current study was to explore the relationship between stress and sequelae of diabetes mellitus using a unique and rich data set comprised of adults enrolled in a digital diabetes mellitus management program, Livongo, in order to inform intervention and product development.

Methods

Product and Participants

Livongo, a digital health company based in Mountain View, California, offers the Livongo for Diabetes Program as a benefit to employees at select US-based companies. The program provides members with (1) a cellular technology-enabled, two-way messaging device that measures blood glucose, stores blood glucose and contextual data, and feeds relevant algorithmic messages back to the individual; (2) unlimited blood glucose test strips; and (3) access to a team of certified diabetes educators for text or phone-based coaching (see Multimedia Appendices 1-3). In-depth overviews of the Livongo for Diabetes program and its efficacy on improving diabetes-related outcomes are available elsewhere [19-21]. Consistent with ecological momentary assessment methodology, each time participants completed a blood glucose check, participants were prompted to report their emotional or mental state by choosing one of the following feelings tags: "I feel fine," "I don't feel well," "Light-headed," "Stressed out," "After exercise," "Ate more," "Increased meds," "Missed meds," or "Other." Participants were not prompted to report their emotional or mental state in the absence of a blood glucose check.

Participants were adults under age 65 with diabetes mellitus who had access to Livongo through their employers between June 2015 and August 2018. A retrospective cross-sectional study was conducted with data collected while participants engaged in the Livongo for Diabetes Program. Medical and pharmacy claims data were obtained for participants for 12-month prestudy and poststudy index date to determine presence of behavioral health conditions. A participant's study index date was determined as the first date with "Stressed out" reported during a blood glucose check. For participants without selection of stress during a blood glucose check, the study index date was set as the first blood glucose check. The data were used to ascertain whether participants were diagnosed with a behavioral health condition or received behavioral health treatment during the 24-month study period. Diagnoses were included based on ICD-10 (International Classification of Diseases, 10th Revision) codes corresponding to indexes F00-F99, "Mental, Behavioral, and Neurodevelopmental Disorders," as well as procedures with current procedural

terminology codes corresponding to therapy, assessment, and other related psychiatric procedures. Pharmacy claims used National Drug Code codes to identify drugs used to treat behavioral health conditions. Participants were grouped into 4 categories identifying the presence and absence of ecological momentary assessment of stress and behavioral health diagnosis/treatment.

The study received institutional review board approval from Aspire IRB for waiver of informed consent and full waiver of Health Insurance Portability and Accountability Act authorization (Protocol-LDR-2016). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments.

Measures

Demographic Information

Demographic data collected at the time of enrollment in Livongo included age, gender, race, ethnicity, body mass index, age first diagnosed with diabetes mellitus, number of years living with diabetes mellitus, and insulin use. Income and education level were estimated based on the American Census Survey, specifically by gathering the mean/median values within a participant's zip code. This method has previously been used in public health research when self-report data on socioeconomic status are unavailable [22].

Glycemic Control

Participants self-reported hemoglobin A_{1c} (HbA_{1c}) at time of enrollment. They then used their FDA-cleared, cellular-enabled glucometer to conduct blood glucose readings as desired or needed. For the purposes of this study, blood glucose data were collected for 12 months after the study index date.

Diabetes Distress

Participants completed the 2-item Diabetes Distress Scale at time of enrollment [23]. This scale screens for the presence of diabetes distress by asking respondents to rate on a scale of 1 to 6 (1=not a problem; 6=a very serious problem) the degree to which they are bothered by 1) "feeling overwhelmed with the demands of living with diabetes" and 2) "feeling that [they] are often failing with their diabetes routines." The total score is calculated by adding the 2 responses. The 2-item Diabetes Distress Scale has been shown to have high sensitivity and specificity [23].

Diabetes Empowerment

Participants completed the 8-item Diabetes Empowerment Scale at time of enrollment [24]. The Diabetes Empowerment Scale assesses self-efficacy in people with diabetes mellitus. Respondents are asked to rate on a scale of 1 to 5 (1=strongly disagree; 5=strongly agree) the degree to which they agree with statements such as "In general, I believe I am able to turn my diabetes goals into a workable plan," "I can ask for support for having and caring for my diabetes when I need it," and "I know enough about myself as a person to make diabetes care choices that are right for me." The total score is calculated by summing all responses and dividing by 8. The Diabetes Empowerment Scale is shown to have high reliability and content validity [24].

Statistical Analyses

To explore the relationship between stress and sequelae of diabetes mellitus among participants using a real-world digital health product, statistical analyses were conducted for primarily descriptive purposes. Demographics, participant characteristics, Diabetes Empowerment Scale scores, and Diabetes Distress Scale scores at enrollment and blood glucose control were compared by reported stress and behavioral health diagnosis/utilization categories. Analyses of variance and 2-tailed *t* tests were used for between group comparisons of continuous variables, and Chi-square test was used for categorical variables group comparisons. The proportion of members with behavioral health diagnosis, procedure, and pharmacy in the pre- and post-study periods was compared for participants with and without stress with McNemar's test. *P* values less than .05 were considered statistically significant. No adjustments for multiple comparisons were made.

Results

Of the 29,270 individuals with diabetes mellitus that enrolled in the Livongo for Diabetes program and received devices, 25,286 (86.3%) engaged with the program by taking at least one blood glucose reading. Of those, 18,398 (72.8%) remained active for 12 months. Approximately 24% of 12-month active individuals (4473/18,398) were linked to available claims data. There were 3263 participants with 24 months of continuous medical and pharmacy claims in the Livongo Diabetes Program during the study period. Their mean age was 51.1 (SD 10.0) years; 1602 (49.1%) were male; 1950 (59.8%) were non-Hispanic; and 1683 (51.6%) were Caucasian. Table 1 contains additional overall population demographics and characteristics arranged by combinations of the presence of stress and behavioral health diagnosis or treatment.

Table 1. Participant demographics and characteristics.

Characteristic	Total sample (N=3263)	Stress, no behavioral health diagnosis/treatment (n=868)	Stress, with behavioral health diagnosis/treatment (n=940)	No stress, with behavioral health diagnosis/treatment (n=538)	No stress, no behavioral health diagnosis/treatment (n=917)	*P* value[a]
Age, years (SD)	51.1 (10.0)	50.6 (10.3)	51.2 (9.8)	51.6 (9.5)	51.0 (10.3)	.28
Gender, n (%)						**.35**
Male	1,602 (49.1)	393 (45.3)	376 (40.0)	264 (49.1)	569 (62.1)	
Female	1,661 (50.9)	475 (54.7)	564 (60.0)	274 (50.9)	348 (37.9)	
Ethnicity, n (%)						**.36**
Hispanic	519 (15.9)	156 (18.0)	138 (14.7)	80 (14.9)	145 (15.8)	
Non-Hispanic	1,950 (59.8)	492 (56.7)	573 (61.0)	335 (62.3)	550 (60.0)	
Unknown	794 (24.3)	220 (25.3)	229 (24.4)	123 (22.9)	222 (24.2)	
Race, n (%)						**<.001**
Caucasian	1,683 (51.6)	418 (48.2)	556 (59.1)	308 (57.2)	401 (43.7)	
Black/ African American	385 (11.8)	119 (13.7)	87 (9.3)	57 (10.6)	122 (13.3)	
Asian/ Chinese/ Japanese/ Korean	208 (6.4)	51 (5.9)	20 (2.1)	28 (5.2)	109 (11.9)	
Native Hawaiian/ Pacific Islander	8 (0.2)	2 (0.2)	3 (0.3)	3 (0.6)	0 (0)	
American Indian/ Alaskan/ Native	19 (0.6)	2 (0.2)	10 (1.1)	2 (0.4)	5 (0.5)	
Latino/ Mexican	1 (0.0)	0 (0)	0 (0)	0 (0)	1 (0.1)	
Other	327 (10.0)	115 (13.2)	75 (8.0)	38 (7.1)	99 (10.8)	
Unknown	632 (19.4)	161 (18.5)	189 (20.1)	102 (19.0)	180 (19.6)	
Annual income, US $, mean (SD)	72,946.87 (25,464.50)	72,164.70 (25,382.00)	71,598.80 (24,102.90)	72,332.60 (24,482.60)	75,429.50 (27,577.40)	.008
Education Level, n (%)						
High school	922 (28.3)	246 (28.3)	270 (28.7)	155 (28.9)	251 (27.4)	.008
Bachelor's degree	584 (17.9)	153 (17.6)	166 (17.7)	95 (17.6)	170 (18.6)	.08
Graduate degree	316 (9.7)	82 (9.4)	90 (9.6)	53 (9.8)	91 (9.9)	.505
Diabetes mellitus type, n (%)						**.10**
Type 1	421 (12.9)	126 (14.5)	108 (11.5)	53 (9.9)	134 (14.6)	
Type 2	2,835 (86.9)	740 (85.3)	830 (88.3)	484 (90.0)	781 (85.2)	
Unknown	7 (0.2)	2 (0.2)	2 (0.2)	1 (0.2)	2 (0.2)	
Duration of illness, years, mean (SD)	8.4 (8.1)	8.6 (7.8)	9.0 (8.6)	8.3 (7.8)	7.8 (7.9)	.009
Insulin use, n (%)						**<.001**
No	2,208 (67.7)	552 (63.6)	622 (66.2)	363 (67.5)	671 (73.2)	
Once per day	428 (13.1)	131 (15.1)	113 (12.0)	77 (14.3)	107 (11.7)	
Less than once per day	627 (19.2)	185 (21.3)	205 (21.8)	98 (18.2)	139 (15.2)	
Blood glucose value over 12 months, mg/dL, mean (SD)	150.1 (44.1)	154.5 (43.9)	152.8 (42.9)	145.7 (43.4)	145.9 (46.1)	<.001
Percent time in specified range over 12 months, mean (SD)						
Less than 54 mg/dL	1.08 (4.00)	1.06 (3.23)	0.85 (2.89)	1.50 (6.24)	1.09 (4.47)	.04
55-70 mg/dL	1.89 (3.86)	1.85 (3.36)	1.79 (3.36)	2.26 (5.47)	1.82 (3.89)	.13
71-180 mg/dL	74.1 (25.6)	72.1 (25.9)	72.9 (25.2)	75.5 (25.6)	76.5 (27.0)	.001

Characteristic	Total sample (N=3263)	Stress, no behavioral health diagnosis/treatment (n=868)	Stress, with behavioral health diagnosis/treatment (n=940)	No stress, with behavioral health diagnosis/treatment (n=538)	No stress, no behavioral health diagnosis/treatment (n=917)	*P* value[a]
More than 180 mg/dL	22.9 (25.5)	25.0 (25.5)	24.5 (25.0)	20.7 (24.6)	20.6 (26.4)	<.001
DDS[b] score, mean (SD)	2.38 (1.18)	2.47 (1.21)	2.77 (1.26)	2.18 (1.09)	2.03 (1.13)	<.001
DES[c] score, mean (SD)	3.84 (0.77)	3.84 (0.84)	3.67 (0.74)	3.94 (0.67)	3.94 (0.80)	.001
Body mass index, mean (SD)	33.4 (7.4)	33.3 (7.4)	34.7 (7.7)	33.5 (7.7)	32.0 (7.1)	<.001

[a]Continuous variable were compared using analysis of variance; categorical variables were compared using chi-square test.

[b]DDS: Diabetes Distress Scale.

[c]DES: Diabetes Empowerment Scale.

Of the 3263 participants with 24 months of continuous medical and pharmacy claims enrolled in the Livongo Diabetes Program during the study period, 1808 (55%) reported feeling "stressed out" at the time of at least 1 blood glucose reading. Participants who scored higher on the 2-item Diabetes Distress Scale, lower on the Diabetes Empowerment Scale, and had greater insulin use at enrollment were more likely to report feeling stressed on at least 1 blood glucose reading (2-item Diabetes Distress Scale score: 2.61.25 vs 2.091.11, respectively, *P*<.001; Diabetes Empowerment Scale score: 3.80.79 vs 3.90.79, respectively, *P*<.001; insulin: 35.1% vs 28.9%, respectively, *P*<.001). Participants who reported feeling stressed were also more likely to exhibit poorer blood glucose control throughout the study (proportion of blood glucose readings >180 mg/dL=0.250.25 vs 0.210.26, respectively, *P*<.001).

Of the 1808 participants who reported feeling stressed at the time of at least 1 blood glucose reading, 940 (52%) also received at least one behavioral health diagnosis or intervention during the study period. Compared to participants who neither reported stress nor received a behavioral health diagnosis/intervention, these participants had higher body mass index (34.77.67 vs 32.87.36, respectively, *P*<.001) and duration of illness (9.08.60 years vs 8.27.86 years, respectively, *P*=.008) at enrollment.

Table 2 contains the blood glucose checking frequency and values during the 12-month period following the study index date. Participants who reported stress started with higher A_{1c} at enrollment and continued to exhibit poorer glycemic control throughout the study (proportion of blood glucose readings >180 mg/dL=0.250.25 vs 0.210.26, respectively, *P*<.001). The presence or absence of behavioral health diagnosis/treatment did not appear to impact blood glucose checking or glucose management. Participants had similar behavioral health diagnoses, procedures, and treatments across the 4 groups. No significant differences were observed. However, participants with stress had more diagnoses and treatments than participants without stress (see Figure 1).

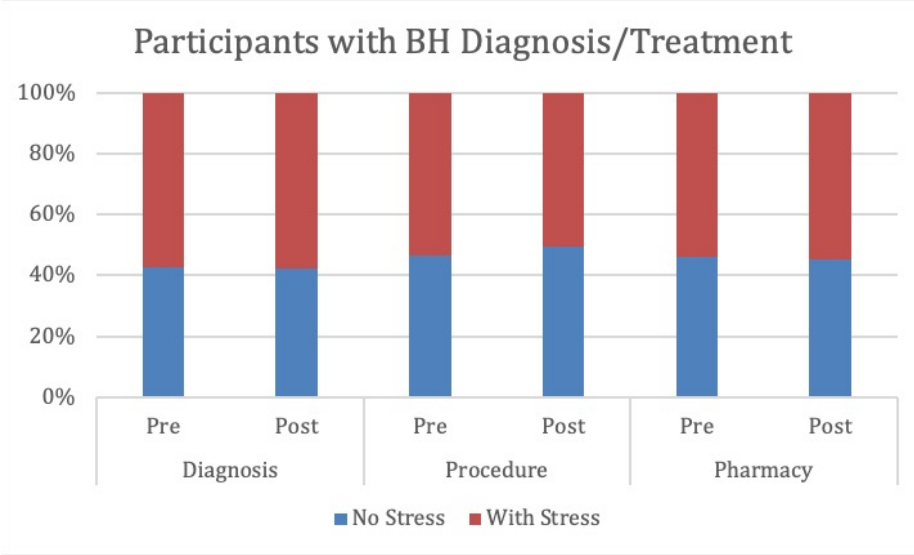
Table 2. Blood glucose checking frequency and values during the 12-month period following study index date.

Characteristic	Stress, no behavioral health diagnosis/treatment (n=868)	Stress, with behavioral health diagnosis/treatment (n=940)	No stress, with behavioral health diagnosis/treatment (n=538)	No stress, no behavioral health diagnosis/treatment (n=917)	*P* value[a]
A_{1C} at enrollment, mean (SD)	7.8 (1.8)	7.6 (1.7)	7.6 (1.7)	7.5 (1.7)	.02
Number of stressed blood glucose checks, value (SD)	9.52 (29)	12.7 (39.1)	N/A[b]	N/A	<.001
Total number of blood glucose checks, value (SD)	329.2 (399.8)	314.6 (406.4)	193.5 (273.6)	203.4 (275.9)	<.001
Blood glucose, values (SD)	154.5 (43.9)	152.8 (42.9)	145.7 (43.4)	145.9 (46.1)	<.001
Maximum blood glucose, value (SD)	322.8 (121.5)	317.9 (126.8)	279.2 (116.6)	274.2 (114.5)	<.001
Glycemic variability, value (SD)	28.8 (11.7)	28.3 (11)	27.7 (12.6)	26 (12.5)	<.001
Percent time in specified range over, value (SD)					
Less than 54 mg/dL	1.1 (3.2)	0.9 (2.9)	1.5 (6.2)	1.1 (4.5)	.04
55-70 mg/dL	1.9 (3.4)	1.8 (3.4)	2.3 (5.5)	1.8 (3. 9)	.13
71-180 mg/dL	72.1 (25.9)	72.9 (25.2)	75.5 (25.6)	76.5 (27.0)	.001
More than 180 mg/dL	25.0 (25.5)	24.5 (25.0)	20.7 (24.6)	20.6 (26.4)	<.001

[a]Analysis of variance was used for between group comparisons.

[b]N/A: not applicable.

Figure 1. Participants with behavioral health diagnosis/treatment. BH: Behavioral health; Pre: 12 months prior to the study index date; Post: 12 months following the study index date.



Discussion

Overview

The purpose of this descriptive study was to explore the relationships between stress, diabetes mellitus–related symptoms, and blood glucose control among people using Livongo, a digital diabetes mellitus management program for people with diabetes mellitus and other chronic conditions. The study was unique in that participants were people with diabetes mellitus using technology in their everyday lives, ecological momentary assessment of stress at the time participants checking their blood glucose was included, and healthcare utilization data to track behavioral health diagnoses and treatment were reviewed.

Principal Results

Approximately half of participants reported experiencing stress. Additionally, stress was related to greater diabetes mellitus distress, lower diabetes mellitus empowerment, greater insulin use, and poorer glycemic control. Over half of participants who experienced stress also had at least one behavioral health diagnosis or received some kind of behavioral health intervention, which was related to greater body mass index and longer duration of illness. In other words, stress among people with diabetes mellitus is associated with reduced emotional and physical health.

Limitations

This study has several strengths and weaknesses. Although participants self-reported clinical data such as A_{1c} at time of enrollment, stress data were collected noninvasively and in real-time. This enabled more accurate assessment of stress, although more analysis is required to evaluate stress intensity and duration on clinical outcomes and association with behavioral health. Further, a large sample size of people with both type 1 and type 2 diabetes mellitus, some of whom had been recently diagnosed and others who had lived with diabetes mellitus for several years, and some of whom reported varying degrees of control, provided an increased generalizability of results.

The study was limited by the single-item ecological momentary assessment prompt following blood glucose measurements, which only allowed one response for a variety of correlated feeling and nonfeeling state constructs (eg, stress and missing medications; exercise and feeling fine) [25]. Although individuals were instructed to select the item they believed best described how they felt at the time, the number of reports of stress were likely undercounted if individuals believed some other item applied to their current situation. Future work could use previous literature to inform separate ecological momentary assessment items, such as using single-item stress measures derived from the Perceived Stress Scale [26]. The study may also have been limited by the use of zip code–based socioeconomic status estimation. Although this method is common in public health research [22], it is important to acknowledge that socioeconomic status itself is known to be related to behavioral and physical health [27]. Therefore, the absence of self-report socioeconomic status data may limit our ability to interpret results.

Comparison With Prior Work

Regardless of the study's limitations, our findings are important in the current context of diabetes mellitus. Despite our nation's tremendous efforts to prevent the disease, its prevalence continues to rise. Experts project that by 2030, diabetes mellitus will affect nearly 55 million Americans, be attributable to 385,800 deaths per year, and cost the US healthcare system US $622 billion [28]. Therefore, it is ever more imperative to find ways to help people with diabetes mellitus manage the emotional, mental, and physical toll of the disease.

Technology, particularly smartphone technology, can be incredibly useful in diabetes mellitus management. Mobile apps can enable people with diabetes mellitus to track their eating, physical activity, and medication use. They can also deliver diabetes mellitus education and support via written content, online chat groups, and health coaching. Cellularly-enabled

glucose meters can provide people with real-time feedback on their glycemic control that they can share with their providers.

Digital products offering a flexible, person-centered approach including diabetes mellitus self-management tools and behavioral health skills and support may exhibit the most promise in improving disease-specific and psychosocial outcomes. Ideally, such products would offer a full spectrum of services to enhance a person's emotional, mental, and physical health. The ideal product would include elements of both collaborative and stepped care, such as screening and assessment, self-help content, guided self-help content with access to coaches to pace the individual or respond to the individual's questions, the opportunity to receive individual treatment from a provider, the opportunity for providers to work with one another in service of the individual's care, and access to a peer community. Research has shown that collaborative and stepped care models offer high levels of patient satisfaction, can help reduce drop out from treatment, are as clinically effective as usual treatment, and are cost effective [29-33]. The ideal product would also be multimodal and highly personalized, offering access via computer, phone, and video in an integrated approach to care when a person is most desirous or in need of care, for instance, when a person has endorsed high stress at the time of a blood glucose check.

Conclusions

In conclusion, this study highlights the relationship between diabetes mellitus and stress in a real-world context. While this finding is not novel, rapid advancements in technology are advancing our ability to assess and treat a myriad of health concerns in real-time in the context of an individual's life. This increased accuracy and timeliness represents an important step forward in the depth of understanding of this connection. Clinicians, researchers, product developers, software engineers, and other technology experts must come together to create clinically effective, cost effective, exciting, and engaging products to help people optimize all aspects of their health.

Acknowledgments

This study was funded by Livongo Health.

Conflicts of Interest

The authors are employees of Livongo, Inc.

Multimedia Appendix 1
Real-Time Tags to Capture Context.
[PNG File , 710 KB - diabetes_v5i4e20888_app1.png]

Multimedia Appendix 2
Real-Time Analytics and Feedback for Blood Glucose Checks.
[PNG File , 702 KB - diabetes_v5i4e20888_app2.png]

Multimedia Appendix 3
Health Nudges, Engagement Powered by Machine Learning.
[PNG File , 747 KB - diabetes_v5i4e20888_app3.png]

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Original Paper

Secondary Impact of Social Media via Text Message Screening for Type 2 Diabetes Risk in Kuwait: Survey Study

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is an international problem of alarming epidemic proportions. T2DM can develop due to multiple factors, and it usually begins with prediabetes. Fortunately, this disease can be prevented by following a healthy lifestyle. However, many health care systems fail to properly educate the public on disease prevention and to offer support in embracing behavioral interventions to prevent diabetes. SMS messaging has been combined with cost-effective ways to reach out to the population at risk for medical comorbidities. To our knowledge, the use of nationwide SMS messaging in the Middle East as a screening tool to identify individuals who might be at risk of developing T2DM has not been reported in the literature.

Objective: The primary aim of this study was to assess the feasibility of conducting a series of SMS messaging campaigns directed at random smartphone users in Kuwait for the detection and prevention of T2DM. It was predicted that 1% of those receiving the text message would find it relevant and participate in the study. The secondary aim of this study was to assess the incidence of participation of those who were forwarded the initial text message by family members and friends.

Methods: In this study, 5 separate text message screening campaigns were launched inviting recipients to answer 6 questions to determine the risk of developing T2DM. If subjects agreed to participate, a link to the prediabetes screening test devised by the Centers for Disease Control and Prevention was automatically transmitted to their mobile devices. Those identified as high risk were invited to participate in a diabetes prevention program.

Results: A total of 180,000 SMSs were sent to approximately 6% of the adult population in Kuwait. Of these, 0.14% (260/180,000) of the individuals who received the SMS agreed to participate, of whom 58.8% (153/260) completed the screening. Surprisingly, additional surveys were completed by 367 individuals who were invited via circulated SMS messages forwarded by family members and friends. Altogether, 23.3% (121/520) qualified and agreed to participate in a diabetes prevention program. The majority of those who chose to participate in the prevention program were overweight, aged 45-65 years, and reported being less physically active than those who chose not to participate (χ^2_2=42.1, P<.001).

Conclusions: Although health care screening via text messaging was found to have limited effectiveness by itself, it exhibited increased reach through shared second-party social media messaging. Despite the fact a subpopulation at possible risk of developing T2DM could be reached via text messaging, most responders were informed about the screening campaign by family and friends. Future research should be designed to tap into the benefits of social media use in health risk campaigns.

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KEYWORDS

SMS; Short text message interventions; mHealth; smartphone; Type 2 diabetes mellitus; prevention

Introduction

Type 2 diabetes mellitus (T2DM) is an international problem of alarming epidemic proportions [1]. The causes of T2DM can be multifactorial, with prediabetes tending to be the predominant one [2]. Prediabetes is an asymptomatic phase in which blood glucose levels are higher than normal but not high enough to be diagnosed with T2DM, characterized by insulin resistance, or both. This phase is associated with either one or both kinds of glucose levels: fasting glucose and impaired glucose tolerance [3]. Environmental and genetic factors as well as a sedentary lifestyle and unhealthy eating habits are known to play key roles. Diabetes mellitus can cause serious chronic medical comorbidities, including heart and blood vessel disease, blindness, neuropathy, limb amputation, and kidney failure [4]. Fortunately, this disease can be prevented by following a healthy lifestyle [5,6]. However, many health care systems fail to properly educate the public on disease prevention and to offer support in embracing behavioral interventions to prevent diabetes.

In 2016, Kuwait was known to have one of the highest percentages of people who lived a sedentary lifestyle, estimated to be 67% of the total population [7,8]. This is due in part to a hot climate (the average daily temperature reaches 45 °C or 113 °F in summer [9]), an overreliance on motor transportation, readily affordable domestic labor, and the advent of technology that encourages less daily physical activity. In addition, an abundance of food supplied on all social occasions and a focus on eating indicative of growing financial affluence contribute to higher rates of obesity [10-13].

SMS messaging has proved to be a cost-effective way to reach out to the population at risk for medical comorbidities, including asthma, hypertension, HIV, and diabetes [14-18]. SMS messaging is rapidly becoming an important communication vehicle worldwide for reaching the general population [19]. SMS messaging is a feasible, accessible, and cost- and time-effective method that ensures instant transmission to the recipient, which can be confirmed through 2-way messaging [20,21]. Mobile SMS, a segment of the mobile health strategy, can serve as a mediator between health care providers and the public [19-22]. Leading health organizations have recommended the use of text messaging in health care settings [23,24]. SMS effectiveness has been examined in previous studies focusing on 2 main domains: behavior change interventions and reminders [25,26]. Unfortunately, according to Gallup polling, SMS text messaging has a lower response rate than telephone surveys, and the percent of response can be as low as 1-2% if the individuals who were sent a general message had never been contacted before [27].

To our knowledge, the use of nationwide SMS messaging in the Middle East as a screening tool to identify individuals who might be at risk of developing T2DM has not been reported in the literature. The impact of circulating short text messages as part of health campaigns to reach those who may have prediabetes, asymptomatic diabetes, or are at high risk for diabetes is unknown. The primary aim of this study was to assess the feasibility of conducting a series of SMSs campaigns among random smartphone users in Kuwait for the detection and prevention of T2DM. It was predicted that 1% of those receiving the text message would find it relevant and participate in the study. The secondary aim of this study was to assess the incidence of participation of those who were forwarded the initial text message by family members and friends.

Methods

Study Design

This pilot study was designed to evaluate the impact of separate SMS messaging health care campaigns directed at owners of smartphones in 6 main governorates in Kuwait. This approach was the initial step of a larger study aimed to help identify and assist persons at risk of developing T2DM. The screening program offered instructions for obtaining confirmatory diagnostic blood testing once it was determined that an individual was at high risk for T2DM. We decided to send text messages to the general population in order to reach potential participants because of the easy accessibility of phone numbers through the national telephone service. Ethics approval for the study was obtained from the Dasman Diabetes Institute's local Research Ethical Committee and the Harvard Medical School Institutional Review Board.

Study Participants

This study was targeted at adults aged 21 years and older, residing in Kuwait, and owning a compatible smartphone (either iPhone or Android). Between October 2017 and December 2018, the telephone company sent an SMS message to 30,000 unique individuals in each of Kuwait's 6 main governorates on 5 separate occasions, thus totaling to 180,000 messages. The 5 separate SMS campaigns were conducted in October 2017, February 2018, April/May 2018, September 2018, and December 2018. The following SMS message was sent in Arabic and English: "Are you interested in knowing the risks of developing diabetes? Your data will be used for research purposes. If interested, reply YES to this message." Those who were interested replied in the affirmative to the SMS message. If the participant agreed to participate in the study, a link to an online Centers for Disease Control and Prevention (CDC) questionnaire [28], which is a validated prediabetes screening test measuring the risk of developing T2DM, was automatically transmitted to their mobile devices. The questionnaire is a simple self-assessment that includes the following questions in both English and Arabic:

1. How tall are you? How much do you weigh? (The replies to these questions established the respondent's BMI.)

2. Is your BMI greater than 27 kg/m^2?

3. How old are you?

4. Do you have a mother, father, sister, or brother with diabetes?

5. Are you physically active? (Being physically active was defined as conducting physical activity 20 minutes a day, 3 times per week.)

6. Are you male or female? If female, have you ever given birth to a baby that weighed more than 9 lb (or 4 kg), and have you ever had diabetes while pregnant?

The test was scored based on risk factors of weight (people with higher BMIs have a higher risk of developing T2DM) [29], older age, family history of diabetes, inactivity, and gender (more men than women have undiagnosed diabetes) [28]. Each response was weighted, and the score was summarized. Those scoring 9 or more were classified as being at high risk for developing T2DM.

Participants who decided to take the survey were requested to provide their contact number and asked whether they would agree to be contacted by one of the investigators to discuss their scores. Completed surveys were received and accessed by research investigators through Research Electronic Data Capture (REDCap), a secure, web-based software platform designed to support data collection for research studies. The platform provides (1) an intuitive interface for validated data capture, (2) audit trails for tracking data manipulation and export procedures, (3) automated export procedures for seamless data downloads to common statistical packages, and (4) procedures for data integration and interoperability with external sources [30,31]. Eligible and willing respondents who scored 9 points or more on the CDC questionnaire were contacted and asked to participate in a future diabetes prevention intervention program.

Statistical Analysis

This study was designed to gather data on the feasibility of identifying persons at risk for developing T2DM through SMS text messaging sent to a random list of individuals in the general population of Kuwait. The primary outcome measure was the number of responders of the SMS campaigns. It was expected that 1% of those receiving the text messages would respond based on the literature for general population surveys among persons who had not been contacted before [27]. Secondary analyses were conducted to examine the demographic and mean score differences of the diabetes screening tests between those who were sent a random text message and those who were forwarded the message by family and friends. It was anticipated that those who were sent the message initially would have lower risk scores and a lower rate of response compared with those who received the message through a family member or friend. Secondary analyses were conducted to help identify demographic differences between the initial responders and those who responded after the SMS was shared by a family member or friend. All variables were assessed using bivariate analyses to establish group differences. This study was designed as a preliminary investigation, and no power calculations were performed. The analyses assumed a 2-tailed test and an α level of .05 to confirm the prediction that no differences would be found between the abovementioned groups. Depending on the nature of the variables, nonparametric (chi-square) and parametric (*t* test) analyses were conducted using Bonferroni correctional analyses for multiple comparisons. We also examined and reported on the qualitative responses of the people who participated in the diabetes screening and diabetes prevention program. The data from this study were analyzed to gather information about the utility of SMS messaging for persons at risk for T2DM.

Results

The study schema is presented in Figure 1.

In this study, 5 separate SMS campaigns were conducted, sending out a total of 180,000 text messages, which targeted about 6% of the adult population in Kuwait (Table 1). Of these, 0.14% (260/180,000) of individuals replied “Yes” to the SMS message, indicating that they would like to know more about their risk of developing diabetes. Thus, the overall response rate was 0.14% (260/180,000). Of these individuals, 58.8% (153/260) took the survey. The largest number of responses originated from the fourth campaign (113/36,000, 0.31%). The results showed that 60.1% (92/153) of those who completed the survey were classified as being at high risk for developing T2DM (risk score≥9).

Figure 1. Selection process of eligible participants based on the response to the SMS campaigns and completion of the online survey.

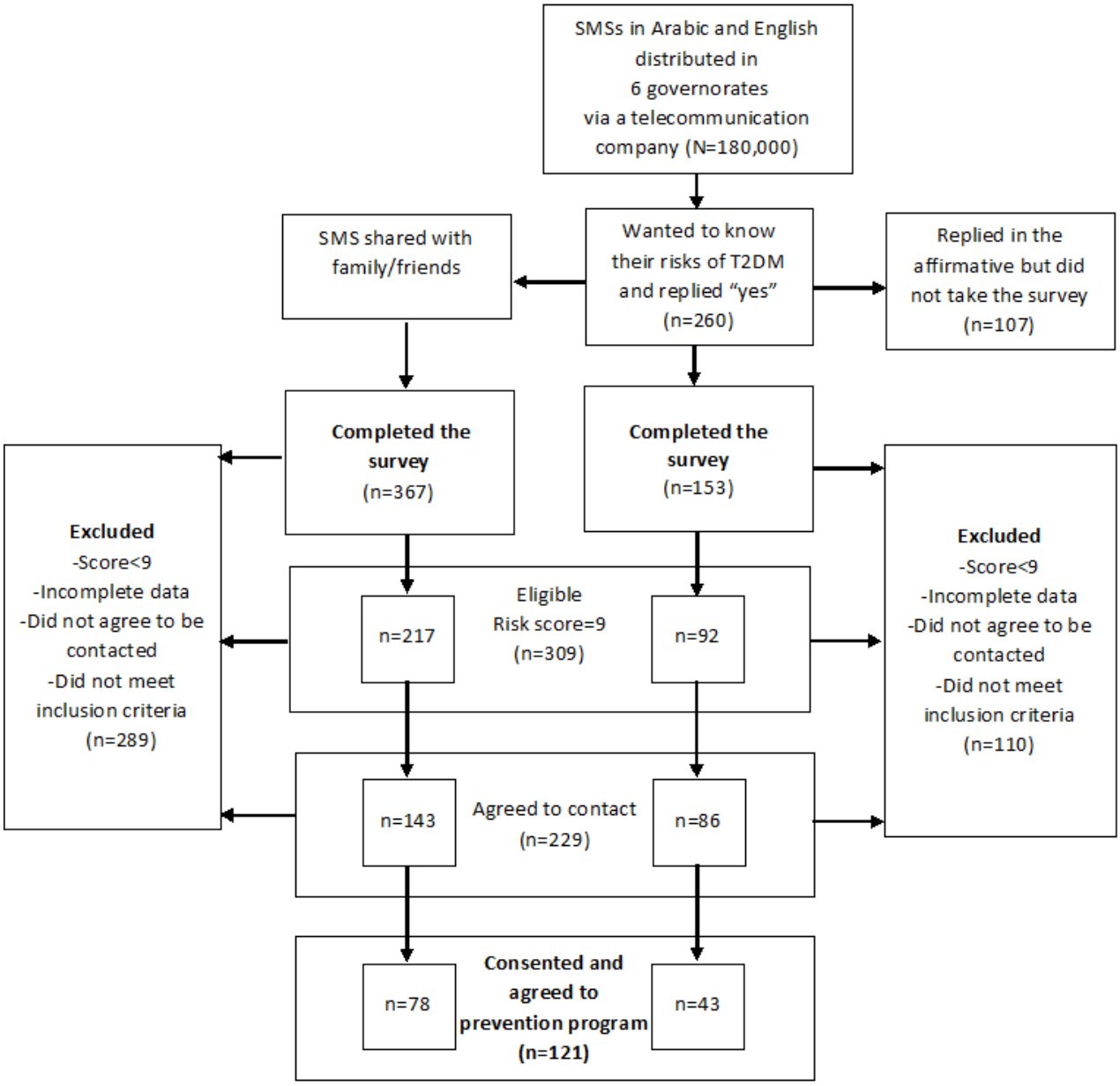

Table 1. Details of respondents for the 5 SMS campaigns originally circulated in 6 governorates in Kuwait between 2017 and 2018.

Type of recruitment	Number of messages sent (N=180,000)	Number who responded (n=260), n (%)	Number who took the survey (n=153), n (%)	Number eligible for prevention study (n=92), n (%)
SMS campaigns				
Campaign 1	36,000	37 (14.2)	13 (5.0)	6 (2.3)
Campaign 2	36,000	43 (16.5)	22 (8.5)	12 (4.6)
Campaign 3	36,000	30 (11.5)	15 (5.8)	7 (2.6)
Campaign 4	36,000	113 (43.5)	76 (29.2)	52 (20.0)
Campaign 5	36,000	37 (14.2)	27 (10.4)	15 (5.8)

A total of 520 individuals took the survey over the course of the study. Of these, 29.4% (153/520) of individuals completed the survey after receiving the original SMS messages (primary outcome). An additional number of surveys were completed by individuals who were not sent the original SMS message (367/520, 70.6%; secondary outcome). These individuals completed the survey after the text message was circulated by family members, friends, and others. Of all the respondents who

completed the survey, 59.4% (309/520) were found to have a risk score≥9. Moreover, 44.0% (229/520) agreed to be contacted, and 23.3% (121/520) of these individuals consented and enrolled in a diabetes prevention study (Figure 1).

Overall, the number of initial responders was very low and below the anticipated 1%. Females agreed to participate in the survey more often than males (349/520, 67.1% vs 171/520, 32.9%; *P*<.001; Table 2). Those between the ages of 21 and 45 years showed the most interest in the study compared to the other age groups (58.3% vs 41.8%). Surprisingly, only 3.3% of those over age 65 showed interest in participating, even though they would be at a higher risk of developing diabetes [32]. Of the subjects who responded, 66% (345/520) reported having parents with T2DM, and 41.6% (209/495) were classified as obese with a reported BMI≥30 [33]. Comparisons were made between those who responded to the initial SMS messaging and those who were informed about the survey through family and friends. Those who were forwarded the message and completed the survey were more often women (258/343, 75.2%; *P*<.001). No other significant differences were found between these two groups. Moreover, 59% (309/520) of the total responders had a risk score≥9, while 36.0% (187/520) scored<9. The remaining 5.2% (27/520) had unknown risk scores due to incomplete and missing data.

Table 2. Characteristics of individuals who responded to SMS campaigns (n=520), and differences among those who responded to the initial SMS and completed the survey (n=153) and those who were forwarded the SMS from family and friends and completed the survey (n=343).

Characteristic	Total (n=520)	Initial SMS (n=153)	Family/friends (n=343)	Differences between initial SMS and family/friends	
				Chi-square (*df*)	*t* test (*df*)
Gender (female), n (%)	334 (67.3)	76 (49.7)	258 (75.2)	31.4 (1)[a]	N/A[b]
Age group (years), n (%)					
≥21-<45	292 (58.3)	97 (63.4)	195 (56.9)	2.0 (2)	N/A
45-65	188 (38.5)	51 (33.3)	137 (39.9)	N/A	N/A
>65	16 (3.3)	5 (3.3)	11 (3.2)	N/A	N/A
BMI, mean (SD)	29.7 (6.0)	30.0 (6.0)	29.6 (6.0)	N/A	0.7 (493)
Underweight, n (%)	2 (0.4)	1 (0.7)	1 (0.3)	1.0 (3)	N/A
Normal	98 (19.8)	27 (17.6)	71 (20.8)	N/A	N/A
Overweight	189 (38.2)	60 (39.2)	129 (37.7)	N/A	N/A
Obese	206 (41.6)	65 (42.5)	141 (41.2)	N/A	N/A
Physically active (yes), n (%)	228 (45.2)	78 (51.0)	150 (43.7)	2.2 (1)	N/A
Parents with diabetes (yes), n (%)	327 (65.5)	106 (69.3)	221 (64.4)	1.1 (1)	N/A
Siblings with diabetes (yes), n (%)	167 (33.2)	54 (35.3)	113 (32.9)	3.4 (1)	N/A
Risk score, mean (SD)	9.2 (4.7)	8.9 (4.7)	9.3 (4.7)	N/A	0.9 (494)
<9	187 (37.7)	61 (39.9)	126 (36.7)	0.4 (1)	N/A
>9	309 (62.3)	92 (60.1)	217 (63.3)	N/A	N/A

[a]*P*<.001.

[b]N/A: Not applicable.

The results showed that 185 individuals had a risk score≥9 but elected not to get a blood test or participate further. Most stated that they did not have time (25/185, 13.5%) or already knew that they had T2DM (21/185, 11.4%), whereas 9% (17/185) had a scheduled appointment but did not show up, 31% (57/185) gave an incorrect phone number or did not provide one, and 23% (43/185) did not answer their phone after multiple attempts.

An invitation to visit a diabetes center (Dasman Diabetes Institute) for a diagnostic blood test and enroll oneself in a prevention study based on the high risk score was accepted by 121 participants (Table 3). Of those who were invited to participate in a prevention program and get a blood test, 62.8% (76/121) were recruited through a shared SMS message through family and friends (39/76, 32.2% by word of mouth; 35/76, 28.9% via WhatsApp; and 2/76, 1.7% by other means). The majority (8/121, 66.9%) of these participants were females. Also, those between the ages of 45 and 65 (56/119, 47.1%), those with BMI scores≥30 (75/119, 63.0%), and those who were mostly Kuwaiti citizens (69/121, 57.0%) tended to pursue further testing. Most of these participants were iPhone users (95/121, 78.5%). Of the 121 individuals who consented to seek a blood test and participate in a diabetes prevention program, no differences were found between those who were initially recruited through 1 of the 5 initial text messaging campaigns

(n=45) and those who were notified through family and friends (n=76).

Among the 520 respondents who completed the screening survey, differences were examined between those who agreed to be enrolled in a diabetes prevention program (n=121) and those who did not (n=399; Table 3). Those who were enrolled tended to be overweight, physically less active, and more likely to belong to the age bracket of 45-65 years compared with those who did not participate in further diabetes prevention (P=.034).

Table 3. Comparison of individuals who were eligible for enrollment in a diabetes prevention program (risk score>9) and agreed to be contacted (n=121) and those who did not enroll in the program (n=399).

Variables	Consented and enrolled (n=121), n (%)	Did not enroll (n=399), n (%)	Differences between consented and enrolled, and did not enroll	
			Chi-square (*df*)	*t* test (*df*)
Gender (female), n (%)	81 (66.9)	269 (67.0)	1.7 (2)	N/A[a]
Age group (years), n (%)				
≥21-<45	62 (52.1)	240 (60.1)	6.8 (2)[b]	N/A
45-65	56 (47.1)	144 (35.9)	N/A	N/A
>65	1 (0.8)	15 (4.0)	N/A	N/A
BMI, mean (SD)	32.3 (5.5)	28.9 (6.0)	N/A	5.6 (493)[c]
Underweight, n (%)	0 (0)	2 (0.5)	40.1 (3)[c]	N/A
Normal	4 (3.4)	94 (25.0)	N/A	N/A
Overweight	40 (33.6)	149 (39.6)	N/A	N/A
Obese	75 (63.0)	131 (34.8)	N/A	N/A
Physically active, n (%)	24 (19.8)	213 (53.1)	42.1 (2)[c]	N/A
Parents with diabetes, n (%)	86 (71.1)	258 (64.7)	4.1 (2)	N/A
Siblings with diabetes, n (%)	51 (42.1)	124 (30.8)	6.3 (3)	N/A
Risk score, mean (SD)	12.3 (2.4)	8.2 (4.9)	N/A	8.7 (494)[c]

[a]N/A: Not applicable.

[b]P=.34.

[c]P<.001.

Discussion

The results of this study suggest that simple SMS messaging applied to a large population of individuals can be a feasible method of reaching a subpopulation of individuals at risk for T2DM. Past studies have demonstrated that SMSs can be used as effective health care reminders and as encouragement to change behaviors, namely for health promotion and disease prevention [25,26]. This study represents one of the first attempts to use text messaging to reach a large population of smartphone users in the Middle East for health care risk screening who might not have otherwise been identified and informed. Although further efforts are needed to refine messaging methods in order to improve acceptability, a surprise finding of this study was the role that social media played in forwarding the initial message to friends and family who might be open to prediabetes screening.

Previous studies have demonstrated that SMS messaging is a feasible, acceptable, and easy way to reach many individuals through their mobile phones and to integrate these services within the health care system [34]. This type of message campaign can be a cost-effective, convenient means to reach many individuals [35-38]. The screening experience using SMS messaging in this study was designed to reach 6% of the targeted adult population; thus, it covered a large area of Kuwait's 6 main governorates. Despite the number of texts sent, only 0.14% (260/180,000) of the subscribers responded to the SMS messaging. It could be concluded that the messaging campaign had limited acceptability, although considering that many likely dismissed the message because they did not have concerns about diabetes, the messaging seems to have reached some who would not have otherwise enquired about their diabetes risk. This study also shows that the impact seemed to extend beyond the use of the messaging. This notion is evidenced by the number of completed surveys submitted based on word of mouth and circulated texts on social media (eg, via WhatsApp). People can forward text, audio, and video messages at no cost. For instance, unlike SMS, WhatsApp offers the use of unlimited characters and information, which could help circulate the survey more widely. Further, people can use their own words to explain their interest and experience in participating in the survey, which would be perceived to be more reliable and trustworthy [39].

This study was unable to obtain data about the number of subscribers who either did not receive the message or did not

read it, or how many read the message but did not reply. Unfortunately, the telephone company used in this study could not determine this information. Quite possibly many individuals were reluctant to respond because they may have distrusted the message. Surprisingly, completed surveys continued to appear well past the time the messages were originally sent. Anecdotal information suggests that some candidates circulated the text message surveys to family members and friends, mainly via the use of other social media (predominantly WhatsApp) after establishing the legitimacy of the survey.

Several reasons might account for the relatively low response rate of the different test messaging campaigns. The selected timing of each campaign played a key role in the acceptability of and responses to the messaging. The delivery of the first 36,000 messages (Campaign 1) faced some technical difficulties with the telecommunication company, which may have accounted for many not receiving the text messages. After resolving these issues, Campaign 2 was conducted close to the time of national holidays in Kuwait (National and Liberation Days). Many Kuwait residents are known to spend this time of the year outside the country. The delivery of the messages in Campaign 3 coincided with the month of Ramadan, and many candidates responded that they would prefer to be contacted after Ramadan. Campaign 4 was initiated around the time not affected by national holidays and events, which might have helped improve its response rate compared to those of the other campaigns (113/260 total responses, 43.5%). We believe that private and public school holidays may have affected the lower response to Campaign 5. In Kuwait, private schools usually close for the Christmas holidays, and this campaign also took place around the examination time for higher education institutes. It is also important to note that replying to the screening SMS was subject to charges payable by the subscriber, which might have been an additional reason that some chose to not reply.

The majority of those who completed the survey were females, had parents or first-degree relatives with T2DM, and were overweight or obese. Thus, these responders could have had their own personal concerns about developing diabetes. Most respondents were not working or had flexible occupations, which might have given them more spare time to respond to messages on their mobile phones. We do not know if a less prestigious diabetes center (other than the Dasman Diabetes Institute) would have limited the interest and acceptability of the messages even further. Although the SMS campaigns did not meet the anticipated impact, the number of completed surveys received was doubled, as people forwarded their SMS messages to family members and friends. Receiving the message from a trusted person rather than an anonymous source might have reduced worries about the message being spam or fraudulent. This notion is corroborated by the number of individuals who were interested in completing the survey but who decided to not provide their contact numbers, who chose to enter invalid numbers, or who declined to be contacted in order to protect their identity or privacy. These individuals may have wanted to learn about their risk for diabetes but may have had privacy concerns or may have decided to pursue information from their own health care providers. It is also noteworthy that those over 65 years tended not to participate (only 17/520 or 3% of the respondents were aged 65 or more) even though they are at higher risk for diabetes compared with younger individuals [3] and would benefit from early detection [40]. This result might be attributed to older people not using text messaging as often as the younger participants.

Individuals who took the time to initiate telephone conversations expressed initial concerns about the source of the message and the link. Some were hesitant to access the link and to fill out the survey, especially since their mobile number was requested. Other factors, including the perception that the SMS messages were focused on diabetes-related complications rather than the risk of developing the disease itself, might have contributed to lower response rates. Thus, selecting the appropriate wording in a limited character text message with limited information may directly affect the comprehension of the message content, especially among those with low health literacy [41-44]. Moreover, it has been suggested that people may not be willing to initiate contact about prevention interventions when they feel healthy [45,46]. Carefully scripting the message and the public relations campaign prior to beginning the survey might likely have improved the response rates. In addition, improvements in the user interface and the message presentation designed to capture the recipient's attention and use of a 2-way message pathway might have increased the motivation to reply and could have enhanced the response rate. A major finding of this study is that, once sent, messages can reach others by being forwarded by family members and friends through social media. This appears to be a cost-free means to improve contact with those who may be at risk for developing a chronic disease.

There are several limitations of this study that need to be discussed. First, this trial was not controlled, and we did not compare a text message campaign with other types of informational campaigns (eg, via mail or telephone). Second, Kuwait has one major phone company, which cooperated in participating in this messaging study. Researchers in other countries may not have the same accessibility to mobile phone numbers. Third, this study reached only a limited percentage of the Kuwaiti population, and only persons owning a compatible mobile phone were included. The results might have been different if other persons or areas were included. Fourth, we were unable to determine why many individuals chose to not respond to the message. The limited number of words and characters allowed in each message, timing of the messages, charges applicable when responding to the message, sending of the messages without repetitions or reminders, and general distrust of random messages may have affected the response rate. Furthermore, the abundant nature of commercial messages may have hindered the effectiveness of our SMS messaging campaigns. Finally, we used the validated CDC prediabetes screening questionnaire, which does not assess dietary patterns. Dietary habits were assessed only among those who chose to participate in the prevention program, and thus, future investigations should include an assessment of dietary habits as part of the screening.

Despite these limitations, this study demonstrates that future use of SMS health campaigns for prediabetes screening could be a feasible way to reach some at-risk individuals. Effective

solutions are needed to maximize the acceptability and effectiveness of these behavioral health campaigns. Future efforts designed to help understand and improve the response rates of SMS messaging to effectively reach those individuals who are at risk for developing a chronic medical condition are needed.

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Conflicts of Interest

None.

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Abbreviations

CDC: Centers for Disease Control and Prevention
REDCap: Research Electronic Data Capture
T2DM: type 2 diabetes mellitus

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Original Paper

Continuous Glucose Monitoring With Low-Carbohydrate Diet Coaching in Adults With Prediabetes: Mixed Methods Pilot Study

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is preventable; however, few patients with prediabetes participate in prevention programs. The use of user-friendly continuous glucose monitors (CGMs) with low-carbohydrate diet coaching is a novel strategy to prevent T2DM.

Objective: This study aims to determine the patient satisfaction and feasibility of an intervention combining CGM use and low-carbohydrate diet coaching in patients with prediabetes to drive dietary behavior change.

Methods: We conducted a mixed methods, single-arm pilot and feasibility study at a suburban family medicine clinic. A total of 15 adults with prediabetes with hemoglobin A_{1c} (HbA_{1c}) levels between 5.7% and 6.4% and a BMI >30 kg/m^2 were recruited to participate. The intervention and assessments took place during 3 in-person study visits and 2 qualitative phone interviews (3 weeks and 6 months after the intervention). During visit 1, participants were asked to wear a CGM and complete a food intake and craving log for 10 days. During visit 2, the food intake and craving log along with the CGM results of the participants were reviewed and the participants received low-carbohydrate diet coaching, including learning about carbohydrates and personalized feedback. A second CGM sensor, with the ability to scan and record glucose trends, was placed, and the participants logged their food intake and cravings as they attempted to reduce their total carbohydrate intake (<100 g/day). During visit 3, the participants reviewed their CGM and log data. The primary outcome was satisfaction with the use of CGM and low-carbohydrate diet. The secondary outcomes included feasibility, weight, and HbA_{1c} change, and percentage of time spent in hyperglycemia. Changes in attitudes and risk perception of developing diabetes were also assessed.

Results: The overall satisfaction rate of our intervention was 93%. The intervention induced a weight reduction of 1.4 lb (P=.02) and a reduction of HbA_{1c} levels by 0.71% (P<.001) since enrollment. Although not significantly, the percentage of time above glucose goal and average daily glucose levels decreased slightly during the study period. Qualitative interview themes indicated no major barriers to CGM use; the acceptance of a low-carbohydrate diet; and that CGMs helped to visualize the impact of carbohydrates on the body, driving dietary changes.

Conclusions: The use of CGMs and low-carbohydrate diet coaching to drive dietary changes in patients with prediabetes is feasible and acceptable to patients. This novel method merits further exploration, as the preliminary data indicate that combining CGM use with low-carbohydrate diet coaching drives dietary changes, which may ultimately prevent T2DM.

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KEYWORDS

prediabetes; type 2 diabetes mellitus; prevention & control; low carbohydrate diet; diet modification; blood glucose self-monitoring

Introduction

Background

Type 2 diabetes mellitus (T2DM) is a preventable disease; however, most of the 84 million adults in the United States who have prediabetes do not participate in evidence-based prevention programs [1-3]. Although the Diabetes Prevention Program (DPP) study found that people with prediabetes can reduce their risk of developing T2DM by 58% through participation in an intensive lifestyle modification program [1], personal and logistical barriers limit participation. Innovative, low-cost methods to prevent T2DM in the primary care setting are needed.

The New American Diabetes Association care guidelines [4] state that low-carbohydrate diet plans may result in improved glycemia [5] and help patients with prediabetes in decreasing postprandial glucose spikes that are frequently followed by crashes and cravings. Low-carbohydrate diets have shown positive effects for the prevention of prediabetes [6,7] and management of T2DM [8,9]. However, patients with prediabetes may lack sufficient motivation and support [7] or knowledge to adopt and maintain a low-carbohydrate diet. Although limited, research has supported the use of health coaching interventions for adults with prediabetes and type 2 diabetes to increase knowledge, increase motivation, and support long-term behavioral changes. For example, health coaching has been used to improve diet quality, exercise adherence, diabetes self-efficacy, diabetes empowerment, social support, and reduce diabetes distress in individuals with type 2 diabetes [10-13]. For adults with prediabetes, DeJesus et al [14] found that a 12-week wellness coaching program improved physical activity, healthy eating behaviors, self-efficacy, and quality of life. Further research is needed to specifically examine the use of health coaching that emphasizes a low-carbohydrate diet for individuals with prediabetes.

Simultaneously, the use of new technology may be another useful strategy for improving engagement and adherence to T2DM prevention programs. In a meta-analysis by Bian et al [15], technology-mediated interventions were shown to lead to clinically significant weight loss in individuals at risk for T2DM, particularly when combined with a DPP model. New low-cost and user-friendly continuous glucose monitors (CGMs) have made it feasible to use CGM technology for diabetes prevention. Although CGMs are primarily used in patients with type 1 diabetes to adjust the insulin dosage and prevent hypoglycemia, more recently, CGMs have also been prescribed for patients with T2DM who face challenges in diabetes management [16]. However, there is a lack of research on CGMs as a prevention or behavior modification tool [17]. In a recent review, Ehrhardt et al [17] described 2 pilot studies examining the impact of CGMs as a behavior modification tool to improve physical activity [18,19]. However, the impact of CGMs on dietary behavior remains to be unknown [18,19]. As CGMs offer their wearers personalized feedback about the effect of dietary choices on blood glucose trends, the use of CGMs could be a viable strategy for dietary interventions that seek to reduce glycemic variability, which is known to increase the risk of adverse outcomes [20].

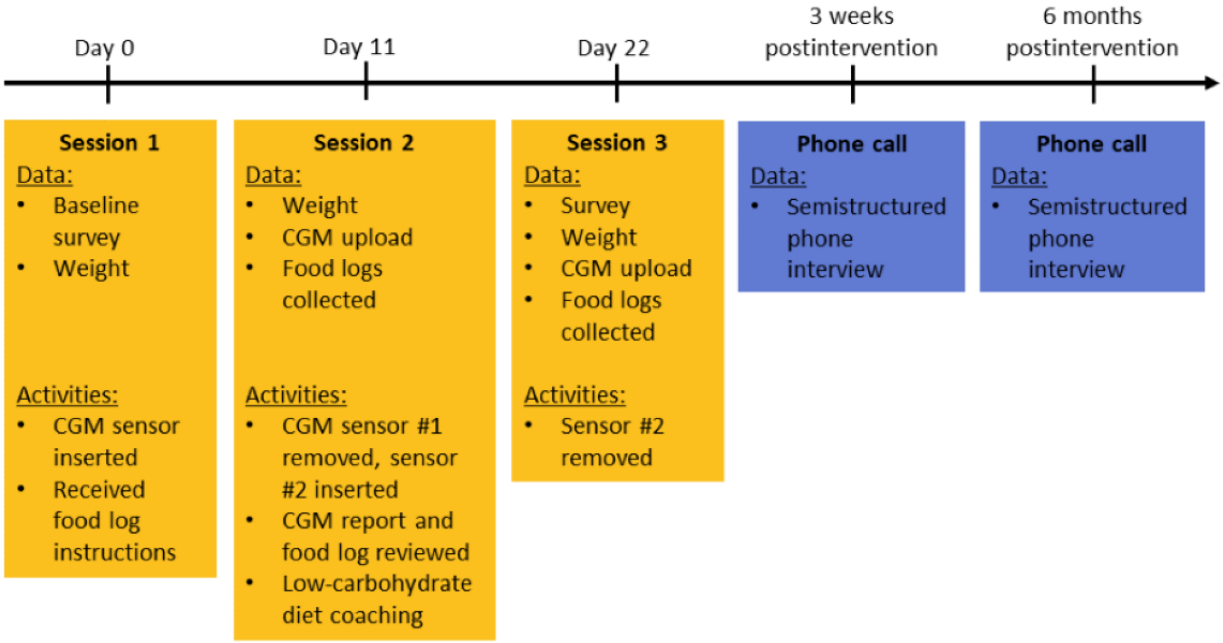
Objectives

To address these 2 important and related gaps in the literature, we developed a novel approach of combining real-time feedback from a CGM with low-carbohydrate dietary coaching. As low-carbohydrate diets are likely to reduce postprandial glucose spikes [21], participants will be able to see the corresponding flattening of blood glucose peaks and crashes as they modify their diet. This integrated approach has the potential to make individuals with prediabetes aware about the impact of carbohydrates on their blood glucose levels, thereby supporting behavior change with personalized feedback. Thus, this pilot study aims to determine the feasibility of combining low-carbohydrate diet coaching with real-time CGM feedback in patients with prediabetes to drive behavior change and reinforce low-carbohydrate diet adherence.

Methods

This was a mixed methods, single-arm, pilot and feasibility study with 15 participants. The participants attended 3 sessions with a study coordinator, which included coaching on a low-carbohydrate diet. The study coordinator for this study was a certified medical assistant. She was provided with instructions on how to implement the intervention and provide low-carbohydrate diet coaching. CGMs were provided at 2 study visits. The primary outcome was participant satisfaction with the intervention: low-carbohydrate diet coaching with continuous glucose monitoring. Secondary outcomes included feasibility, weight change, the percentage of time spent in hyperglycemia, side effects of CGM wear, and use of CGMs. Figure 1 shows the overall design diagram.

Figure 1. Pilot and feasibility design diagram. CGM: continuous glucose monitor.



Subjects and Recruitment

Eligible participants were identified from a southeast Michigan Family Medicine office by searching existing electronic health record data. Participants were required to be of 21 years of age or above, have a BMI >30 kg/m^2, and have an HbA_{1c} level between 5.7% and 6.4% in the last year. Participants were excluded if they were on diabetes medications (eg, metformin), previously had bariatric surgery, were pregnant or breastfeeding, or classified themselves as vegan or vegetarian. In addition, participants were required to be interested in changing their diet to improve their health, have a phone, and speak, read, and write in English.

Eligible participants received a letter explaining the study and its requirements with an opt-out postcard. Those who did not opt out were contacted via phone with further information. Interested and eligible participants met the study coordinator at the family medicine office to be enrolled for their baseline visit. All subjects signed a written consent, and the study was approved by the University of Michigan Institutional Review Board.

Intervention

Participants attended 3 sessions with the study coordinator (Figure 1). At visit 1, participants received information on CGM use and an Abbott Libre Pro sensor was applied to their arm. At the time of the study, the Abbott Libre Pro sensor was able to record data for a total of 10 days before the sensor period ended and the sensor needed to be replaced. The sensor did not record any blood glucose values during the wearing period. Participants were asked to wear the sensor for the 10-day sensor period and to complete a food log, documenting what they consumed, their fatigue levels, and their cravings 2 hours after eating. Participants received a copy of the book *Always Hungry* [22] that describes a low-carbohydrate diet program.

At visit 2 (11 days later), participants returned for a one-on-one low-carbohydrate diet coaching session with the study coordinator. The first sensor was removed, and data were uploaded, reviewed, and printed for the participant. Participants received coaching on low-carbohydrate diets, which included a comparison of their completed food logs with the CGM data, information on the recommended carbohydrate intake, and resources to determine the carbohydrate content of popular foods. They were asked to have a low-carbohydrate diet (less than 100 g per day) for the duration that they wore the second sensor, which also lasted for 10 days. Participants were advised to increase their protein and water intake. Participants also received additional training on CGM use, and the Abbott Libre personal sensor (which allows viewing real-time glucose data) was applied to their arm.

At visit 3 (11 days later), participants had the second sensor removed and data were uploaded and printed for review. Participants reviewed their food logs with their CGM trends with the study coordinator. Participants were given compensation of US $25.

Quantitative Methods

Data Collection

Outcome Measures

Satisfaction, Feasibility, and Acceptability

Participant satisfaction was measured through postintervention surveys as well as through qualitative interviews. Participants were asked, on a 5-point Likert scale, to indicate (1) how satisfied they were with the intervention (low-carbohydrate diet with CGM use), (2) how likely they were to recommend a low-carbohydrate diet to others with prediabetes, (3) how likely they were to recommend a CGM to a family member or friend with prediabetes, and (4) how likely they were to purchase a CGM to test their blood glucose. The last item did not include specific information about the cost of a CGM or availability of

insurance coverage. Feasibility and acceptability were measured based on successful recruitment and enrollment of 15 study participants, CGM wear times of 20 to 22 days in total, CGM data retrieval, and completion of food logs. Interviews explored participants' experiences with the low-carbohydrate diet, coaching, CGM use, and any barriers the participants faced.

Weight

At each visit, participant weight was measured in pounds using a standing scale, without shoes and heavy clothing.

Estimated HbA_{1c}, Average Daily Glucose, and Percentage of Time Spent in Hyperglycemia

All glucose-related variables were calculated using Abbott Freestyle Libre CGM software. The estimated HbA_{1c} level was calculated using the Nathan formula [23]. The average daily glucose was calculated as the mean of all the glucose sensor readings for a 24-hour period. The percentage of time spent in hyperglycemia was defined and calculated as the period in which glucose levels were >140 mg/dL for over 24 hours.

Perceived Risk of Diabetes

We measured the perceived risk of diabetes by asking questions developed from the KORA FF4 study [24] pre- and postintervention. Items included estimates of the risk of participants having diabetes at present (6-point Likert scale from negligible to very high), developing diabetes in the next 3 years (yes, no, and I do not know), and whether diabetes is a serious disease (4-point Likert scale from not serious to very serious).

Risk Perception Survey for Developing Diabetes

Risk perception for developing diabetes was measured using the risk perception survey for developing diabetes (RPS-DD) preintervention and postintervention [25]. A total of 3 subscales were included: personal control subscale (4 items), optimistic bias subscale (2 items), and worry subscale (2 items). Each item was presented as a statement and scored on a 4-point Likert scale (1=strongly agree; 4=strongly disagree). Subscale scores and a composite score were calculated for each participant, with higher scores indicating a higher level of the assessed underlying construct: more personal control, optimistic bias, and worry.

Modified Weight Loss Readiness Test II

Participants were asked questions based on a modified form of the Weight Loss Readiness Test II motivation questions, which were previously used in a pragmatic clinical trial of the DPP for Veterans Health Administration patients with prediabetes [26]. Participants rated how motivated they were to lose weight, exercise, eat a healthy diet, and avoid developing diabetes. Items were scored on a Likert scale ranging from 1 (*very motivated*) to 5 (*not motivated at all*).

Data Analysis

We performed descriptive statistical analyses for demographic variables. For categorical variables (eg, satisfaction, feasibility, and acceptability of the intervention), we calculated frequencies for each category. For all continuous variables, we conducted paired *t* tests to examine changes from baseline to postintervention. All statistical analyses were conducted using STATA statistical software (StataCorp) [27].

Qualitative Methods

Data Collection

We conducted semistructured interviews [28] with participants at 2 points: approximately 3 weeks after the intervention and 6 months after the intervention. All participants were invited to complete both interviews. The interview guide was designed to elicit participant experiences across several domains, including living with prediabetes, efforts to reduce risk of developing diabetes, experience with the low-carbohydrate diet and coaching, use of CGMs, and intentions moving forward. Interviews were conducted by a qualitative methodologist (MD) and a family medicine resident (OY) trained and mentored in qualitative research. All interviews were conducted via phone or web conference and were audio-recorded.

Data Analysis

Audio recordings were professionally transcribed. We conducted 2 inductive, thematic analyses [29] to understand participant perspectives during the intervention. First, we analyzed transcripts from 3 weeks after the intervention. Two investigators (OY and MD) reviewed the first 2 transcripts to develop codes that represented meaningful concepts in the data. Codes were agreed upon and then applied to 2 additional transcripts. We discussed the coding scheme to ensure that codes were consistently applied across transcripts and discrepancies were resolved. The remaining transcripts were coded by both investigators. Next, we summarized the content of each code by reviewing all data segments assigned to an individual code. The code summarizes detailed variation within each code and illustrative quotes. After creating the summaries, we developed themes that incorporated multiple, interrelated codes that were reported by more than one participant. The same process was completed for the interviews conducted 6 months after the intervention.

Mixed Methods Analysis

The purpose of the mixed methods analysis was to develop hypotheses that may explain the differences in the intervention outcomes and to identify focus areas for future iterations of the intervention. To integrate the quantitative and qualitative approaches, we compared the thematic results of different groups of participants based on significant quantitative results: reduction in HbA_{1c} levels and weight loss. First, we compared the experiences (in the form of qualitative themes and quotes) reported by participants who had a less-than-average reduction in HbA_{1c} levels with those reported by the participants who had an above-average reduction in HbA_{1c} levels. Second, we compared the experiences of those with less-than-average weight loss with those with greater-than-average weight loss. For both comparisons, we created joint displays, a visual strategy that can be used to bring together quantitative and qualitative results for a mixed methods analysis and interpretation [30,31].

Results

A total of 15 participants were enrolled in this study. The mean age was 54.5 (SD 9.1) years. Participants had a mean enrollment HbA_{1c} level of 5.9% (SD 0.23), BMI of 35.8 (SD 4.7) kg/m^2, and starting weight of 232.7 (SD 45.1) lbs. Of the total 15 participants, 10 (67%) were women, 11 (73%) identified as White, and 4 (27%) identified as African American. Table 1 shows the participant demographics.

Table 1. Participant demographics of the pilot feasibility study (N=15).

Characteristics	Values
Age (years), mean (SD)	54.5 (9.1)
Enrollment HbA_{1c}[a] (%), mean (SD)	5.9 (0.23)
BMI (kg/m^2), mean (SD)	35.8 (4.7)
Starting weight (lbs), mean (SD)	232.7 (45.1)
Gender, n (%)	
Male	5 (33)
Female	10 (67)
Race, n (%)	
White	11 (73)
African American	4 (27)
Education, n (%)	
Completed high school	15 (100)
Bachelor's degree	8 (53)

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

Feasibility and Satisfaction Results

All 15 participants wore both sensor 1 and sensor 2 for an average of 9.8 (SD 1.9) and 9.6 (SD 0.8) days, respectively. Of the total, 80% (12/15) of the participants completed food log number 1 and 87% (13/15) completed food log number 2. All participants attempted a low-carbohydrate diet during the intervention. Of the total, 13 participants completed both interviews. Of the total, 93% (14/15) of the participants reported satisfaction with the intervention, whereas 7% (1/15) reported neutral satisfaction.

When asked if they would recommend a low-carbohydrate diet to others with prediabetes, 100% (15/15) were extremely likely (n=12) or likely to (n=3) recommend. A total of 10 participants said they were extremely likely to recommend wearing a CGM to a family member or a friend with prediabetes, whereas 4 participants said they were likely, and 1 reported neither likely nor unlikely. When asked how likely they were to buy a CGM to test their blood glucose levels, 3 reported extremely likely, 6 likely, 3 neutral, 2 unlikely, and 1 did not answer. There were no major adverse events reported for the duration of this study with CGM use.

Quantitative Results

Results were significant for the reduction in HbA_{1c} levels from the final estimated HbA_{1c} level to HbA_{1c} level measured at the time of enrollment (–0.71%; $P<.001$) and weight change from the second to final visit (–1.4 lb; $P=.02$). The percentage of time spent in hyperglycemia (>140 mg/dl) and average daily glucose were not significant but tended to decrease during the intervention period (Table 2). Pre- and posttest scores for the 3 measures presented in Table 3.

Table 2. Changes in hemoglobin A_{1c}, weight, and blood glucose.

Measure	Mean (SD)	SE	*P* value
Hemoglobin A_{1c}(%)			
Enrollment[a]	5.9 (0.23)	0.06	N/A[b]
Sensor 1[c]	5.2 (0.38)	0.10	N/A
Sensor 2[c]	5.2 (0.37)	0.10	N/A
Δ[d]: Sensor 2—Enrollment	–0.71 (0.46)	0.12	<.001
Δ: Sensor 2—Sensor 1	–0.01 (0.31)	0.08	.87
Weight (lbs)			
Visit 1 (starting weight)	232.7 (45.1)	11.7	N/A
Visit 2	233.2 (46.2)	11.9	N/A
Visit 3	231.8 (45.9)	11.8	N/A
Δ: Visit 3—Visit 1	–0.89 (2.94)	0.76	.26
Δ: Visit 3—Visit 2	–1.41 (2.18)	0.56	.02
Average daily glucose (mg/dL)			
Sensor 1	103.8 (10.6)	2.8	N/A
Sensor 2	102.9 (10.9)	2.9	N/A
Δ: Sensor 2—Sensor 1	–0.93 (8)	2.1	.67
Time spent in hyperglycemia[e](%)			
Sensor 1	7.1 (7.9)	2.1	N/A
Sensor 2	4.5 (5.6)	1.5	N/A
Δ: Sensor 2—Sensor 1	–2.6 (6.5)	1.7	.16

[a]Measured hemoglobin A_{1c} (HbA_{1c}) by clinical laboratory.

[b]N/A: not applicable.

[c]HbA_{1c} estimated from continuous glucose monitor data.

[d]Delta or difference.

[e]Glucose >140 mg/dL.

Table 3. Pre- and postscores of the KORA FF4, RPS-DD, and modified Weight Loss Readiness Test II.

Tool	Participants, n (%)	Mean prescores, mean (SD)	Mean postscores, mean (SD)	Mean delta	SE	*P* value
KORA FF4						
Diabetes risk at present[a]	14 (93)	4.21 (1.31)	2.71 (1.20)	–1.5	0.402	.002
Risk of developing diabetes in the next 3 years[b]	8 (53)	1.13 (0.35)	1.63 (0.52)	0.5	0.19	.003
How serious of a disease is diabetes?[c]	14 (93)	3.64 (0.74)	3.78 (0.43)	–0.14	0.21	.50
RPS-DD[d]						
Personal control	13 (87)	14.31 (1.60)	14.54 (2.07)	0.23	0.30	.46
Optimistic bias	15 (100)	3.33 (1.05)	4 (1)	0.67	0.33	.06
Worry	10 (67)	4.7 (1.42)	5.3 (1.64)	0.6	0.40	.17
Composite	8 (53)	7.63 (0.90)	7.92 (1.02)	0.29	0.21	.21
Modified Weight Loss Readiness Test II[e]						
Lose weight	15 (100)	1.53 (0.52)	1.4 (0.63)	–0.13	0.19	.49
Exercise	15 (100)	2.13 (1.06)	2 (1)	–0.13	0.19	.49
Have a healthy diet	15 (100)	1.4 (0.51)	1.33 (0.62)	–0.067	0.15	.67
Avoid developing diabetes	15 (100)	1.4 (0.63)	1.33 (0.72)	–0.067	0.12	.58

[a]Likert scale of 1-6 with a higher score indicating higher risk.

[b]Scored 1=yes, 2=no. Answers of I don't know were excluded from analysis.

[c]Likert scale of 1-4 with a higher score indicating more seriousness.

[d]RPS-DD: risk perception survey for developing diabetes. Likert scale from 1-4 with a higher score indicating a higher level of the assessed underlying construct.

[e]Likert scale of 1-5 with a lower score indicating increased motivation.

Perceived Risk of Diabetes

The estimated risk of developing disease at the present moment decreased during the intervention (mean 4.21, SD 1.31 vs 2.71, SD 1.20; n=14; *P*=.002). Participants believed that their risk of developing diabetes in the next 3 years was less following the intervention (1.13, SD 0.35 vs 1.63, SD 0.52; n=8; *P*=.003). The perception of the seriousness of diabetes among participants was not significantly different following the intervention (n=14; *P*=.50).

Risk Perception of Developing Diabetes

Composite scores for the risk of developing diabetes increased from 7.63 to 7.92 during the intervention. Participants' sense of personal control over their health and diabetes was not significantly different before and after the intervention (n=13; mean 14.31, SD 1.60) and 14.54, SD 2.07), respectively; n=13; *P*=.46). Optimistic bias average scores increased from 3.33 (SD 1.05) to 4.00 (SD 1); n=15; *P*=.06 and approached significance. This increase corresponds to participants who believed that they are less likely to develop T2DM than their peers following the intervention. The change in worry about developing diabetes was not significant (mean 4.7, SD 1.42 vs 5.3, SD 1.64; n=8; *P*=.17).

Readiness to Lose Weight, Exercise, Eat Healthy, and Avoid Diabetes

Participant motivation did not change significantly; however, it trended toward increased motivation postintervention to lose weight, exercise, eat a healthy diet, and avoid getting diabetes.

Qualitative Results

A total of 13 participants completed 2 semistructured interviews at approximately 3 weeks and 6 months after the intervention, whereas 2 participants declined to attend the interview. The thematic analysis resulted in 3 themes that spanned both time points: (1) participants reported no major barriers to CGM use, (2) all participants attempted a low-carbohydrate diet, and (3) CGMs helped participants to visualize the impact of carbohydrates on glucose trends, inciting dietary changes (Textbox 1 lists the themes and related participant experiences).

Textbox 1. Themes and related participant experiences during the pilot and feasibility study.

Participants reported no major barriers to continuous glucose monitor (CGM) use

- Reported CGMs were comfortable to wear
- Described no adverse effects
- Reported barriers to CGM use outside of the intervention

All participants attempted a low-carbohydrate diet

- Experienced positive physical effects
- Described barriers to diet
- Modified the diet for sustainability

CGMs helped to visualize the impact of carbohydrates on glucose trends, inciting dietary changes

- Preferred seeing glucose trends in real time
- Reflected on impact of carbohydrates on glucose levels
- Felt reassured by trends in CGM data
- Felt unsure of the need for CGM outside of the intervention

Theme 1: Participants Reported No Major Barriers to CGM Use

Across participants, wearing the CGM did not cause adverse effects. Participants described that CGM insertion was relatively painless and that they did not feel discomfort wearing it (eg, "I mean after I got used to it, it was fine. It didn't bother me at all," [Participant 105, Interview 1]). However, a few participants noted that the CGM sensor could get in the way at times (eg, getting caught on clothes or pushed against throughout the day), but this was not a major barrier that prevented its use. For example, one participant reflected the following:

> *I didn't even realize it was there. I think, probably when I would get out of the shower, or different clothes that I'd be putting on or taking off made me aware of it being there. But, other than that, I completely forgot about it.* [Participant 179, Interview 1]

In a social setting, a few participants shared that peers noticed them wearing the sensor. One participant explained the following:

> *[Others would notice it] when I go to water therapy. So it was like what's that? You know. Then I would tell 'em. So yeah, other than that, you know, just people curious as far as what was the function of it.* [Participant 222, Interview 1]

As a result, 1 participant reported that they would not be as comfortable wearing the sensor during the summer when their arms would be exposed.

Participants reported that CGM use was less invasive and painful compared with using a glucometer to monitor their glucose levels. For example:

> *At first I could feel that [the sensor] was there. Then, after a little bit, I didn't even notice it. I liked that they had [the CGM] and I wouldn't need to prick my finger all the damn time.* [Participant 144, Interview 1]

In the interviews conducted 6 months after the intervention, participants continued to report that wearing a CGM is an easy and comfortable way to monitor their blood glucose levels. Although they did not continue wearing a CGM after the intervention, 1 participant expressed their preference for wearing the sensor:

> *[The monitor] was a very easy way for people to check their sugar counts. It was very good to monitor it that way. I think some people think it will really feel terrible on their arm, or they wouldn't want that. I heard a couple comments people said to me, and I said, "I don't even feel it" (laugh). I mean it's just an easy way to do it. I would wear one if I truly had to.* [Participant 102, Interview 2]

One participant, who received a prescription and wore the sensor after the intervention, further described how the CGM was a discrete option for blood glucose monitoring and how it was suitable for her lifestyle:

> *Once I got it [the CGM] and read through the directions, I'm like oh, there's an app; I could have just used that, and not have to worry about it. And that's what I used when I traveled was just the app. It's nice too because if you're in a business meeting and nobody knows you have it on, you just kind of put your phone up next to it, and you know what it* [your glucose] is. Nobody knows; it's discrete. [Participant 193, Interview 2]

However, the participant above was the only participant who reported obtaining another CGM after the intervention. Others reported that they did not get a CGM after the intervention for various reasons. One participant tried to get a CGM, but their insurance did not cover it, whereas others stated that they did not know it was an option for them:

> *I felt like the insurance wouldn't cover it because I wasn't really in that range* [prediabetes] anymore. [Participant 199, Interview 2]

Several described not needing to use a CGM after the intervention because their participation helped them to understand how to eat to prevent hyperglycemia or prevent diabetes:

> *I considered [getting a prescription]. I noticed when I was doing the monitoring, my numbers were pretty good. I remember the eating that I did when I was on the monitor, so I stuck to that diet in hopes that my numbers would be about the same.* [Participant 169, Interview 2]

However, some participants were willing to reconsider wearing a CGM sensor if they needed to *get back on track* to prevent diabetes or if they were diagnosed with diabetes:

> *Right now I think as long as I'm doing 6 month A_{1c} checkups, and it's going lower, that I'm okay that I don't feel I need to continuously monitor it. But if it starts to trend like it was coming back up, I think I would wear one, just to try to get back on track and get it lower. And keep me off medicine.* [Participant 193, Interview 2]

Theme 2: All Participants Attempted a Low-Carbohydrate Diet

All participants reported reducing their carbohydrate intake during the intervention. Overall, participants reported consuming more protein and vegetables and reducing simple carbohydrates. One participant described the dietary changes they made during the intervention:

> *For dinner was usually chicken, and a salad, and more vegetables. And every now and then, my sister would make some pasta, but it wasn't always the big blue bowl that I would eat, it would be the little small bowl. I really worked on not eating what I was used to eating.* [Participant 231, Interview 1]

Some reported positive effects such as feeling better, sleeping better, and having more energy:

> *Physically [I] definitely felt better. I don't think I was as tired. I definitely felt I didn't have a lot of the swings that I normally have in terms of being tired or lethargic.* [Participant 199, Interview 1]

Those who were able to maintain the low-carbohydrate diet continued to see positive changes that motivated them to sustain the dietary changes, including increased weight loss, increased energy, improved sleep, and lowered HbA_{1c}:

> *When I was a little heavier, I did not like the way I looked or felt. So I've actually enjoyed and appreciated being a lot slimmer. Between feeling better and looking better, that keeps me motivated to keep up the same type of eating habits. Not to mention, in the time my A_{1c} has continued to drop. So, my family has a history of diabetes, and I do not want to be included in that list if I can help it.* [Participant 169, Interview 2]

Barriers to a Low-Carbohydrate Diet

Despite trying the diet, there were some barriers to low-carbohydrate diets reported across participants. Some participants described feeling bored with food choices, whereas others still had to give up their old eating habits. For example, 1 participant reflected on the diet:

> *Probably after about 4 days it was a lot harder to do, just because you kinda get sick of all of the same choices I s'pose. I don't know, it's just really protein heavy, and it just got a little bit… my mind knew better, but my mouth wanted certain things.* [Participant 199, Interview 1]

> *Being creative with meals is difficult. I was pretty much protein vegetable, protein vegetable, protein vegetable, you know. It gets boring after a while, so I think variety's important.* [Participant 219, Interview 1]

Participants also emphasized that to maintain a low-carbohydrate diet, it is imperative to plan ahead and have healthy choices available:

> *I'm tryin' you know, like I said every day to figure out what my meals are gonna be. Instead of just eating anything in the refrigerator. And before, whatever is in the refrigerator sometimes wasn't the healthiest. I mean it's not easy by no means. Eating healthy is not easy.* [Participant 231, Interview 1]

Some participants also reported that they felt the need to get rid of old eating habits and continue to make good choices, particularly when having cravings:

> *Oh, nothin' really made it difficult. Just tryin' to, maintain that, every day you know…We got a lot a food in the house, so every day is just makin' the right choice.* [Participant 222, Interview 1]

Others described the difficulty of making healthy choices when people around them, including family members, friends, and colleagues, do not maintain the same lifestyle. This was particularly salient around winter holidays.

Maintenance and Modification of a Low-Carbohydrate Diet

In the interviews conducted 6 months after the intervention, the majority of the participants reported that they were trying to maintain their diet after the intervention. Most participants had modified the diet to be "less strict" but "still healthy." For example, participants reported avoiding processed foods, eating more fruits and vegetables, and being more carb conscious. Many participants described intermittently straying from the low-carbohydrate diet before returning to a less restrictive version:

> *Well just last week I started on it again. Not as strict as I was before. But, I said no, I have to start doing something again. So, I just kind of started it. I tried to cut out all carbs, but now I'm allowing myself a*

> *few more carbs. So, you know, maybe it won't be so restrictive for me.* [Participant 102, Interview 2]

Participants reported similar barriers in the interviews conducted 6 months after the intervention, including having to break old habits and dealing with cravings for higher-carbohydrate and processed foods:

> *Well, put it this way, I'm not very successful at following the low carb, high protein diet. And so yeah, I fell off it. I had done that once before. It seems difficult, for whatever reason. You know you say to yourself I wanna change somethin', so you eat, and then, you know I want a hamburger (Laugh) So, you just kinda fall off. And it's just the story of my life, lack of discipline.* [Participant 219, Interview 2]

In addition, some participants reported that maintaining a low-carbohydrate diet was too expensive. One participant explained the following:

> *Believe it or not, it's actually cheaper to eat carbs than it is to eat healthy . . . Fruits and vegetables are so much more expensive now, and, it's just easier to grab a bag a chips or something.* [Participant 179, Interview 2]

Yet, most of the participants described trying to continue eating better, even if every choice was not low in carbohydrates.

Theme 3: CGMs Helped to Visualize the Impact of Carbohydrates on Glucose Trends, Driving Dietary Changes

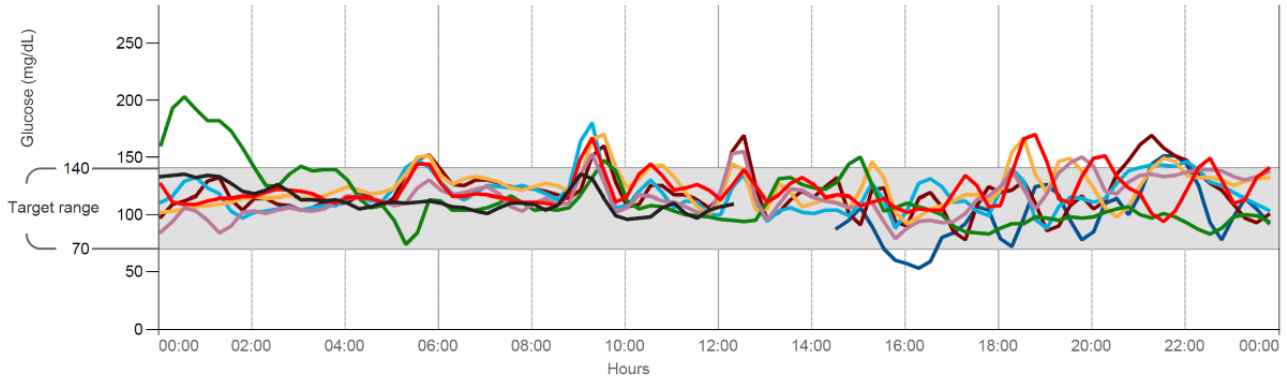
Overall, participants were able to use the CGM data to help them understand fluctuations in blood glucose trends. During the first week of the study, participants reviewed CGM data alongside their food logs with the study coordinator. Participants were able to visualize the impact of food on their blood glucose levels and understand trends.

In the first interview, 1 participant reported that they learned how their regular eating habits affected their glucose levels:

> *I was fascinated, and very excited to see the results of it. The first week I just continued to eat normally, and, I was able to see... what I was doing, and it was horrible. I mean I had mountains and valleys. It was just up and down all day long, based on the way that I ate normally every single day.* [Participant 213, Interview 1]

The experience of this participant in visualizing peaks and valleys is evident in the daily patterns available from their CGM for the first week (Figure 2).

Figure 2. Example of continuous glucose monitor data downloaded from Abbott software and reviewed with participants during low-carbohydrate diet coaching with the study coordinator. Each individual colored line represents the collected glucose data for a distinct 24-hour period.

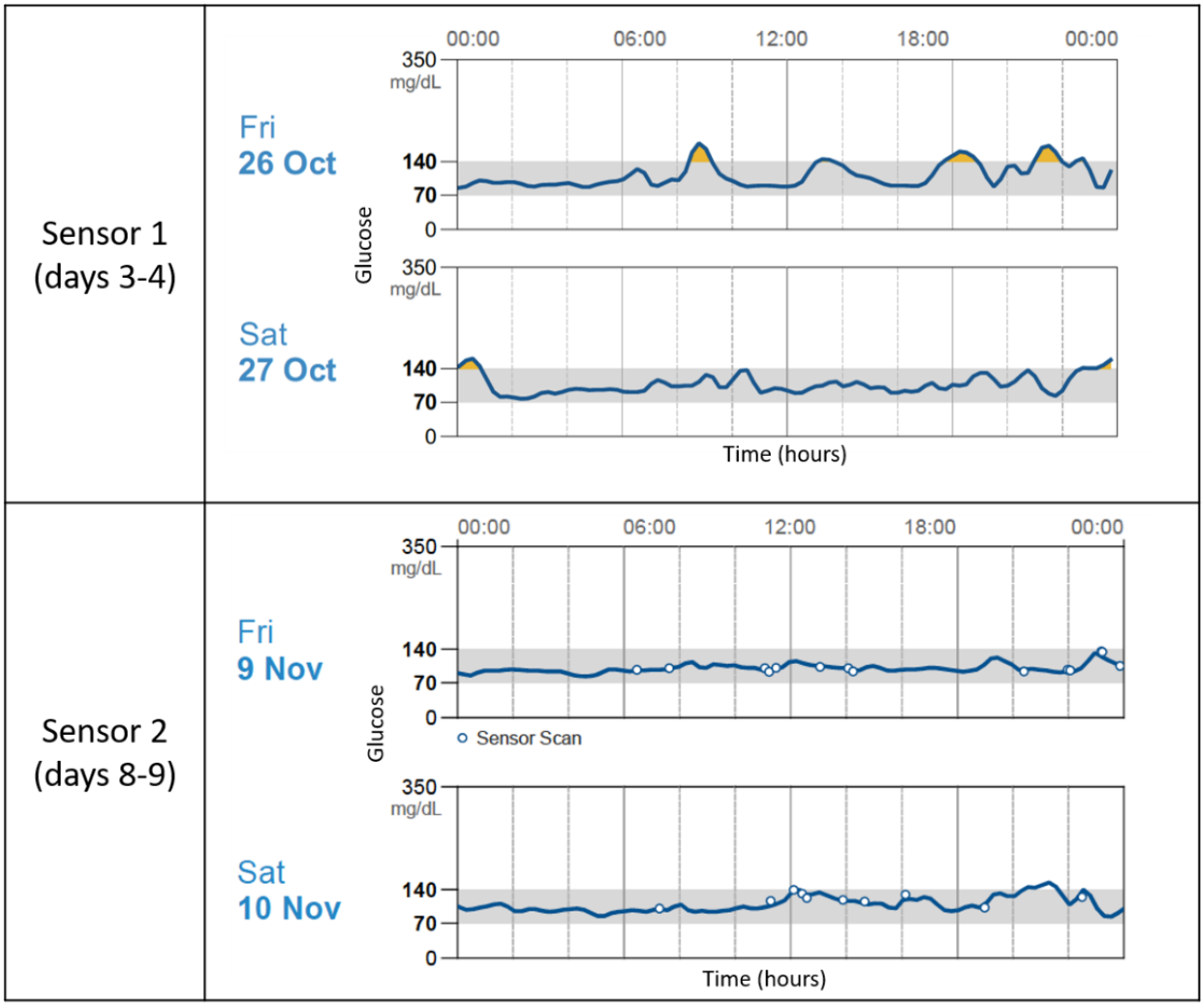


In the second week, participants were able to use the CGM scanner to see their real-time blood glucose levels. Participants unanimously preferred seeing the data in real time to compare the changes in their blood glucose with the foods they had eaten. One participant explained the following:

> *I was more conscious of it, I was able to see in real time what I was eating was doing to me. You can listen to dieticians and all this other stuff, and if you can't really see it, you don't know, you don't realize.* [Participant 141, Interview 1]

Many participants not only understood the impact of carbohydrates on their blood glucose level but also modified their behavior based on the CGM data. For instance, 1 participant explained their blood glucose trends, a sample of which is also depicted in Figure 3:

Figure 3. Example of participant glucose trends from both sensor periods captured by Abbott continuous glucose monitor software.



I knew when I really binged out. It [the glucose level] went way up, and then crashed, it never went out of that range, but you could still see the crash. I realized, oh, this is what they're talkin' about. I would know that that's not a good way to eat, and I would change my thinking process for my next decision on what I was eating. [Participant 144, Interview 1]

For others, seeing the real-time data was reassuring, as it confirmed that they were making better choices:

I didn't adjust anything, it's just that I thought this is better for me to see instantaneously. I had that instant gratification of 'Oh, okay. It's 93. Oh, okay. It's 120. Okay, I'm doin' good. [Participant 153, Interview 1]

In the interviews conducted 6 months after the intervention, participants continued to reflect on their experience of wearing the CGM, even though they were not presently wearing one:

The visual was good to see how your body responds to what you eat. And then I guess the lesson in all of that is, to be able to continue to make good choices when you're not hooked up. [Participant 199, Interview 2]

Mixed Methods Results

We compared the thematic results of different groups of participants based on significant quantitative results: reduction in HbA_{1c} and weight loss. First, we compared the experiences reported by participants who had a less-than-average reduction in HbA_{1c} levels (<0.71%; n=6) with those reported by participants who had an above-average reduction in HbA_{1c} levels (≥0.71%; n=7). This analysis revealed that regardless of the amount of HbA_{1c} reduction, participants reported that using CGM data to visualize changes in their blood glucose and learning how different foods affected their body was beneficial. All participants reported paying more attention to their blood glucose trends. To illustrate, below are 2 representative quotes about visualizing changes in glucose trends from participants on either end of the HbA_{1c} range.

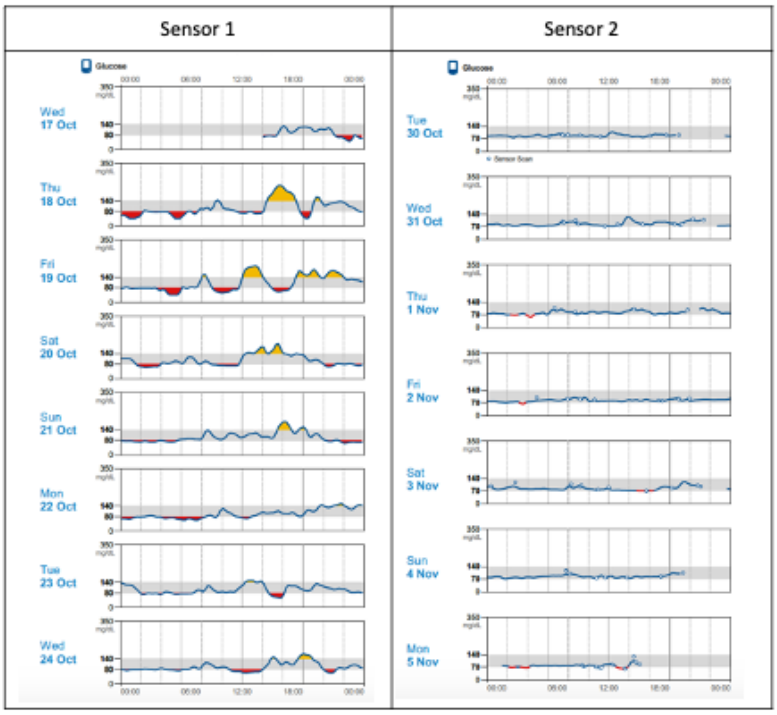
For example, from the participant with the highest amount of HbA_{1c} reduction during the intervention period:

[The CGM] kinda made me more aware. Like yesterday was a Friday, I probably went out and had a piece a cheesecake and… um, like once in a while I'll have wine or something. So, I would actually like

see it, what that did to my blood sugar, like how it spiked it up. But if I stayed within the parameters, I was fine. It was just on the nights that I go out or something, or the family gets together, that's when I notice it spikes up and down. [Participant 105, Interview 1]

The spikes that this participant described are evident in the CGM data (Figure 4). During the first week of wearing the sensor (before implementing the low-carbohydrate diet), this participant had blood glucose levels with significant variation and episodes of hyperglycemia. In the second sensor period, while implementing the low-carbohydrate diet, the glucose variability decreased significantly.

Figure 4. Comparison of daily glucose trends captured by Abbott continuous glucose monitor for one participant from both sensor periods of the intervention.



A participant with a lower reduction in HbA_{1c} similarly described feeling reassured by being able to visualize the impact of carbohydrates on blood glucose trends:

Even on the day that I had the cookies and stuff. I could see it did go up, and that was like whoa, yeah. There's a reason for that. Um, and then it came back down. So I could actually see what was happening. But the thing is, I wasn't eating the potatoes, I wasn't eating the pasta, and that was pretty much the norm for me. So I didn't see it go up. But that was a pleasant thing. So it kinda reinforced to me that yes, I am doing the right thing. And yeah I am okay sticking with this, and doing everything kind of according to the book. [Participant 102, Interview 1]

Second, we compared the experiences of those who had lost an above-average amount of weight during the intervention (>1.41 lbs; n=7) with those who had lost less than average or gained weight (n=6). Participants who had lost above-average weight often described the diet as easier than the other diets they had tried. In addition, they began to see positive results, including weight loss and feeling better physically. These participants described that they were planning ahead and being more intentional. In contrast, those who gained weight or lost less-than-average weight often had more difficulty with the diet for various reasons, including challenges eating a low-carbohydrate diet during holidays, work events, and family events where the environment is less controlled. Other challenges included giving up old habits and dealing with the emotional aspects of dieting. A comparison of participant experiences according to their average weight change is highlighted in the joint display (a mixed methods strategy for depicting integrated analysis and findings) in Table 4.

Table 4. Joint display comparing trial outcomes with patient experiences.

Weight change and corresponding participant experience	Illustrative quote
Above-average weight loss	
Diet was easier to implement, motivated to eat well	*It's been easy to be honest with ya. You know, I don't crave bread, I don't eat bread, I eat a lot more vegetables, very, very little fried food. I mean, it's been easy . . . And once I walked around with that thing in my arm and I was scannin' myself every day that just that put a whole new perspective on it.* [Participant 169, Interview 1]
Saw positive changes	*I'm sleeping better at night. I have more energy I'm in more control of myself, meaning, you know, it'd be like when I was bored, oh, I'd go to the cupboard or something, and just get a little bit of this or a little bit of that. But now I just feel like I eat 3 to 4 times a day and that's all I need.* [Participant 102, Interview 1]
Planning or intentionality	*So right now I'm kind of finding my… baseline on what my triggers are. I haven't really been counting carbs, but I did reach out to my doctor, and I started using continuous glucose monitors, to see if it would help me (Um-hm) So, modified, I guess, yes. I… I'm not necessarily counting carbs, but I'm seeing which foods spike my sugar right now. I've only had it in for maybe 4 days.* [Participant 193, Interview 2]
Below-average weight loss	
Difficulty implementing diet	*It's just that to me a low carb diet is a hard diet . . . and they're hard to cook. I mean you know, people like me, I'm used to eating pasta, potatoes, you know stuff like that. And those things are easy, quick, you know.* [Participant 141, Interview 1] *I don't do really well on low carb. When I go no carb or low carb, I don't do well. My brain does not do well without [carbs]. I just don't do well. I get emotional… I was crying, I was having mood swings.* [Participant 144, Interview 2]
Culture of food	*[There were] different parties and different things that I had at work that involved eating. Meetings where I had to take people out for lunch when we get a new hire, and a lot of times you can't really find things that fit specifically into what you'd like [to eat].* [Participant 179, Interview 2]
Hard to change habits	*You have to break your whole habits. I think from what I've seen it's probably a good diet, but it's definitely not easy . . . I mean, we're… well I'm 71, my wife's 71, my daughter's 45, and we've… lived like this for a long time. So to just up and change everything is hard.* [Participant 141, Interview 1]

Discussion

Principal Findings

We investigated the feasibility of using CGMs combined with low-carbohydrate diet coaching for a dietary intervention in patients with prediabetes. Overall, we found that using CGMs and low-carbohydrate diet coaching is a feasible and acceptable modality for supporting behavior change. All 15 participants wore the CGM sensors and attempted a low-carbohydrate diet during the intervention. Mixed methods results indicated that participants were overwhelmingly satisfied with the intervention and no major adverse effects were noted. Of the secondary outcomes, the reduction in HbA_{1c} and weight loss were significant. Interviews revealed that participants used the data from their CGM to understand the impact of foods with varying quantities of carbohydrates on their body.

Our findings suggest that the use of CGM with low-carbohydrate diet coaching may lead to a reduction in HbA_{1c} and weight loss in patients with prediabetes. Overall, participants described changing their eating behavior as a result of seeing their CGM data, either during low-carbohydrate diet coaching sessions or while receiving real-time feedback from the CGM. These findings are consistent with previous studies conducted on patients with T2DM, where participants who used CGMs for real-time blood glucose readings had greater reduction in HbA_{1c} and glycemic variability than the control group [32]. In this study, participants reported making immediate changes to their next meal because they could see trends and predict how certain foods would affect their blood glucose levels. Despite this, there was no difference in estimated HbA_{1c} between Sensor 2 and Sensor 1. This may have been due to the Hawthorne effect, where wearing the blinded sensor caused participants to consume a diet lower in carbohydrates during the first week of the intervention than they normally would because their blood glucose was being monitored. Further research is needed with a longer intervention period to evaluate the impact of this intervention on individuals with prediabetes.

Others have similarly found that patients with T2DM view CGM technology as an efficient tool to visualize blood glucose readings, monitor trends, and prompt dietary change [33]. Our study is unique as it combines CGM use with low-carbohydrate diet coaching. As carbohydrates drive fluctuation in blood glucose and therefore the trends visible in CGM data, coaching with CGM data provides patients with direct personalized feedback about their carbohydrate consumption. A larger trial studying the independent effects of low-carbohydrate coaching compared with those of CGMs would be valuable to evaluate the synergy of the 2 components of our intervention.

Our findings suggest that an approach combining low-carbohydrate diets and real-time CGM feedback is an acceptable and feasible approach to dietary change among patients with prediabetes. Although exploratory, the mixed methods analysis revealed that participants with the most weight loss had an easier time implementing the diet with intentionality, planning, and motivation. Participants who had the least amount of weight loss or gained weight described more barriers, particularly in breaking old habits or the *culture of food* around them. This is consistent with results of previous qualitative

research on barriers (eg, social expectations, financial constraints) and facilitators (eg, motivation to prevent diabetes) to dietary change in patients with prediabetes [34]. Low-carbohydrate diet coaching with CGM feedback may be particularly helpful in supporting participants with prediabetes to maintain motivation or overcome barriers. For example, some participants in our study felt motivated by seeing the reduction in variability (ie, more *time in range*) in their CGM data. In the future, additional coaching that supports participants to set small goals to reduce glucose variability may help to increase motivation. Future investigations of low-carbohydrate diet coaching may also explore the ability of coaching to overcome barriers, including breaking old habits and navigating social events when implementing a low-carbohydrate diet.

Previous research has demonstrated that people with prediabetes underestimate their risk of developing diabetes [24]. In our study, after the intervention, participants felt more reassured that they did not have diabetes, which is likely due to the intervention educating them about their prediabetes status. In addition, they felt that they had a lower risk of developing diabetes in the next 3 years, more personal control, and increased optimistic bias after completing the intervention. When considered alongside the qualitative results, these findings suggest that participants may feel confident that they can maintain positive changes during the intervention, such as weight loss, reduction in estimated HbA_{1c}, and time spent *in range* in their CGM data. As the knowledge of prediabetes [35] and perceived risk of developing T2DM [36,37] have been associated with self-care in individuals with prediabetes, further research should investigate the role that CGM data and low-carbohydrate diet coaching may play in influencing these variables.

Limitations

The primary aim of this pilot study was to assess feasibility. However, with the small sample size and short duration of the study, results must be interpreted cautiously. Given small changes in estimated HbA_{1c} and weight, the results may be due to measurement error. In addition, the duration of the intervention was a total of 22 days, and short-term effects of weight loss may be expected with motivated individuals meeting with the study coordinator every 11 days. HbA_{1c} was not reassessed at enrollment due to the scope of the pilot and feasibility study and was used as the baseline HbA_{1c} for participants. Although our results indicated a significant decrease in HbA_{1c} during the intervention, we used an estimated HbA_{1c} level from CGM data rather than a laboratory test. The estimated HbA_{1c} has fallen out of favor due to inaccuracy [38] and may overestimate changes during the short intervention period. However, estimated HbA_{1c} and the corresponding CGM tracings can be helpful for educational purposes, including understanding how foods differentially impact blood glucose or how physical symptoms (eg, fatigue, low mood) may be related to variations in blood glucose levels [38]. In addition, our pilot and feasibility study did not formally assess low-carbohydrate diet adherence with grams of carbohydrates or grading food logs. Finally, our study sample was comprised primarily of White, female participants. Further research is needed to generalize these preliminary pilot and feasibility findings to other participants with prediabetes.

Conclusions

The use of CGM feedback with low-carbohydrate diet coaching is feasible for adults with prediabetes, and participants were satisfied with their experience. This novel method deserves further exploration as most studies have focused on CGM use among patients with T2DM rather than use of this device alongside dietary coaching to drive behavior changes to prevent diabetes. Despite the high efficiency of CGM use, there are still barriers that may limit its clinical applications, including provider knowledge of CGMs and out-of-pocket costs for patients. Further research should be conducted to investigate how CGM technology and low-carbohydrate coaching can be used synergistically to prevent diabetes. Future studies are needed to explore the specific mechanisms that support behavior change, including the impact of CGM technology and low-carbohydrate diet coaching on participant knowledge, engagement, and motivation. In addition, more knowledge about sustainability and long-term impact is needed. As the cost of CGM decreases and the technology becomes more ubiquitous, this may become an important strategy for diabetes prevention.

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Conflicts of Interest

A research discount was provided on CGMs by Abbott. Our team currently has other research projects funded by industry partners, including Apple and Dexcom.

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Abbreviations

CGM: continuous glucose monitor
DPP: Diabetes Prevention Program
HbA_{1c}: hemoglobin A_{1c}
RPS-DD: Risk Perception Survey for Developing Diabetes
T2DM: type 2 diabetes mellitus

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